

NO. _____

FILED IN
2nd COURT OF APPEALS
FORT WORTH, TEXAS

Court of Appeals for the Second District of Texas
Fort Worth, Texas

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DEBRA SPISAK
Clerk

Texas Health Huguley, Inc., d/b/a Texas Health Huguley Hospital Ft. Worth South;
Dr. Jason A. Seiden; John Does #1-5; Jane Roes #1-5

v.

Erin Jones, Individually and as Legal Representative and Next Friend of Jason
Jones.

On Accelerated Interlocutory Appeal from the 342nd District Court, Tarrant
County, Texas, Cause No. 342-329996-21

Honorable Kimberly Fitzpatrick, Presiding Judge

EMERGENCY MOTION FOR TEMPORARY ORDER AND RELIEF

TO THE HONORABLE JUSTICES OF THE SECOND COURT OF APPEALS:

Appellants, Texas Health Huguley, Inc. d/b/a Texas Health Huguley Hospital
Fort Worth South, Jason Seiden, M.D., and John Does #1-5 and Jane Roes #1-5
respectfully request that the Court issue a stay of the trial court's November 8, 2021
order granting temporary injunction requiring Appellants to grant privileges or
temporary privileges to Mary Talley Bowden, M.D. for the sole purpose of
prescribing and administering Ivermectin to patient Jason Jones at Texas Health

Huguley Hospital. Ex. 1, Order Granting Temporary Injunction. Tex. R. App. P. 29.3; *In re Geomet Recycling LLC*, 578 S.W.3d 82, 87 (Tex. 2019). In support of this Motion, Appellants would show the Court as follows:

INTRODUCTION

The trial court’s November 8, 2021 order granting temporary injunction requires Appellants, who are not the credentialing authority at Huguley Hospital, to temporarily grant privileges to Dr. Bowden, a Texas otolaryngologist without intensive care experience, who has not seen Mr. Jones, an ICU patient, and who is not a credentialed member of the Texas Health Huguley medical staff, for the sole purpose of prescribing and administering Ivermectin to Mr. Jones at Huguley Hospital. This order puts Appellants in an untenable position—abide by the trial court’s order and violate both state and federal law or refuse to follow the trial court’s order and face the consequences of potential contempt.

Although all parties mourn for Mr. Jones’s heartbreaking situation, it is with the sincerest devotion and adherence to sound medical judgment that Appellants insist that (1) the prescription and administration of Ivermectin to Mr. Jones is medically inappropriate; (2) Appellants cannot order non-employed physicians on a third-party credentialing committee to grant privileges; and (3) Appellants are prohibited by law from bypassing their own credentialing process given that they are not operating under emergency orders. Moreover, Appellees’ underlying cause of

action is for a declaratory judgment, which claim could never give rise to the relief granted in the temporary injunction. Accordingly, Appellants ask for emergency relief in the form of a stay of the trial court’s November 8, 2021 order and all further proceedings pending this Court’s consideration of the merits of the interlocutory appeal.

STANDARD FOR RELIEF

Rule 29.3 provides that, during an interlocutory appeal, a court of appeals “may make any temporary orders necessary to preserve the parties’ rights until disposition of the appeal and may require appropriate security.” Tex. R. App. P. 29.3. As the Supreme Court explained, “in the rare case where immediate action by the court of appeals is truly ‘necessary’ to preserve the parties’ rights, . . . the legislature has decided that the court of appeals should be the available forum, and Rule 29.3 empowers the court of appeals to act.” *In re Geomet Recycling LLC*, 578 S.W.3d 82, 87-88 (Tex. 2019).

Examples of circumstances in which Rule 29.3 has been applied include: enjoining enforcement of an ordinance that was to go into effect during appeal, *Tex. Ass’n of Bus. v. City of Austin*, No. 03-18-00445-CV, 2018 WL 3967045, at *1 (Tex. App.--Austin Aug. 17, 2018, order) (per curiam), to prevent a city from taking actions to impair public use of a boat dock during an interlocutory appeal, *McNeeley v. Watertight Endeavors, Inc.*, NO. 03-18-00166-CV, 208 WL 1576866, at *1-2

(Tex. App.—Austin Mar. 23, 2018, order (per curiam), and to enjoin parties from executing on a writ of possession or removing a roof from property during an interlocutory appeal. *Noble Capital Servicing, LLC v. Action Roofing & Constr., Inc.*, No. 03-19-00092-CV, 2019 WL 654599 (Tex. App.--Austin Feb. 15, 2019, order) (per curiam).

The circumstances of this case merit a stay of underlying proceedings, including the temporary injunction order, because of the irreparable harm to Appellants in forcing medical treatment contrary to their professional judgment and the disruption to the overall credentialing process which involves third parties not before the court. Moreover, the trial court has awarded relief to Jones that she did not request in her pleadings and which is not related to her alleged cause of action.

BACKGROUND FACTS

Mr. Jones's spouse, Erin Jones, who is not a physician nor health care provider, sued Appellants on October 26, 2021 under the Declaratory Judgments Act to force Appellants to administer Ivermectin to Mr. Jones, based on a prescription from Mary Talley Bowden, M.D., a Houston, Texas otolaryngologist who has not seen Mr. Jones and who is not a credentialed member of the Texas Health Huguley medical staff. Ex. 2, Original Petition, Ex. 6, First Amended Petition, Ex. 7, Second Amended Petition. Alternatively, during the temporary injunction hearing, Jones

petitioned the trial court to order Texas Health Huguley to grant privileges to Dr. Bowden so she could administer Ivermectin to Mr. Jones. Ex. 8 at p. 18, ll. 1-7.

On October 26, 2021, the same day the lawsuit was filed, the 323rd Family District Court issued an Order Granting Jones' Application for Temporary Restraining Order at **7:54 a.m.** (the "TRO"). Ex. 15. Appellants filed a motion to dissolve in the trial court and a petition for writ of mandamus and request for emergency relief from the TRO in this Court. Ex. 4. The 323rd District Court, sua sponte, transferred the case to another civil district court and Jones ultimately agreed to dissolve the TRO. Ex. 5.

Temporary Injunction Hearing

The case was eventually assigned to the 342nd District Court, which held evidentiary hearings via zoom on November 1 and 2, 2021 on Jones' request for temporary injunction. Ex. 8-10. The trial court heard the following testimony:

Mrs. Jones testified that Mr. Jones was diagnosed with COVID-19 on September 23, hospitalized on September 28, and then placed on a ventilator on October 7. Ex. 8 p. 22, ll. 9-18. Mr. Jones was initially hospitalized at Harris Southwest, where he refused the COVID protocol of Remdesivir, and he discharged from the hospital against medical advice. Ex. 8 p. 28, ll. 12-25. Mr. Jones did not get along with his physician at Harris Southwest because "they were pushing [the COVID protocol] and he didn't want it." Ex. 8 p. 29, ll. 20-24. Mr. Jones was later

transported to Huguley Hospital by ambulance on September 28, 2021 and then placed on a ventilator on October 7, 2021. Ex. 8 p. 22, ll. 9-18, p. 29, ll.17-19. Mr. Jones refused Remdesivir at Huguley Hospital as well. Ex. 8 p. 31, ll. 15-19.

Mrs. Jones testified that her husband's condition had not improved. Ex. 8 p. 23, ll. 2-8. Mrs. Jones asked the hospital to administer Ivermectin to Mr. Jones and they declined. Ex.8 p. 25, ll. 9-11. Before hospitalization, Mr. Jones had asked his primary care provider to prescribe him Ivermectin and it refused. Ex. 8 p. 34, ll. 23-25. Mrs. Jones then found Dr. Bowden online and she prescribed Ivermectin after a telehealth visit with Mrs. Jones. Ex.8 p. 35, ll. 20-25, p. 36, ll. 1-21. Dr. Bowden did not review Mr. Jones's records or visit with Mr. Jones prior to administering the prescription. Ex.8 p. 37, ll. 1-25.

Dr. Jason Seiden, Mr. Jones's treating physician, board certified in pulmonary medical, critical care medicine, sleep medicine, and hospice and palliative care medicine, assistant chief of staff and medical director of the medical intensive care unit at Huguley Hospital, testified about Mr. Jones's treatment and the COVID protocols at the hospital. Ex. 8, pp. 48, ll. 9-25; p. 49, ll. 1-8. Ivermectin is not part of Huguley Hospital's COVID protocol. Ex. 8, p. 50, ll. 18-25. Dr. Seiden testified that there is not a single authoritative body that recommends Ivermectin at any stage in the treatment of COVID-19. Ex. 8, p. 51, ll. 3-11. Ivermectin is not approved or

recommended by any governing agency for the treatment of COVID-19. Ex. 8, p. 51, ll. 12-19.

Dr. Seiden clarified that Mr. Jones was not healthy when he was first admitted to the hospital, he had a stroke at the age of 42, untreated sleep apnea and obesity, hypertension and was a former smoker. Ex. 8, p. 54, ll. 1-6. Mr. Jones was offered the entire recommended protocol for COVID-19 and he refused most of that protocol. Ex. 8, p. 54, ll. 9-20. Mr. Jones did not ask Dr. Seiden for Ivermectin. Ex. 8, p. 55, ll. 1-6. The first time Dr. Seiden was asked for Ivermectin was through this legal action. Ex. 8, p. 55, ll. 1-6. Dr. Seiden has not prescribed Ivermectin to Mr. Jones because it is on an FDA warning not to be used in the treatment of COVID-19 infection. Ex. 8, p. 58, ll. 9-18. In addition, one of the purported uses of Ivermectin is to prevent further viral replication or reproduction in the cells but because Mr. Jones is no longer being treated for COVID-19, rather the damage caused by COVID, he no longer requires treatment for the virus itself. Ex. 8, p. 60, ll. 8-18. Thus, even if Ivermectin were approved, there is no clinical reason to administer it to Mr. Jones. Ex. 8, p. 60, ll. 19-22.

Dr. Bowden is an otolaryngologist, who currently works in private practice. Ex. 9, p. 12, l. 22. She acknowledged in her testimony that she had only spoken to Mrs. Jones and had not examined Mr. Jones or requested or reviewed his medical records. Ex. 9, p. 19, ll. 2, 11-12. She was also surprised to learn that Mr. Jones

had not undergone a tracheostomy, which was contrary to what Mrs. Jones relayed to her. Ex. 9, p. 21 ll. 5-9. Dr. Bowden was also unaware of Mr. Jones' true medical history, which she asserted did not matter. Ex.9, p. 22, ll. 4-10. Mr. Jones was prescribed Calcitriol, Melatonin, Fluvoxamine, Atorvastatin, and Cyproheptadine by Dr. Bowden, in addition to Ivermectin. Ex.9, p. 25, ll. 1-14. Dr. Bowden did not remember prescribing Cyproheptadine but stated that she prescribed everything on FLCC's protocol for patients in the hospital, which she relied on rather than her independent medical judgment. Ex.9, p. 25, ll. 18-20. She indicated that she did not have a concern about the potential side effects of Atrovastatin, or the other prescribed medicines. Ex.9, p. 27, ll. 20-21.

Dr. Bowden indicated that she would go to "Dallas," to administer the Ivermectin and manage any clinical complications. Ex. 9, p. 29, ll. 6-15. However, she admitted that she had not applied for privileges at Texas Health Huguley, nor did she have an advanced practice nurse who could operate under her medical license. Ex.9, p. 13, ll. 23-25, p. 32, ll. 6-8.

Jones also called Senator Bob Hall to testify about the "Medical Freedom Act." Ex.9, p. 36, ll. 16-25. Although Mr. Hall testified that the Medical Freedom Act allowed patients to try experimental medications, the law could not be cited, nor did the Court take judicial notice of the purported statute. Ex.9, p. 40, ll. 5-11.

Tandra Cobern, the hospital's Director of Medical Staff Services, testified to the credentialing process for a physician to gain temporary privileges, which mirrors that required by the CMS Conditions of Participation and Joint Commission standards. Ex. 9, p. 42, ll. 5-18. There are also limitations because Mr. Jones is in the MICU, a closed unit. Ex. 9, p. 42-43, ll. 22-25, 1-6. Ms. Cobern further testified that in the event even temporary privileges are granted, the practitioner's privileges are limited to the scope of their medical competence. Ex. 9, p. 43, ll. 1-12. Here that practice for Dr. Bowden would be otolaryngology and not intensive care.

Post-Hearing Briefing

Appellants submitted additional briefing in opposition to Jones's requested relief. Ex. 11. The trial court held an additional telephonic hearing on November 5, 2021 and the parties submitted additional briefing in response. Ex. 12, 13. On November 8, the trial court granted, in part, Jones' application for temporary injunction and ordered Defendants to grant temporary privileges to Dr. Bowden so that she could administer Ivermectin to Mr. Jones. Ex. 1. This relief is not requested in Jones's pleadings.

On November 8, 2021, immediately after receipt of the trial court's order, Appellants filed a notice of accelerated interlocutory appeal from this order and seek emergency relief in the form of a stay of this Order because (1) a stay is necessary to preserve the status quo; (2) the order requires Appellants to take actions against

state and federal law; and (3) the relief granted in the order is in no way related to the claim for relief in the pending lawsuit.

I. A stay is necessary to preserve the status quo pending this Court's consideration of the Interlocutory Appeal.

A stay of the November 8, 2021 order and further proceedings in this matter is necessary to preserve the status quo and this Court's jurisdiction over the interlocutory appeal.

As it stands, the trial court has substituted the professional medical judgment of a hospital, all of its employed health care providers, and the physicians attending to the care of Mr. Jones for its own, based on nothing other than a purported "prescription" from an unqualified physician that is not credentialed at Texas Health Huguley. Moreover, the trial court's order concerns a third-party credentialing committee over which Appellants have no control. As such, Appellants are caught in the middle of an untenable choice: adhere to their obligation to provide health care in accordance with their professional medical judgment and be found in contempt, or comply with the Order that violates federal and state law.

Under *In re Geomet*, Appellants ask this Court "to protect it from [the] irreparable harm" that will result if it must comply with the temporary injunction order. *In re Geomet Recycling LLC*, 578 S.W.3d 82, 87 (Tex. 2019). Here, the irreparable harm associated with compliance with the trial court's order is a complete

disruption of the credentialing process established by Texas Health Huguley and contrary to governing state and federal law. Ex. 1.

A. Governing state and federal law.

There is no dispute that federal law requires hospitals to form medical staffs that are governed by bylaws and rules and regulations, the membership of which are determined by its members and credentialing committees. Texas Health Huguley's Medical Staff Services Director, Tandra Cobern, testified that the Conditions of Participation are mirrored by the Bylaw and Rules of Regulations of the hospital, as well as standards promulgated by The Joint Commission, the independent non-profit organization that accredits and certifies more than 22,000 health care organizations and programs in the United States, and that is the oldest and largest standards-setting accrediting body in health care. Texas law mirrors the Conditions of Participation.

In adopting rules for hospitals, "conditions of participation for certification under Title XVIII of the Social Security Act (42 U.S.C. § 1395 et seq.) and the standards of The Joint Commission are used "to achieve consistency with those conditions and standards." Tex. Health & Safety Code § 241.026(b). A hospital's license may be suspended or revoked also for failing to comply with any provision of Texas Health and Safety Code Chapters 241 or 311. 25 T.A.C. § 133.121(1)(A).

25 Texas Administrative Code § 133.41(f) outlines the rules and responsibilities of the "Governing body" of a hospital, which is "responsible for the

organization, management, control, and operation of the hospital, including appointment of the medical staff.” 25 T.A.C. § 133.41(f)(1). The governing body must be formally organized in accordance with written bylaws. *Id.* at (f)(2). The medical staff of a hospital must have bylaws, rules, and regulations which are implemented and enforced. *Id.* at (f)(4)(A) (emphasis added); *see also Ex. 10*, Exhibits 9 and 10 of the hearing record, Texas Health Huguley’s Bylaws and Rules and Regulations for the Medical Staff, respectively. Further, the governing body “shall determine, in accordance with state law and with the advice of medical staff, which categories of practitioners are eligible candidates for appointment to the medical staff.” 25 T.A.C. § 133.41(f)(4)(F). “The medical staff shall examine credentials of candidates for medical staff membership and make recommendations to the governing body on the appointment of the candidate.” *Id.* at (k)(1)(B); *see also* Tex. Health & Safety Code § 241.101. Moreover, the governing body “shall be responsible for and ensure that any policies and procedures adopted by the governing body to implement the requirements of this chapter shall be implemented and enforced.” 25 T.A.C. § 133.41(f)(4)(F)(I) (emphasis added).

B. Standards for credentialing.

In order to treat a hospital’s patient, a physician must have privileges at that hospital. “A hospital’s bylaw requirements for staff privileges may require a physician...to document the person’s current clinical competency and professional

training and experience in the medical procedures for which privileges are requested.” *Id.* at (f)(4)(F)(IV). Texas law requires that a credentials committee review an applicant’s request for privileges. “A hospital’s credentials committee shall act expeditiously and without unnecessary delay when a licensed physician...submits a completed application for medical staff membership or privileges.” *Id.* at (f)(4)(F)(VIII). A hospital’s medical staff “shall adopt, implement, and enforce bylaws, rules, and regulations to carry out its responsibilities.” *Id.* at (k)(3). Medical staff bylaws “shall describe the qualifications to be met by a candidate in order for the medical staff to recommend that the candidate be appointed by the governing body.” *Id.* at (k)(3)(D). Bylaws should also “include criteria for determining the privileges to be granted and a procedure for applying the criteria to individuals requesting privileges.” *Id.* at (k)(3)(E).

Physicians are not permitted to perform “acts that are beyond the scope of the respective license held.” Tex. Health & Safety Code § 241.102(a) (emphasis added). Physicians are not entitled to membership or privileges on a medical staff. *Id.* at (d). All physicians must recognize the limitations of their ability and shall not offer services outside the provider’s scope of practice or use techniques that exceed their professional competency. 25 T.A.C. § 448.202. Providers “shall provide

adequate and appropriate services consistent with best practices and industry standards. 25 T.A.C. § 448.201.

With respect to the administration of medications, hospitals may only prepare and administer drugs and biologicals “in accordance with federal and state laws, the orders of the individuals granted privileges by the medical staff, and accepted standards of practice.” *Id.* at (o)(4) (emphasis added). The prescription and administration of medications that are non-therapeutic violates the Texas Medical Practice Act. Tex. Occ. Code § 164.053(a)(5). Similar restrictions govern the practice of nurses and pharmacists (25 T.A.C. § 133.41(q); *see also* 25 T.A.C. § 448.1001(b) (“Prescription medication shall be used only for therapeutic and medical purposes and shall be administered as prescribed by an appropriately licensed professional”).

C. Requiring emergency privileges so Dr. Bowden can treat Mr. Jones violates federal and state law.

Texas Health Huguley’s Bylaws (Ex. 9, § 4.2.2.1), in accordance with federal and state law as shown above, outline the members and duties of its Credentials Committee. Note that the voting members of the Committee are physicians on the Medical Staff. *Id.* Texas Health Huguley’s physicians are not employed by the hospital, and as such are not under the hospital’s control. The Credentials Committee reviews all Applications and Requests for Clinical Privileges and

requests for advancement and making recommendations to the Medical Executive Committee regarding such Application and requests. *Id.* at § 4.2.2.2.1.

Texas Health Huguley’s Medical Staff’s members must “[a]bide by the Medical Staff Bylaws, Rules and Regulations, the Hospital’s policies and procedures, regulatory requirements (*i.e.* the above-referenced Texas Administrative Code provisions and the CMS Conditions of Participation), and the professional code of ethics of the Member’s profession. *Id.* at § 5.4.1. Members of the Medical Staff must be competent. *Id.* at § 5.5.2.

To be granted temporary privileges, the President of the Medical Staff, Chair of the Credentials Committee, and the Department Chair must endorse the Applicant, and an Applicant’s request “may be granted only when there is an important patient care, treatment or service need.” *Id.* at § 6.12.2. There is no need for an otolaryngologist to be granted temporary privileges at Texas Health Huguley, especially when considering that the patient is critically-ill in the Intensive Care Unit, a close unit of the hospital limited to “intensivists” such as Dr. Seiden. Dr. Bowden, an otolaryngologist without intensive care experience, cannot show nor has she shown that she is needed or qualified to provide the treatment requested.

D. There is no exception which permits the order of emergency privileges.

Jones argues that there is an exception to the formal credentialing process that permits Dr. Bowden’s credentials because of a pandemic-related waiver under

federal law. To the extent Jones has validly raised this argument and shown that it applies, her argument is misplaced. First, the CMS waiver applies only to federal law when the hospital is under an emergency procedure. Here, Texas Huguley is still subject to state law and is not under emergency protocols as it is fully-staffed.

II. A stay is also necessary so that Appellants are not held in contempt for non-compliance with an order in violation of state and federal law.

Texas courts have recognized that mandatory injunctions are tenuous when what is interfered with is the independent medical judgment of health care providers. Courts have “disavowed any attempt to second-guess the propriety or adequacy of a particular course of treatment” because it is “a question of sound professional judgment.” *Muniz v. Texas Dep’t of Crim. Just.*, 2008 WL 2764518 at *3 (Tex.App.—Corpus Christi Jul. 17, 2008, no pet.) (rejecting request for preliminary injunction ordering defendants to provide patient operation—“Courts should not intervene upon allegations of mere negligence, mistake, or difference of opinion”). Federal courts have also held that “judges are not ‘better qualified than appropriate professionals’ to make decisions relating to the physical and mental health of patients and that, to the extent possible, ‘interference by the federal judiciary with the internal operations of...institutions...should be “minimized.”” *Costa v. Bazron*, 464 F.Supp. 3d 132, 141 (D.D.C. 2020) (quoting *Youngberg v. Romeo*, 457 U.S. 307, 322-23 (1982)); *See also Youngberg*, 457 U.S. at 323 (“[W]e emphasize that courts must show deference to the judgment exercised by a qualified professional”—

“[T]here certainly is no reason to think that judges or juries are better qualified than appropriate professionals in making such decisions.”); *Bowring v. Godwin*, 551 F.2d 44, 48 (4th Cir. 1977) (“[W]e disavow any attempt to second-guess the propriety or adequacy of a particular course of treatment. Along with other aspects of health care, this remains a question of sound professional judgment. The courts will not intervene upon allegations of mere negligence, mistake or difference of opinion.”).

Here, the temporary injunction overrides proper deference to the independent, professional, and clinical judgment of the patient’s health care providers. Appellants request a stay of the temporary injunction and underlying proceeding pending this Court’s consideration of the merits of the interlocutory appeal.

III. A stay is also necessary so that Appellants are not held in contempt for non-compliance with an order that is wholly unrelated to Jones’s cause of action, to the extent a cause of action even exists.

In granting or refusing a temporary injunction, the trial court is vested with broad discretion to determine only one issue: whether the party requesting temporary relief is entitled to preservation of the status quo of the subject matter pending a trial on the merits. *Tex. Dep’t of Public Safety v. Martin*, 882 S.W.2d 476 (Tex. App.—Beaumont 1994, no writ). An order granting injunctive relief that does not set forth the act to be restrained with sufficient specificity is void. *Hoist Liftruck Mfg., Inc v. Carruth-Doggett, Inc.*, 485 S.W.3d 120, 123 (Tex. App.—Houston [14th Dist.] 2016, no pet.). Here, the order granting the temporary injunction cannot possibly

meet this standard—it does more than merely keep the status quo, it orders Appellants to take action that is not in any way related to the claim for declaratory relief. And, the action being ordered has nothing to do with keeping the status quo pending a trial on the merits. Rather, it awards Jones relief on the ultimate issue in the case without affording Appellants the due process right to present complete evidence and arguments in their defense.

Keeping the status quo in this case is properly characterized as keeping the ultimate subject of the litigation, Mr. Jones, alive. Appellants have gone through extraordinary efforts to do so—Dr. Seiden testified that he saved Mr. Jones’ life twice just in the last week by emergently inserting tubes in his chest cavity to clear trapped air caused by multiple collapsed lungs. Obviously, this case presents profoundly regrettable circumstances, as the Court itself remarked during the temporary injunction hearing, but the rule of law must be followed.

Moreover, a temporary injunction is inappropriate because Jones has no probable right to relief on his underlying cause of action. To prevail on a request for injunctive relief, a plaintiff must plead and prove three specific elements: (1) a cause of action against the defendant; (2) a probable right to the relief sought; and (3) a probable, imminent, and irreparable injury in the interim.” *Butnaru v. Ford Motor Co.*, 84 S.W.3d 198, 204 (Tex. 2002). Here, Jones seeks a declaratory judgment that gives his wife a legal right to dictate treatment determinations for her husband and

requires Appellants to administer a medication purportedly prescribed by a non-credentialed and wholly unqualified provider. Ex. 2, 6, 7.

A trial court only has jurisdiction over a declaratory judgment claim if it is a claim for which the Uniform Declaratory Judgments Act applies. Tex. Civ. Prac. & Rem. Code § 37.002, 37.003. Under the Uniform Declaratory Judgments Act, Chapter 37 of the Texas Civil Practice and Remedies Code, the only subject matter for relief permitted is that of “[a] person interested under a deed, will, written contract, or other writings constituting a contract or whose rights, status, or other legal relations are affected by a statute, municipal ordinance, contract, or franchise.” Tex. Civ. Prac. & Rem. Code § 37.004(a).

In this case, Jones has not pleaded any *valid* interest under a deed, will, written contract, or other writing constituting a contract, nor have they pleaded that their rights are affected by any statute, municipal ordinance, contract, or franchise. Instead, Jones seeks a declaration determining the rights of the parties under a nebulously-referenced “Patient/Physician contract” and the “hypocritic [sic] Oath.”

There is simply no cause of action, declaratory or otherwise, against health care providers for failure to administer a medication that is not clinically indicated and outside of the standard of care. Because Jones asserts no valid cause of action, there cannot be a probable right to relief. Accordingly, the order granting the

temporary injunction is void and, at the very minimum, a stay should be ordered pending this Court's review of the interlocutory appeal.

PRAYER FOR STAY

For the reasons stated herein, Appellants respectfully request that this Court grant temporary relief by issuing an order staying the underlying temporary injunction order as well as all further proceedings in the trial court until this Court resolves the issues raised in Appellants' interlocutory appeal.

PRAYER FOR ACCELERATED BRIEFING SCHEDULE

Because of the emergency nature of this interlocutory appeal, Appellants also ask this Court to order an accelerated briefing schedule. Appellants propose to file their opening brief on the merits by November 12, 2021 and ask that Appellee's responsive brief be due November 19, 2021.

CONCLUSION

For the reasons stated above, Appellants respectfully request that this Court (1) grant Appellants' requested stay of the November 8, 2021 order granting temporary injunction, and (2) institute a condensed briefing schedule, so that the merits of this interlocutory appeal may be considered on an emergency basis and Appellants request all other relief to which they are entitled.

Respectfully submitted,

By: /s/ Joshua D. Ross

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ATTORNEYS FOR APPELLANTS

**CERTIFICATION OF NOTICE TO ALL PARTIES
BY EXPEDITED MEANS**

This certifies that the undersigned notified all parties to this action that this Motion is being filed by electronic filing on this 8th day of November, 2021 at approximately 7:00 p.m.

/s/ Joshua D. Ross
Joshua D. Ross
Attorney for Appellants

CERTIFICATION

Pursuant to TEX. R. APP. P. 52.3(j), I certify that I have read this Motion and have concluded that every factual statement in the Motion is supported by competent evidence included in the exhibits or record.

/s/ Joshua D. Ross
Cantey Hanger LLP

CERTIFICATE OF CONFERENCE

Appellants' counsel has conferred with counsel for Jones numerous times to avoid the necessity for this Motion but an agreement could not be reached.

/s/ Joshua D. Ross
Cantey Hanger LLP

CERTIFICATE OF SERVICE

This is to certify that a true and correct copy of Appellants' Emergency Motion for Temporary Order and Relief has been served upon all counsel of record as noted on this the 8th day of November, 2021, via electronic service.

/s/ Joshua D. Ross

Joshua D. Ross

Attorney for Appellants

NO. _____

Court of Appeals for the Second District of Texas
Fort Worth, Texas

Texas Health Huguley, Inc., d/b/a Texas Health Huguley Hospital Ft. Worth South;
Dr. Jason A. Seiden; John Does #1-5; Jane Roes #1-5

v.

Erin Jones, Individually and as Legal Representative and Next Friend of Jason
Jones.

On Accelerated Interlocutory Appeal from the 342nd District Court, Tarrant
County, Texas, Cause No. 342-329996-21

Honorable Kimberly Fitzpatrick, Presiding Judge

VERIFICATION OF EXHIBITS ATTACHED TO MOTION

THE STATE OF TEXAS §
 §
COUNTY OF TARRANT §

Before me, the undersigned Notary Public, on this day, personally appeared
Joshua D. Ross, a person whose identity is known to me. After I administered an
oath to him, upon his oath, he said the following:

“My name is Joshua D. Ross and I am capable of making this affidavit, and the facts in this affidavit are true to my personal knowledge.

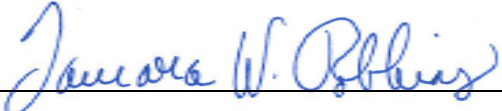
“I am one of the attorneys of record for Appellants. A true and correct copy of the Order Granting Plaintiff’s Temporary Injunction is attached hereto as Exhibit 1. A true and correct copy of Plaintiff’s Original Petition for Emergency Medical Declaratory Judgment, Application for TRO, Defendants’ Motion to Dissolve TRO, Order to Transfer, Plaintiff’s First Amended Petition, and Plaintiff’s Second Amended Petition are attached as Exhibits 2, 3, 4, 5, 6, and 7. A true and correct copy of the transcript of the temporary injunction hearing is attached as Exhibits 8, 9 and 10. A true and correct copy of Defendant’s Response in Opposition is attached as Exhibit 11. A true and correct copy of Defendants’ letter brief to the court is attached as Exhibit 12. A true and correct copy of Plaintiff’s letter brief is attached as Exhibit 13. A true and correct copy of Plaintiff’s First Amended Preliminary Injunction Motion is attached as Exhibit. Exhibit 4. A true and correct copy of the Order granting TRO is attached as Exhibit 15. A true and correct copy of the Notice of Accelerated Appeal filed by Appellants is attached as Exhibit 16. To the extent file-marked copies

are not attached, I certify that the copy attached herein was filed with the court on the date identified in the certificate of service.”

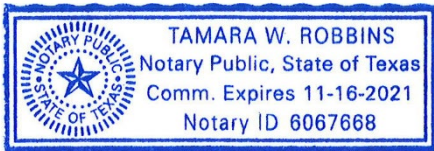


Joshua D. Ross

SUBSCRIBED AND SWORN TO BEFORE ME by Joshua D. Ross on
November 8, 2021.



Notary



CAUSE NO: 342-329996-21

**ERIN JONES, Individually and as
Legal Representative and
Next Friend of Jason Jones**

Plaintiff,

v.

**TEXAS HEALTH HUGULEY, INC.,
d/b/a TEXAS HEALTH HUGULEY
HOSPITAL FT. WORTH SOUTH;
DR. JASON A. SIEDEN;
JOHN DOES #1-5; JANE ROES #1-5;**

Defendants.

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§ **IN THE DISTRICT COURT OF**
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§ **TARRANT COUNTY, TEXAS**
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§ **342nd JUDICIAL DISTRICT**
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TEMPORARY INJUNCTION ORDER & ORDER SETTING TRIAL

The Court having considered Plaintiffs’ Erin Jones, Individually and as Legal Representative and Next Friend of Jason Jones, Petition and Motion for Temporary Injunction, and upon reviewing all pleadings, affidavits, exhibits, arguments of the parties, the testimony of witnesses and hearing evidence from both parties, all Counsel of record being present, the Court hereby makes the following findings of fact and conclusions of law.

FINDINGS OF FACT

1. Plaintiff, Jason Jones, is a patient at Texas Health Huguley Hospital. The Petition seeks Emergency Medical Declaratory Judgment and Emergency Injunctive Relief against Defendants to administer the drug Ivermectin to Jason Jones.
2. Jason Jones was admitted to Defendant Hospital on September 28, 2021 and diagnosed with COVID-19.
3. On October 7, 2021, Jason Jones was sedated, intubated and placed on a ventilator.
4. Since October 7, 2021, Jason Jones has been on a ventilator in a medically induced coma,

continuing to decline.

5. Defendants have treated Jason Jones with their Covid-19 protocol and refuse to deviate from their protocol and administer an alternative medical treatment with the use of the drug ivermectin, despite the fact that their Covid-19 protocol has not improved his condition.

6. Dr. Mary Talley Bowden, M.D. has prescribed ivermectin for Jason Jones. Dr. Bowden is a Board-Certified Physician duly licensed to practice medicine under the laws of the State of Texas.

7. Dr. Bowden testified that she has successfully treated hundreds of covid patients with ivermectin and that Jason Jones would have a good chance of survival if treated with ivermectin. She further testified that ivermectin is safe and effective for covid patients, and that off-label use of approved FDA drugs, including ivermectin, is within the standard of care.

8. Plaintiff, Erin Jones, in her capacity as surrogate decision-maker, has consented to Dr. Bowden treating her husband, Jason Jones, with ivermectin.

9. Plaintiff, Erin Jones, testified that her husband, Jason Jones, requested to be treated with ivermectin prior to being placed on a ventilator.

10. Plaintiff, Erie Jones, testified that she is willing to execute an informed consent as well as a release and waiver, to the Defendant in regard to Jason Jones' treatment with ivermectin.

CONCLUSIONS OF LAW

1. Under Texas law, to determine whether the remedy of injunctive relief is warranted, Courts consider several factors.

2. There is sufficient evidence that Jason Jones' medical condition and health continues to decline as he has been on a ventilator, in a medically induced coma for 30 days, and imminent harm and irreparable injury in this matter will include death which by its nature is an irreparable loss.

3. Plaintiff has no adequate remedy at law, and Plaintiff has demonstrated a likelihood of success and a balance of equities favors the granting of injunctive relief in order to preserve the life of Jason Jones.

4. The Court takes judicial notice that the Centers for Medicare and Medicaid Services in 2020 waived requirements under 42 CFR §482.22(a)(1)-(4) for Texas Hospitals regarding the credentialing and privileging process due to covid-19. Further, the Centers for Medicare and Medicaid Services reaffirmed said waiver in May, 2021, allowing new physicians to be able to practice in a hospital before being credentialed and granted privileges. Pursuant to said waiver, no Federal or State would be violated by allowing Dr. Bowden to administer ivermectin to Jason Jones.

5. Furthermore, no Federal or State law would be violated as Medicaid and/or Medicare does not apply to Jason Jones. Jason Jones' private medical insurance is covering his hospitalization and medical costs, and no claim for reimbursement would be made to Texas or the Federal Government.

6. The Court takes judicial notice of the Texas Health and Safety Code, Chapter 489 "Access to Investigational Treatments for Patients with Terminal Illnesses". This law confirms the right of terminal patients to use an investigational drug, such as ivermectin.

7. Texas Health and Safety Code §489.052 further incorporates the doctrine of informed consent; in this case, Erin Jones, may provide informed consent on the patient's behalf.

8. Texas Health and Safety Code §489.054 and §489.151 further grants immunity to the hospital, physicians and providers "for any harm done to the patient resulting from the investigation drug".

9. The Court takes judicial notice of the Texas Health and Safety Code, Chapter 313 "Consent to Medical Treatment Act". §313.002 allows for a Surrogate decision-maker to

consent to medical treatment on behalf of an incapacitated person. §313.004(1) specifically states “the patient’s spouse” may consent to medical treatment on behalf of the patient; in this case, Erin Jones, may consent to medical treatment on behalf of her husband Jason Jones.

10. Further, the Texas Health and Safety Code §313.007 limits liability for hospitals, physicians and staff for the medical treatment consented to under this chapter.

11. The Court takes judicial notice of the Texas Civil Practice & Remedies Code, Chapter 74, §155 “Liability of Physicians, Health Care Providers, and First Responders during Pandemic”. Effective June 14, 2021, the Texas Legislature has conveyed immunity to the hospitals and physicians treating patients suffering from a pandemic disease.

12. Pursuant to Texas Civil Practice & Remedies Code, §74.155, Defendants hereunder are “not liable for an injury, or death arising from care, treatment, or failure to provide care or treatment relating to or impacted by a pandemic disease”.

Having found that Plaintiff met its burden for a Preliminary Injunction,

IT IS HEREBY:

ORDERED, that pending further order of this Court, the Defendants, their agents, and assigns, and any third parties acting on its behalf, upon receipt of this Order, shall grant Dr. Mary Talley Bowden, M.D. and/or her nurse working under her authority, temporary emergency privileges, which shall not be unreasonably delayed or denied, solely to administer Ivermectin to Jason Jones, pursuant to the order and the attached Prescription of Dr. Bowden; and it is further

ORDERED, that Dr. Bowden and/or her nurse working under her authority, is limited solely to the ivermectin portion of her prescription, which shall consist of crushing the ivermectin pills and flushing them into the feeding tube of Jason Jones; and it is further

ORDERED, that Dr. Bowden and/or her nurse working under her authority, is granted access in the ICU at Texas Health Huguley Hospital to Jason Jones for the sole purpose of

administering ivermectin to Jason Jones, and shall further provide notice to the Hospital of when she shall be administering the ivermectin to Jason Jones; and it is further

ORDERED, that Defendants, Texas Health Huguley, Inc., d/b/a Texas Health Huguley Hospital Ft. Worth South, and Dr. Jason A. Sieden, are not required to administer ivermectin to Jason Jones nor are they required to provide the medication for Dr. Bowden; and it is further

ORDERED, upon the completion of the administration of ivermectin to Jason Jones, Dr. Bowden and/or her nurse working under her authority, shall leave the hospital and that all other matters concerning Jason Jones will be under the control and authority of the Defendants; and it is further

ORDERED, that Dr. Bowden shall be available to consult with Jason Jones' hospital physicians regarding treatment of any adverse reaction to the ivermectin; and it is further

ORDERED, that in the event Jason Jones develops a serious adverse reaction to the ivermectin, the Hospital by and through their Physicians, can make the decision to discontinue the use of ivermectin;

At the hearing, Plaintiff agreed, on the record, to release Defendants, Defendants' employees, agents, officers, physicians, nurses, executors, assigns, or any third party acting on Defendants' behalf of any and all liability related to Mr. Jason Jones and the administration of ivermectin by Dr. Bowden:

Plaintiff's counsel drafted a proposed release, releasing Defendants, Defendants' employees, agents, officers, physicians, nurses, executors, assigns, or any third party acting on Defendants' behalf of any and all liability related to Mr. Jason Jones and the administration of ivermectin by Dr. Bowden. IT IS THEREFORE ORDERED that Plaintiff shall execute and deliver said release to Defendants prior to the administration of the ivermectin by Dr. Bowden.

ORDERED, that Plaintiff shall pay a cash bond in the amount of \$1.00 to the Clerk of the

Court by November 2, 2021, in connection with the above injunctive order; it is further

ORDERED, that all parties shall appear before the Honorable Kimberly L. Fitzpatrick on the 8 day of August, 2021 at 8:30 a.m. / ~~p.m.~~ for Trial and Hearing on a Permanent Injunction.

Signed on November 8, 2021.



Honorable Kimberly L. Fitzpatrick



BreatheMD
OPTIMAL AIRWAY HEALTH

Prescription Form

Date: 10/22/21. Patient: Jason Jones DOB 12/4/1972

Ivermectin 3mg. Give 21 tablets per NGT qD, Dispense 210 tablets, Refill:2

Calcitriol 0.25mcg per NGT QD, Dispense: #30, Refill:2

Melatonin 12mg per NGT QHS , Dispense: #30, Refill:2

Fluvoxamine 50mg per NGT BID, Dispense #60, Refill:2

Cyproheptadine 8mg per NGT TID, Dispense #90, Refill:2

Zinc 100mg per NGT QD, Dispense #30, Refill: 2

Famotidine 80mg per NGT BID, Dispense #60, Refill 2

Avorstatin 80mg per NGT QD, Dispense #30, Refill 2

Flutamide 250mg per NGT TID, Dispense #90, Refill 2

Spirolactone 100mg per NGT BID, Dispense #60, Refill 2

Finasteride 10mg per NGT QD, Dispense #30, Refill 2

Nitazoxanide 500mg per NGT BID, Dispense #60, Refill 2

IV Infusions Recommended:

- Methylprednisolone 80mg IV bolus then 40mg IV BID
- Vitamin C 25mg IV BID x 3 days
- Thiamine 200mg IV BID
- Therapeutic Plasma Exchange

Prescriber: 3600 Kirby Dr. Suite F
Mary Talley Bowden, MD Houston, TX 77098
Tx license: K9770 713-492-2340
NPI: 1699858282

713-206-8988 (cell)

EXHIBIT 2

FILED
TARRANT COUNTY

2021 OCT 26 PM 4:40

THOMAS A. WILDER
DISTRICT CLERK

CAUSE NO: 323-117290-21

ERIN JONES, INDIVIDUALLY AND AS
LEGAL REPRESENTATIVE AND
NEXT FRIEND OF JASON JONES

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Plaintiff,

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IN THE DISTRICT COURT OF

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v.

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TARRANT COUNTY, TEXAS

§

TEXAS HEALTH HUGULEY, INC.,
d/b/a TEXAS HEALTH HUGULEY
HOSPITAL FT. WORTH SOUTH;
DR. JASON A. SIEDEN;
JOHN DOES #1-5; JANE ROES #1-5;

§

323rd JUDICIAL DISTRICT

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Defendants.

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**PETITION FOR EMERGENCY MEDICAL DECLARATORY JUDGMENT
AND EMERGENCY INJUNCTIVE RELIEF**

COMES NOW, ERIN JONES as Wife of JASON JONES, Plaintiff, by and through undersigned counsel, and files this Petition for Emergency Medical Declaratory Judgment and Emergency Injunctive Relief against Defendants, TEXAS HEALTH HUGULEY, INC., d/b/a TEXAS HEALTH HUGULEY HOSPITAL FORT WORTH SOUTH; DR. JASON A. SIEDEN; JOHN DOES #1-5; JANE ROES #1-5; and for good cause shows the Court the following.

I. INTRODUCTION

1. This is a civil action for Emergency Declaratory and Injunctive Relief brought by the Plaintiff, ERIN JONES, who is the Wife of JASON JONES; who is currently a patient in the Intensive Care Unit at TEXAS HEALTH HUGULEY HOSPITAL FORT WORTH SOUTH

(“Defendants’ Hospital”), who is diagnosed with COVID-19 and intubated.

2. The physicians caring for Mr. Jones at Defendants’ Hospital have taken a “wait and see” approach towards any further treatment of Mr. Jones. Mr. Jones’s Doctor, Mary Talley Bowden, M.D., has prescribed Ivermectin be administered to Mr. Jones in an effort to save Mr. Jones’ life. The attending doctors at Defendants’ Hospital, despite having no answers of their own, have and continue to refuse to administer Ivermectin to Mr. Jones in contravention of Dr. Bowden’s orders.

3. Mrs. Jones seeks a declaration determining the rights of the parties including that the Defendants be compelled to abide by the Patient/Physician contract and their hypocritic Oath and to “Do No Harm” by withholding treatment to Mr. Jones. Further, the Plaintiff seeks a declaration that the Defendants honor the decisions of, and instructions given by Mrs. Jones, as Wife of Mr. Jones. Further, the Plaintiff seeks an emergency order compelling the Defendants to recognize Dr. Bowden’s medical order and prescription and requiring the Defendants to administer Ivermectin to their mutual patient, Mr. Jones, and comply with Dr. Bowden’s medical orders for further prescriptions for Mr. Jones in his battle with COVID-19. Plaintiff seeks an emergency Order of Specific Performance.

4. Mrs. Jones additionally seeks an order for such other, further and different relief as the Court deems just, equitable and proper.

II. JURISDICTION AND VENUE

5. Mrs. Jones is not seeking monetary or compensatory damages as her cause of action simply relates to the enforcement of Mrs. Jones’ decisions and instruction as Wife of Mr. Jones, and Dr. Bowden’s order and prescription; this Court has subject matter jurisdiction over this matter and the parties.

6. Venue lies in Tarrant County Defendants' primary place of business is in Tarrant County, and the cause of action arose in Tarrant County.

III. PARTIES

7. The Plaintiff, Erin Jones, is a citizen of the United States of America, a resident of the State of Texas, over the age of 18, Wife of Jason Jones, and therefore has standing to bring this Complaint.

8. The Defendant Doctors are hospitalists working at Defendants' Hospital, and who are managing Mr. Jones' care and treatment.

9. The Defendant, Texas Health Huguley, Inc., d/b/a Texas Health Huguley Hospital Fort Worth South has a principal business address of 11801 South Freeway, Burleson, TX 76028 (Attn: Penny L. Johnson), and is the physical hospital where Mr. Jones is a patient in the Intensive Care Unit, diagnosed with COVID-19, breathing only with the assistance of a ventilator.

IV. STATEMENT OF FACTS

10. On September 23, 2021, Mr. Jones was diagnosed with COVID-19.

11. On September 28, 2021, Mr. Jones was taken by ambulance to Defendants' Hospital and admitted.

12. From September 28, 2021 through October 7, 2021, he was treated in accordance with the Defendants' Hospital's COVID-19 protocol, which included steroids and antibiotics.

13. On or about October 7, 2021, Mr. Jones' condition worsened to such an extent that he was transferred to Defendants' Hospital ICU, where he was sedated, intubated, and placed on a ventilator.

14. Since October 7, 2021, Mr. Jones has been on a ventilator in a medically induced

coma, continuing to decline.

15. The Defendant Hospital has exhausted its COVID-19 treatment protocol, and has no further treatment options for Mr. Jones; his situation is truly “wait and see”.

16. As a 48-year-old male placed on a ventilator, Mr. Jones’ chances of survival have dropped to less than 30%.

17. At this point, there is nothing more the Defendants can do, or will do for Mr. Jones. Defendants have exhausted their course of treatment and COVID-19 procedure in treating Mr. Jones which is unacceptable to Mrs. Jones.

18. Mrs. Jones investigated other forms of treatment for COVID-19.

19. Mrs. Jones requested, as Mr. Jones’ Wife, that Defendants administer Ivermectin pursuant to its dosage schedule.

20. Mrs. Jones offered to sign a release thereby releasing Defendants, their agents, assigns, any third parties acting on its behalf, and any doctors acting on their behalf, from any and all liability in administering the Ivermectin to Mr. Jones.

21. Despite the aforementioned, Defendants refused and are unwilling to administer the Ivermectin to Mr. Jones.

22. Mr. Jones is on death's doorstep; there is no further COVID-19 treatment protocol for Defendants to administer to Mr. Jones; Mrs. Jones does not want to see Mr. Jones die, and she is doing everything she can to give her husband a chance to live.

23. Mrs. Jones sought the medical advice of Mary Talley Bowden, M.D., with regard to Mr. Jones’ prior medical history, current medical condition, and the usage of Ivermectin in treating COVID-19 and its after effects.

24. Dr. Bowden supports the use of Ivermectin to treat Mr. Jones and has prescribed

Ivermectin to him.

25. Defendants refuse to administer and comply with Dr. Bowden's prescription.

26. Mrs. Jones seeks a declaratory judgment declaring that Defendants follow Dr. Bowden's order and prescription to administer Ivermectin to their mutual patient, Mr. Jones; and a declaration that Defendants comply with the wishes and directives of Mrs. Jones, as Wife of Mr. Jones. Mrs. Jones has no other option but to bring the instant declaratory judgment civil action.

V. CAUSE OF ACTION

As and for a Cause of Action Against Defendants, Mrs. Jones alleges as follows:

27. Repeats and realleges each and every allegation previously made as if restated herein.

28. Mrs. Jones is the Wife of Mr. Jones.

29. Mr. Jones is a patient at Texas Health Huguley Hospital Fort Worth South, with very little chance of survival.

30. Mr. Jones has been diagnosed with COVID-19 and is currently in the Intensive Care Unit at Texas Health Huguley Hospital Fort Worth South; he is only breathing with the assistance of a ventilator.

31. Despite requesting that Defendants administer Ivermectin to Mr. Jones based on her authority as Mr. Jones's Wife, and Dr. Bowden's order and prescription, Defendants have refused and are unwilling to do so.

32. Despite Mrs. Jones' offer to sign a full release, releasing and relieving Defendants from any and all liability concerning the administration of Ivermectin to Mr. Jones, Defendants have refused and are unwilling to do so.

33. Despite Defendants exhausting its COVID-19 protocol with nothing left to treat

Mr. Jones, Defendants refuse to administer Ivermectin to Mr. Jones based on upon Dr. Bowden's order and prescription.

34. As a result of Defendants' refusal to administer the Ivermectin to Mr. Jones pursuant to Dr. Bowden's order and prescription, Mr. Jones, through his Wife, Mrs. Jones, has been damaged.

35. Mrs. Jones does not have an adequate remedy at law to enforce her authority as Wife of Mr. Jones, and/or Dr. Bowden's order and prescription.

36. Plaintiff alleges that Defendants have without justification breached their express and/or implied contract with Plaintiff and Mr. Jones in failing to provide proper medical care and have breached their collective obligation and oath to "do no harm" as it relates to Defendants' unjustified refusal to administer medical and pharmaceutical therapy to Mr. Jones in an effort to save his life which has been ordered by Dr. Bowden.

37. Defendants have violated Texas and Federal Law by denying Mr. Jones his legal right to make rational treatment decisions and choices, individually and through his Wife, Mrs. Jones. Defendants have further unlawfully ignored instructions clearly expressed by the Plaintiff, Mr. Jones's legally authorized representative, thereby violating his right to exercise informed consent to accept and/or decline proposed treatment.

38. Unless such conduct is enjoined and restrained, there is a substantial likelihood that such conduct, to wit: refusal to administer Ivermectin, will continue and Mr. Jones will lose all chance to preserve his life creating irreparable loss, damage and injury for which there is no adequate remedy at law.

39. Mrs. Jones does not have an adequate remedy at law to enforce her authority as Wife of Mr. Jones and/or Dr. Bowden's order and prescription.

40. Mrs. Jones has not made any prior applications for the relief requested herein.

41. It is Mrs. Jones' belief that she has made out a cause of action for declaratory judgment.

VI. RELIEF SOUGHT

Based on the facts and the law, Mrs. Jones is entitled to a declaratory judgment from this Court, declaring and enforcing her authority as Wife of Mr. Jones and Dr. Bowden's order and prescription to administer Ivermectin to Mr. Jones.

Mrs. Jones respectfully requests that this Court enter an order declaring that Defendants comply with (1) her reasonable requests as Mr. Jones's Wife; and (2) Dr. Bowden's order and prescription to administer Ivermectin to their mutual patient, Mr. Jones.

WHEREFORE, Mrs. Jones respectfully requests that this Court Order the following:

(A) Enter a judgment in favor of Mrs. Jones on the Complaint in its entirety and against the Defendants;

(B) Pursuant to Mrs. Jones's valid authority as Wife of Mr. Jones, that the Defendants comply with Dr. Bowden's order and prescription to administer Ivermectin to their mutual patient, Mr. Jones;

(C) Award Mrs. Jones all relief allowed by law and equity, including, but not limited to, declaratory, preliminary and permanent injunctive relief; and

(D) A judgment granting Mrs. Jones such other, further and different relief that the Court deems just, equitable and proper.

Respectfully submitted,

/s/ Jerri Lynn Ward

Jerri Lynn Ward
1510 Texas Avenue South
College Station, TX 77840
(512) 302-1103
Email: jward@garloward.com

ATTORNEYS FOR PLAINTIFF

EXHIBIT 3 Hand filed
at Court on
10/26/21
@ 7:55 a.m.
All

CAUSE NO. 323 117290 21

ERIN JONES, INDIVIDUALLY AND AS
LEGAL REPRESENTATIVE AND
NEXT FRIEND OF JASON JONES
v.

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JUDICIAL DISTRICT
THOMAS A. WILDER
DISTRICT CLERK
2021 OCT 26 PM 12:44
TARRANT COUNTY TEXAS

FILED
TARRANT COUNTY

TEXAS HEALTH HUGULEY HOSPITAL, FT.
WORTH, SOUTH
DR. JASON A. SIEDEN
JOHN DOES #1-5, JANE ROES #1-5
DEFENDANTS.

§
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PLAINTIFFS' APPLICATION FOR TEMPORARY RESTRAINING ORDER & INJUNCTION

TO THE HONORABLE JUDGE OF SAID COURT:

COMES NOW Erin Jones Individually and as Next Friend of Jason Jones and files her Application for Temporary Restraining Order and Injunction on behalf of her husband, respectfully showing the Court as follows:

I. Summary

1. Jason Jones is in the hospital suffering COVID-19. Jason has not positively responded to his current treatment protocol. Texas Health Huguley Hospital, Ft. Worth South (HOSPITAL) and its doctors, nurses, and other medical professionals, Dr. Jason A. Sieden John Does #1-5 (collectively, the "Does") and Jane Roes #1-5 (collectively, the "Roes") have refused to treat Jason with the drug known as Ivermectin because, upon information and belief: (1) Ivermectin has not yet received official approval of regulatory agencies for the treatment of COVID-19; and (2) MMMC, the Does, and the Roes (collectively, "Defendants") are concerned with their potential liability for treatment of Jason with Ivermectin for COVID-19 in the absence of official approval of regulatory agencies for the treatment of COVID-19. Jason has received a

prescription for Ivermectin, which is attached hereto as Exhibit A. HOSPITAL, the Does, and the Roes are concerned with their potential liability for treatment of Jason with Ivermectin for COVID-19 in the absence of official approval of regulatory agencies for the treatment of COVID-19. Jason and his wife, Erin Jones, his legal representative and surrogate decision-maker, requests a temporary restraining order and temporary injunction ordering Defendants to administer him Ivermectin in accordance with the prescription attached hereto as Exhibit A as part of his medical treatment.

II. Facts

2. The following facts are verified.

3. Jason was admitted as a patient to HOSPITAL and diagnosed with COVID-19.

The Does and Roes are the medical professionals that have rendered and continue to render medical treatment to Jason while he has been hospitalized at HOSPITAL.

4. Jason has not responded well to his current medical treatment and his condition has deteriorated substantially to the point where Jason is at medically substantial risk of death.

5. Jason has been prescribed Ivermectin. A true and correct copy of this prescription is attached hereto as Exhibit A.

6. Notwithstanding, Defendants have refused to treat Jason with the drug commonly known as Ivermectin because, upon information and belief, Ivermectin has not yet received official approval of regulatory agencies for the treatment of COVID-19. Defendants have declined to do so because, upon information and belief, Defendants are concerned with their potential liability for treatment of Jason with Ivermectin for COVID-19 in the absence of official approval of regulatory agencies for the treatment of COVID-19.

7. Considering his deteriorating condition, Jason desires for Defendants to treat him with Ivermectin, notwithstanding the current absence of official approval of regulatory agencies for the treatment of COVID-19. Erin Jones stipulates, as Jason's legal representative that she shall release Defendants, and any and all other persons, from any and all liability for any damages and injuries, up to and including death, that may be proximately caused by the administration of the treatment of Jason with Ivermectin in accordance with his prescription that is attached hereto as Exhibit 1

III. Arguments & Authorities

8. To obtain a temporary injunction, an applicant must plead and prove: (1) a cause of action against the defendant; (2) a probable right to the relief sought; and (3) a probable, imminent, and irreparable injury in the interim. *Id.* To establish a probable right to relief, a party is not required to prove that it will prevail at a final trial. *Id.* Rather, a probable right of recovery is shown by alleging a cause of action and presenting some evidence tending to sustain it. *Id.*

9. The potential loss of life is an obviously irreparable injury.

10. Jason's live pleading pleads viable cause of action for declaratory judgment based upon her constitutional right to life. The verified factual allegations set forth in this application present some evidence on each element of this cause of action. Therefore, Jason has satisfied the first two elements to be entitled to the relief requested.

11. The verified factual allegations set forth in this application present some evidence that Jason will suffer probable injury without the temporary injunctive relief requested. Death is irreversible.

12. The bond to secure the temporary restraining order and temporary injunction should be nominal because Defendants will suffer no damages on account of the requested

temporary restraining order. After all, Jason has stipulated to release Defendants from any liability related to the requested temporary restraining order. Therefore, Jason requests the bond be set at \$1.00.

13. The Court should enter a temporary restraining order and a temporary injunction compelling Defendants, and their respective officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with any of the foregoing who receive actual notice of the order by personal service or otherwise to immediately administer Jason Ivermectin in accordance with the prescription attached hereto as Exhibit A as part of her medical treatment.

IV. Prayer

WHEREFORE, PREMISES CONSIDERED, Plaintiffs pray a temporary restraining order and temporary injunction be entered as requested herein, and the Court award Plaintiffs all such other and further relief, both general and special, at law or in equity, to which they may be entitled.

Respectfully submitted
GARLO WARD,P.C
1511 Texas Ave. South
College Station, Texas 77840
www.garloward.com
(512) 302-1103|
Telephone (512) 302-1103

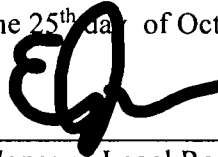
By: *Jerri Lynn Ward, J.D.*
Jerri Lynn Ward

Texas State Bar No. 20844200
jward@garloward.com
ATTORNEY FOR PLAINTIFFS

VERIFICATION

My name is Erin Jones, I am over the age of 18, and my address is c/o Garlo Ward at 1511 Texas Ave, South, College Station, Texas 77840 I have personal knowledge of the factual allegations in paragraphs 1-7, and they are true and correct. I declare under penalty of perjury the foregoing is true and correct.

EXECUTED in Tarrant County, State of Texas, on the 25th day of October, 2021.



Erin Jones as Legal Representative & Next
Friend of Jason Jones

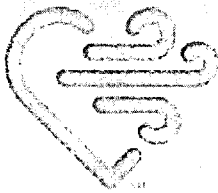
CERTIFICATE OF CONFERENCE

Pursuant to Local Rule 3.06 and 3.30, I certify that to the best of my knowledge, Defendants are not represented by counsel in the matter made the basis of the relief sought. Therefore, a conference was not held with Defendants on the merits of this application.

Jerri Lynn Ward, J.D.

Jerri Lynn Ward, J.D.

EXHIBIT 1



BreatheMD
OPTIMAL AIRWAY HEALTH

Prescription Form

Date: 10/22/21. Patient: Jason Jones DOB 12/4/1972

Ivermectin 3mg. Give 21 tablets per NGT qD, Dispense 210 tablets, Refill:2

Calcitriol 0.25mcg per NGT QD, Dispense: #30, Refill:2

Melatonin 12mg per NGT QHS, Dispense: #30, Refill:2

Fluvoxamine 50mg per NGT BID, Dispense #60, Refill:2

Cyproheptadine 8mg per NGT TID, Dispense #90, Refill:2

Zinc 100mg per NGT QD, Dispense #30, Refill: 2

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Finasteride 10mg per NGT QD, Dispense #30, Refill 2

Nitazoxanide 500mg per NGT BID, Dispense #60, Refill 2

IV Infusions Recommended:

- Methylprednisolone 80mg IV bolus then 40mg IV BID
- Vitamin C 25mg IV BID x 3 days
- Thiamine 200mg IV BID
- Therapeutic Plasma Exchange

Prescriber: Mary Talley Bowden, MD
Tx license: K9770
NPI: 1639859282

3600 Kirby Dr. Suite F
Houston, TX 77098
713-492-2340

713-206-8988 (cell)

EXHIBIT 4

FILED
TARRANT COUNTY
2021 OCT 28 AM 9:03
THOMAS A WILDER
DISTRICT CLERK
IN THE DISTRICT COURT

CAUSE NO. 323-117290-21

ERIN JONES, INDIVIDUALLY AND AS
LEGAL REPRESENTATIVE AND
NEXT FRIEND OF JASON JONES

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Plaintiff,

v.

OF TARRANT COUNTY, TEXAS

TEXAS HEALTH HUGULEY HOSPITAL,
FT. WORTH SOUTH, DR. JASON SIEDEN
JOHN DOES #1-5, JANE ROES #1-5

Defendants.

323RD JUDICIAL DISTRICT

**DEFENDANTS' EMERGENCY MOTION TO DISSOLVE
TEMPORARY RESTRAINING ORDER**

TO THE HONORABLE JUDGE OF SAID COURT:

COMES NOW Texas Health Huguley, Inc. d/b/a Texas Health Huguley Hospital Fort Worth South (“Huguley Hospital”), incorrectly named in the style as Texas Health Huguley Hospital, Ft. Worth South, and Dr. Jason Seiden, Defendants in the above-styled and numbered Cause, who make and file this their Emergency Motion to Dissolve Temporary Restraining Order and would show the Court the following:

I. INTRODUCTION

On October 26, 2021, the Court granted an *ex parte* application for a temporary restraining order requiring a hospital and, for all intents and purposes, everyone working in the hospital, to administer a medication to a patient. Plaintiffs' request for relief, and the Court's errant granting of relief, is defective, null and void, and should be dissolved and rescinded *in toto*. Plaintiff has wholly failed to establish an entitlement to the extraordinary remedy of injunctive relief, as the Court has no statutory or common law jurisdiction to dictate to health care providers the particulars

of medical or health care and treatment. Appellate courts have rejected a trial court's attempt to override the medical judgment of physicians, and there is no legal authority supporting a patient's (or a patient's agent's) right to force a physician to comply with requests for care inconsistent with that physician's judgment. In addition, the underlying cause of action pleaded by Plaintiff is invalid and defective, and the evidence supporting Plaintiff's request for relief is incompetent as a matter of law.

II. FACTUAL AND PROCEDURAL BACKGROUND

Jason Jones was admitted to Huguley Hospital on September 28, 2021 with COVID. His condition deteriorated. He is sedated, ventilated, and has a poor prognosis.

Unbeknownst to the hospital or Mr. Jones' care providers, on October 26, 2021, the Court issued an Order Granting Plaintiff's Application for Temporary Restraining Order ("TRO") attached hereto as Exhibit "1." The Order was presented to medical and nursing staff at Huguley Hospital. The TRO has no cause number and appears to have been presented to the Court before court was called to session on October 26, 2021—it is handwritten on the TRO that the document was "Hand Filed at 7:55 a.m.," before the courthouse is even open. The TRO ostensibly requires Huguley Hospital and other unnamed medical and nursing staff to administer a medication to a hospitalized COVID patient purportedly prescribed by an otolaryngologist in Houston, Texas that does not have clinical privileges at Huguley Hospital. The Court's Order was served upon Defendants on October 27, 2021. This Motion timely follows.

Plaintiff's Petition for Emergency Medical Declaratory Judgment and Emergency Injunctive Relief, oddly, was filed at 4:40 p.m. (indicated by a hand-stamped file mark), over nine hours after the TRO was signed. This circumstance wrecks of manifest impropriety, as Tarrant County Local Rules require cases to be filed with the District Clerk's office and assigned to courts

randomly and “designated for the subject matter of the litigation”—the 323rd Judicial District Court is a statutorily authorized juvenile court and would not be assigned this matter had local rules been followed. It appears Plaintiff has forum-shopped this matter to a venue more likely to grant the relief requested, appeared before the Court before court was even in session, and wholly disregarded local rules and the Texas Rules of Civil Procedure.

Further, the underlying cause of action upon which Plaintiff bases her Application for a temporary restraining order is for a declaratory judgment “declaring and enforcing [Plaintiff’s] authority as Wife of Mr. Jones and Dr. Bowden’s order and prescription to administer Ivermectin to Mr. Jones.” Plaintiff has not properly stated a cause of action under the Uniform Declaratory Judgments Act; Chapter 37 of the Texas Civil Practice and Remedies Code. Without a valid cause of action and probable right to recover, the restraining order is defective on its face and the Order granting relief is void.

II. ARGUMENT AND AUTHORITY

“A temporary injunction is an extraordinary remedy and does not issue as a matter of right.” *Walling v. Metcalfe*, 863 S.W.2d 56, 57 (Tex. 1993) (per curiam). “A temporary injunction’s purpose is to preserve the status quo of the litigation’s subject matter pending a trial on the merits.” *Butnaru v. Ford Motor Co.*, 84 S.W.3d 198, 204 (Tex. 2002). “A prohibitive injunction forbids conduct, whereas a mandatory injunction requires it.” *Tri-Star Petroleum Co. v. Tipperary Corp.*, 101 S.W.3d 583, 592 (Tex.App.—El Paso 2003, pet. denied). Under Texas law, mandatory injunctive relief “is proper only if a mandatory order is necessary to prevent irreparable injury or extreme hardship.” *Id.*; see also *Rhodia, Inc. v. Harris County*, 470 S.W.2d 415, 419 (Tex.Civ.App.—Houston [1st Dist.] 1971, no writ). In this case, the Court has issued mandatory injunctive relief, requiring Defendants to administer medication not otherwise prescribed.

A. Courts Reject the Substitution of Independent Medical Judgment

Here, rather than preserving the status quo, the Court has issued an order granting, in essence, mandatory injunctive relief, *i.e.* affirmative action which contravenes the status quo. The Court has ordered Defendants to administer a medication that is currently not prescribed by any licensed physician that is credentialed by Huguley Hospital, and which is inconsistent with not only the patient's physicians but also the standard of care. As such, the Court's order requires the surrender of the patient's physicians' clinical judgment to that of another physician that is not credentialed in the hospital and, by definition, has not adequately examined the patient, as well as to the judgment of the Court, which is not a licensed physician with any legal authority to dictate a patient's plan of care.

Texas courts have recognized that mandatory injunctions are tenuous when what is interfered with is the independent medical judgment of health care providers. Courts have "disavowed any attempt to second-guess the propriety or adequacy of a particular course of treatment" because it is "a question of sound professional judgment." *Muniz v. Texas Dep't of Crim. Just.*, 2008 WL 2764518 at *3 (Tex.App.—Corpus Christi Jul. 17, 2008, no pet.) (rejecting request for preliminary injunction ordering defendants to provide patient operation—"Courts should not intervene upon allegations of mere negligence, mistake, or difference of opinion"). Federal courts have also held that "judges are not 'better qualified than appropriate professionals' to make decisions relating to the physical and mental health of patients and that, to the extent possible, 'interference by the federal judiciary with the internal operations of...institutions...should be "minimized." *Costa v. Bazron*, 464 F.Supp. 3d 132, 141 (D.D.C. 2020) (quoting *Youngberg v. Romeo*, 457 U.S. 307, 322-23 (1982)); *See also Youngberg*, 457 U.S. at 323 ("[W]e emphasize that courts must show deference to the judgment exercised by a qualified

professional”—“[T]here certainly is no reason to think that judges or juries are better qualified than appropriate professionals in making such decisions.”); *Bowring v. Godwin*, 551 F.2d 44, 48 (4th Cir. 1977) (“[W]e disavow any attempt to second-guess the propriety or adequacy of a particular course of treatment. Along with other aspects of health care, this remains a question of sound professional judgment. The courts will not intervene upon allegations of mere negligence, mistake or difference of opinion.”).

Here, the Court has failed to give proper deference to the independent, professional, and clinical judgment of the patient’s health care providers, and has equally failed to give the same deference to the exercise of medical judgment that previous federal and state courts have given. Defendants have exercised clinical judgment, including with respect to the patient’s plan of care, but the Court has abused its discretion by ordering them to administer a certain medication despite any legal authority or evidence to support the Court’s decision.

B. Plaintiff’s Evidence to Support Verified Facts is Incompetent

In Plaintiff’s Application for Temporary Restraining Order & Injunction, it is asserted that “Jason has been prescribed Ivermectin,”¹ and a copy of the purported prescription is attached to the Application as Exhibit “1.” The “Prescription Form” purports to have originated from Mary Talley Bowden, M.D. of BreatheMD in Houston, Texas. According to Dr. Bowden’s public profile available through the Texas Medical Board, she is an otolaryngologist (a/k/a ear, nose, and throat) and specializes in sleep medicine.² Dr. Bowden is not a credentialed member of the Huguley Hospital medical staff.

A host of evidentiary deficiencies are readily apparent. First, while Plaintiff’s Application is supported by Plaintiff’s verification, any evidentiary support for the purported prescription of

¹ See Plaintiff’s Application for Temporary Restraining Order & Injunction, at 2.

² See Exhibit “2.”

Ivermectin to Jason Jones is completely untethered from all concepts of competence. There is no affidavit from Dr. Bowden that sets forth her qualifications to provide COVID-related care to Mr. Jones, much less any support for how an otolaryngologist would be qualified to be involved in the acute care of a severely-ill hospitalized, sedated and ventilated COVID patient. Further, there is no information related to how Mr. Jones came to be in Dr. Bowden's care, when or how she examined him such that she could be in any position to make an assessment and plan of care, issue diagnostic orders, or prescribe medications. Of note, the "prescription form" is dated October 22, 2021. Mr. Jones has been in-patient at Huguley Hospital since September 28, 2021. There is not a single medical record attached to Plaintiff's Petition or Application that would provide the Court a shred of assurance that the "care" rendered to the patient by Dr. Bowden (if any) was reasonable, prudent, and consistent with the standard of care. In fact, Plaintiff states (correctly) numerous times in her Application that Ivermectin is not approved by the Federal Drug Administration to be dispensed in the manner required by the Court's Order.

Plaintiff's Application is without even a scintilla of competent evidence upon which her verified facts are based. Without such, Plaintiff cannot show a "probable right to the relief sought," and therefore is not entitled to the extraordinary remedy of mandatory injunctive relief. She has asked the Court to override the medical judgment of credentialed physicians and health care providers at Huguley Hospital, and substitute that judgment with the Court's judgment as to medications to be administered to a patient based upon a purported prescription from an unqualified and non-credentialed physician that has neither examined the patient nor provided the Court any assurances that she is qualified to issue any care and treatment decisions related to Mr. Jones, credentialed to care for patients at Huguley Hospital, or that she actually has prescribed Mr. Jones Ivermectin, when she examined the patient, where the records are of her encounter with the

patient, and upon what assessment and plan of care her purported prescription of Ivermectin is based. Quite frankly, that the Court would grant the relief requested on so little is shocking and disappointing.

C. Impropriety and Forum-Shopping are Readily Apparent

Tarrant County Local Rule 3.30(a) states that “[n]o application for action for relief of any kind shall be presented to a judge until the application or case has been filed with the clerk and assigned to a court, unless it is impossible to do so.” In this case the Court’s Order was signed at 7:54 a.m. on October 26, 2021. Plaintiff’s Application for Temporary Restraining Order & Injunction were file-marked by the Tarrant County District Clerk’s Office at 12:14 p.m. the same day. A handwritten note above the file mark indicates that Application was “Hand Filed with Court on 10/26/21 @ 7:55 a.m., one minute *after* the Order was granted. As such, the Court’s Order was submitted before the Court was even in session and before the Application was filed.

Tarrant County Local Rule 1.03(a) states that “cases will be filed by random selection in courts designated for the subject matter of the litigation.” Pleadings, even *ex parte* requests for immediate relief, are to be submitted to the clerk, who then creates a new file and randomly assigns the case to a district judge. *Id.* These rules of random assignment are specifically intended and designed to prevent forum-shopping, either by litigants or politically-motivated attorneys or judges. It is readily apparent that the system was circumvented in this case. Upon information and belief, Plaintiff’s Application was never submitted to the Tarrant County District Clerk’s Office in order to be randomly assigned to a district judge. First, the 323rd Judicial District Court is the only district court in Tarrant County that does not use an electronic filing system—explaining the hand-stamped file mark. Such would appear on the documents if, and only if, they were “filed” at the 323rd.

Secondly, and more to the point, had this matter been subject to random assignment as required by Tarrant County Local Rules, the 323rd would have been ineligible to receive the assignment, as the Court is designated as the juvenile court for Tarrant County pursuant to Texas Family Code § 51.04(b). Even the Court's own website notes that it "hears Child Welfare and Juvenile Delinquency cases,"³ which this matter is neither.

There is no other rational explanation for this matter coming before the 323rd Judicial District Court than forum-shopping and apparent political motives. The undersigned references the case styled *Tinslee Breau Lewis, a Minor and Mother, Trinity Lewis, on her Behalf v. Cook Children's Medical Center*, Cause No. 323-112330-19, and its procedural history, as evidence of the reasonable deduction that improper motives are afoot. These circumstances in and of themselves require the dissolution of the Court's Order, or at the very least the transfer of this matter to a properly assigned district court.

D. Plaintiff has not stated a Claim for Relief

To prevail on a request for injunctive relief, Plaintiff must plead and prove three specific elements: (1) a cause of action against the defendant; (2) a probable right to the relief sought; and (3) a probable, imminent, and irreparable injury in the interim." *Butnaru*, 84 S.W.3d at 204. Plaintiff requests a declaratory judgment that gives her a legal right to dictate treatment determinations for her husband requires Defendants to administer a medication purportedly prescribed by a non-credentialed and wholly unqualified provider.

Under the Uniform Declaratory Judgments Act, the only subject matter for relief permitted is that of "[a] person interested under a deed, will, written contract, or other writings constituting a contract or whose rights, status, or other legal relations are affected by a statute, municipal

³ <https://www.tarrantcounty.com/en/juvenile-courts/323rd-district-court.html>.

ordinance, contract, or franchise.” Tex. Civ. Prac. & Rem. Code § 37.004(a). Such persons may have determined any question of construction or validity arising under the instrument, statute, ordinance, contract, or franchise and obtain a declaration of rights, status, or other legal relations thereunder. *Id.* In this case, Plaintiff has not pleaded any *valid* interest under a deed, will, written contract, or other writing constituting a contract, nor has she pleaded that her rights (or those of her husband) are affected by any statute, municipal ordinance, contract, or franchise. Instead, Plaintiff alleges that she seeks a declaration determining the rights of the parties under a nebulously-referenced “Patient/Physician contract” and the “hypocritic [sic] Oath.”

Plaintiff does not articulate on her reference to a “Patient/Physician contract.” She has not presented any contract to the Court for examination or inspection; there are no allegations about the terms of this phantom “contract,” nor is there any information in Plaintiff’s Petition or Application from which the Court could decipher what rights any party has or does not have that can be declared. Plaintiff does not present any competent evidence that declining to administer Ivermectin to Mr. Jones constitutes a violation or breach of the “Patient/Physician contract,” nor does she present any evidence that declining to provide Ivermectin constitutes medically improper care. The pleading is unequivocally defective. It is as if Plaintiff, knowing that to provide the Court jurisdiction to consider her request for relief under the Uniform Declaratory Judgments Act required some contract or other writing to underlie the requested relief, included “Patient/Physician contract” merely to state magical words to avoid a plea to the jurisdiction. Such conduct violates Texas Rule of Civil Procedure 13, among other pleading rules, and is subject to sanctions.

Plaintiff also seeks declaratory relief as to her “authority” as the “Wife” of Mr. Jones. There is no subject matter of relief available under the Uniform Declaratory Judgments Act for relief based upon the mere spousal relationship. Giving Plaintiff the benefit of the doubt, perhaps

she means to state that she has the legal authority to act as medical power of attorney for her husband, and thus her requests related to his care should be honored by his health care providers. Even this ground falls short of providing the Court jurisdiction. Plaintiff has failed to cite to any authority recognizing a patient's (or the patient's agent's) legal right to force a physician or health care provider to comply with the patient's treatment request even if the physician or health care provider believes such treatment is not medically appropriate.

Plaintiff also conclusively asserts that "Defendants have violated Texas and federal law by denying Mr. Jones his legal right to make rational treatment decisions and choices."⁴ She does not, however, state what Texas and federal laws her pleadings refer to, much less point the Court to a law that gives Mr. Jones and/or his "Wife" and their supposed "legal right to make rational treatment decisions and choices" legal priority over Defendants' legal and countervailing rights to make treatment decisions based upon the exercise of their own reasonable and prudent medical judgment. In other words, even if Mr. Jones had a legal right to take Ivermectin, there is no authority, nor could Plaintiff ever cite to any, that such a "right" compels a physician or health care provider to administer it to him.

Plaintiff further alleges that Defendants have violated Plaintiff's "right to exercise informed consent to accept and/or decline proposed treatment." Not only is this not a proper subject matter for declaratory relief, but Plaintiff's reliance on informed consent as a concept is misplaced and makes no logical sense. Mr. Jones cannot, by definition, exercise informed consent for a medication that he is not being administered. Informed consent relates to a patient's rights to know the risks and hazards of certain care and treatment before the care and treatment takes

⁴ See Plaintiff's Petition, at ¶ 37.

place. It does not give patients the legal right to demand care and treatment from a physician or substitute their own judgment for that of a physician or health care provider.

At any rate, it is notable that there is no recognized, valid, cause of action against a hospital for failing to administer a drug that is outside the standard of care. *See, for example, DeMarco v. Christiana Care Health Servs., Inc.*, No. CV 2021-0804-MTZ, 2021 WL 4343661 (Del. Ch. Sept. 24, 2021). The Court in *Demarco* addressed essentially the same issue as in this case. That Court denied a TRO finding that “[u]nder the present standard of care, healthcare providers have no duty to administer ivermectin to a COVID-19 patient” and that refusing to administer ivermectin did not breach the physician, patient relationship. *Id.* at 9. The same is true here. There is no cause of action against the hospital for failure to administer a medication that is outside of the standard of care, a circumstance Plaintiff essentially admits in her pleadings. Because there is no valid cause of action, there cannot be a probable right to relief.

Moreover, Courts addressing this issue have found that granting injunctive relief would adversely impact:

“the safe and effective development of medications and medical practices. ... a hospital's standard of care decisions, mandating doctors and nurses to provide care they believe unnecessary, ethical concerns of all doctors involved, patient autonomy, fiduciary duty, accreditation standards for patient protections, obligating one's doctor to carry out the treatment regimen/plan of another doctor, ... and whether a court should mediate or legislate from the bench.” *Id.* at 12.

What Plaintiff seeks is anathema to the obligation of physicians and health care providers to act in their patient's best interests. “The American Medical Association itself has stated that ‘[p]hysicians are not ethically obliged to deliver care that, in their best professional judgment, will not have a reasonable chance of benefitting their patients[,] [and p]atients should not be given treatments simply because they demand them.’ Because the AMA generally recognizes that physicians have an ethical duty to exercise independent medical judgment, the question becomes

whether a doctor's fiduciary obligation legally requires the doctor 'just say no' to a demanding patient...Because of patients' limited ability to make medical decisions for themselves, however, physicians – to properly serve the best interests of their patients – must always exercise their independent medical judgment and provide access only to appropriate medical services. Thus, to satisfy their fiduciary obligation, physicians should authorize access only to those services that reflect and represent the exercise of their independent medical judgment and that are medically indicated for their patient – that is, to provide access consistent with the patient's medical needs and condition. To ensure that physicians retain their valued and valuable role in the physician-patient relationship, physicians must always exercise their independent medical judgment, even when doing so is contrary to the expressed wishes of the patient and may jeopardize the physicians financial well-being or other self-interests.” Thomas L. Hafemeister & Richard M. Gulbrandsen, Jr., *The Fiduciary Obligation of Physicians to “Just Say No” if an “Informed” Patient Demands Services That Are Not Medically Indicated*, 39 SETON HALL L. REV. 3356, 373-74 (2009).

III. CONCLUSION

For the reasons stated herein, the Court should dissolve its Order Granting Plaintiff's Application for Temporary Restraining Order. Plaintiff's Petition and Application are defective on their face, were improperly presented to the 323rd Judicial District Court, and are not based on even the slightest scintilla of competent evidence. Plaintiff has not and cannot meet her burden to obtain the relief that the Court erroneously and imprudently granted, and the Order in and of itself is one that is impossible for Defendants to comply—Defendants cannot allow their independent medical and professional judgment be superseded and overridden by the Court or a non-credentialed and unqualified provider. The Court's Order manifestly violates public policy and Texas law, and should be dissolved *in toto*.

IV. PRAYER

WHEREFORE, PREMISES CONSIDERED, Defendants pray the Court immediately dissolve its Order and for all other and further relief, both general and special, at law or in equity, to which Defendants may show themselves to be justly entitled.

Respectfully submitted,

By: /s/ Joshua D. Ross
Joshua D. Ross
State Bar No. 24046760
jross@canteyhanger.com

Scharli S. Branch
State Bar No. 24103566
ssbranch@canteyhanger.com

CANTEY HANGER LLP
Cantey Hanger Plaza
600 W. 6th Street, Suite 300
Fort Worth, Texas 76102
(817) 877-2800 Telephone
(817) 877-2807 Facsimile

ATTORNEYS FOR DEFENDANTS

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was served on counsel for the Plaintiff on the 28th day of October, 2021 via email and facsimile

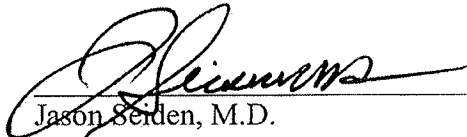
/s/ Joshua D. Ross
Joshua D. Ross

VERIFICATION OF JASON SEIDEN, M.D.

STATE OF TEXAS §
 §
COUNTY OF TARRANT §

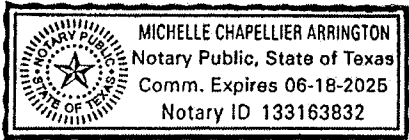
Before me, the undersigned authority, a Notary Public in and for the State of Texas, on this day personally appeared Jason Seiden, M.D., who after being by me first duly sworn, upon his oath deposes and says:

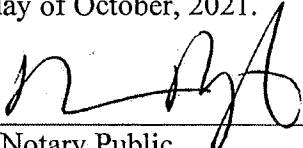
1. My name is Jason Seiden, M.D. I am over eighteen (18) years-of-age and I am fully competent to make this Verification. I have reviewed the factual representations made in Defendants' Emergency Motion to Dissolve Temporary Restraining Order, which incorporates this Verification, and to the best of my knowledge the factual assertions are true and correct.



Jason Seiden, M.D.

Subscribed and sworn to before me on this the 28 day of October, 2021.





Notary Public
State of Texas

Exhibit

1

Hand Filed w/
Court on
10/26/2021
@ 7:55 a.m.
(12)

CAUSE NO. _____

ERIN JONES, INDIVIDUALLY AND AS
LEGAL REPRESENTATIVE AND
NEXT FRIEND OF JASON JONES
V.

§
§
§
§

_____ JUDICIAL DISTRICT

TEXAS HEALTH HUGULEY HOSPITAL, FT.
WORTH, SOUTH
DR. JASON A. SIEDEN
JOHN DOES #1-5, JANE ROES #1-5
DEFENDANTS.

§
§

TARRANT COUNTY, TEXAS

ORDER GRANTING PLAINTIFF'S APPLICATION FOR TEMPORARY RESTRAINING ORDER

ON THIS DAY came on to be considered the Application for Temporary Restraining Order and Injunction (the "Application") filed by ("Plaintiff") on an *ex parte* and emergency basis. After considering the Application, which is verified, including the Exhibit A attached thereto, and the argument of counsel, the Court has resolved to render this Order. It is therefore

FOUND that there is some evidence to support each of the following findings of fact: (1) Dr. Jason A. Sieden, Texas Health Huguley Hospital, Ft. Worth South and its doctors, nurses, and other medical professionals, John Does #1-5 (collectively, the "Does") and Jane Roes #1-5 (collectively, the "Roes") (collectively, "Defendants") have refused to treat Plaintiff Jason Jones with the drug known as Ivermectin; (2) Plaintiff was admitted as a patient to Texas Health Huguley Hospital, Ft. Worth South, owned and operated by Texas Health Resources and AdventHealth., Jason Jones was diagnosed with COVID-19; (3) Dr Sieden and the Does and Roes are the medical professionals that have rendered and continue to render medical treatment to Plaintiff while he has been hospitalized at Texas Huguley Hospital, Ft. Worth South;

(4) Plaintiff has not responded well to his current medical treatment and his condition has deteriorated substantially to the point where Plaintiff is at medically substantial risk of death; (5) Plaintiff has been prescribed Ivermectin, and a true and correct copy of this

prescription is attached hereto as Exhibit 1; (6) notwithstanding, Defendants have refused to treat Plaintiff with the drug commonly known as Ivermectin because, upon information and belief, Ivermectin has not yet received official approval of regulatory agencies for the treatment of COVID-19; (7) Defendants have declined to do so because, upon information and belief, Defendants are concerned with their potential liability for treatment of Plaintiff with Ivermectin for COVID-19 in the absence of official approval of regulatory agencies for the treatment of COVID-19; (8) considering his deteriorating condition, Plaintiff desires for Defendants to treat him with Ivermectin, notwithstanding the current absence of official approval of regulatory agencies for the treatment of COVID-19; (9) Plaintiff, Erin Jones, as legal representative and next Friend of Jason Jones, stipulates that she shall release Defendants, and any and all other persons, from any and all liability for any damages and injuries, up to and including death, that may be proximately caused by the administration of his treatment with Ivermectin in accordance with his prescription that is attached hereto as Exhibit A (1); it clearly appears from the specific facts shown in the Application, which is verified, that immediate and irreparable injury will result to Plaintiff before notice can be served and a hearing had thereon; (11) the injury sought to be avoided includes death, which is irreparable by definition; and (12) the Application is being granted without notice to Defendants because death could potentially result if the granting of the Application is delayed to allow notice to Defendants. It is further

ORDERED that the Application is **GRANTED**. It is further

ORDERED that, for a period of 14 days from the signing of this Order, under penalty of contempt, Defendants, along with their agents, servants, employees, and attorneys, and all persons in active concert or participation with any of the foregoing who receive actual notice of the injunction by personal service or otherwise, are compelled to immediately administer Jason

Jones Ivermectin in accordance with the prescription attached hereto as Exhibit A as part of his medical treatment. It is further

\$ 25.00 (A)

ORDERED that Plaintiff shall post a bond in the amount of \$1.00, which Plaintiff can pay at the time Plaintiff files the petition for this cause and/or the application with the Clerk of the Court and/or other instrument through the Texas e-File system. It is further

ORDERED that a hearing on a temporary injunction for this temporary restraining order shall be held at 4 o'clock p.m. on the 8th day of November, 2021, in the courtroom for the 323rd Judicial District Court in Tarrant County, Texas, unless notice is given before this date and time that this matter will be heard elsewhere.

RENDERED and SIGNED at 7:54 o'clock ^{am} on this 25th ^{26th PD} day of October, 2021.



The Hon. Alex Kim, Judge Presiding

APPROVED AS TO FORM & SUBSTANCE

Jerri Lynn Ward, J.D.

Attorney for Plaintiffs



BreatheMD
OPTIMAL AIRWAY HEALTH

Prescription Form

Date: 10/22/21. Patient: Jason Jones DOB 12/4/1972

Ivermectin 3mg. Give 21 tablets per NGT qD, Dispense 210 tablets, Refill:2

Calcitriol 0.25mcg per NGT OD, Dispense: #30, Refill:2

Melatonin 12mg per NGT QHS, Dispense: #30, Refill:2

Fluvoxamine 50mg per NGT BID, Dispense #60, Refill:2

Cyproheptadine 8mg per NGT TID, Dispense #90, Refill:2

Zinc 100mg per NGT OD, Dispense #30, Refill: 2

Famotidine 80mg per NGT BID, Dispense #60, Refill 2

Atorvastatin 80mg per NGT OD, Dispense #30, Refill 2

Flutamide 250mg per NGT TID, Dispense #90, Refill 2

Spirololactone 100mg per NGT BID, Dispense #60, Refill 2

Finasteride 10mg per NGT OD, Dispense #30, Refill 2

Nitazoxanide 500mg per NGT BID, Dispense #60, Refill 2

IV infusions Recommended:

- Methylprednisolone 80mg IV bolus then 40mg IV BID
- Vitamin C 25mg IV BID x 3 days
- Thiamine 200mg IV BID
- Therapeutic Plasma Exchange

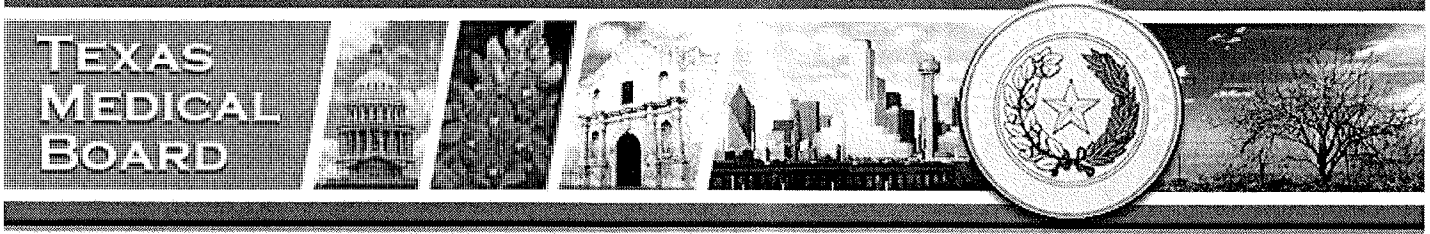
Prescriber: Mary Talley Bowden, MD
Tx license: K9770
NPI: 1699858202

3600 Kirby Dr. Suite F
Houston, TX 77098
713-492-2340

713-206-8988 (cell)

Exhibit

2



PUBLIC VERIFICATION / PHYSICIAN PROFILE

PHYSICIAN

NAME: MARY TALLEY BOWDEN MD

DATE: 10/27/2021

**THE INFORMATION IN THIS BOX HAS BEEN VERIFIED
BY THE TEXAS MEDICAL BOARD**

Date of Birth: 1972

License Number: K9770 Full Medical License

Issuance Date: 05/19/2000

Expiration Date of Physician's Registration Permit: 08/31/2022

Registration Status: ACTIVE

Registration Date: 03/28/2017

Disciplinary Status: NONE

Disciplinary Date: NONE

Licensure Status: NONE

Licensure Date: NONE

Medical School of Graduation:

At the time of licensure, TMB verified the physician's graduation from medical school as follows:
MED COLL OF GEORGIA, AUGUSTA UNIV, GEORGIA

Medical School Graduation Year: 1998

TMB Filings, Actions and License Restrictions

The Texas Medical Board has the following board actions against this physician. (This may include any formal complaints filed by TMB, as well as petitions and/or responses related to licensure contested matters, at the State Office of Administrative Hearings.)

NONE

Investigations by TMB of Medical Malpractice

Section 164.201 of the Act requires that: the board review information relating to a physician against whom three or more malpractice claims have been reported within a five year period. Based on these reviews, the following investigations were conducted with the listed resolutions.

NONE

Status History

Status history contains entries for any updates to the individual's registration, licensure or disciplinary status types (beginning with 1/1/78, when the board's records were first automated). Entries are in reverse chronological order; new entries of each type supersede the previous entry of that same type. These records do not display status type. Should you have any questions, please contact our Customer Information Center at 512-305-7030 or verificic@tmb.state.tx.us

Status Code: AC **Effective Date:** 03/28/2017

Description: ACTIVE

Status Code: DQ **Effective Date:** 09/30/2016

Description: DELINQUENT-NON PAYMENT

Status Code: AC **Effective Date:** 01/15/2015

Description: ACTIVE

Status Code: DQ **Effective Date:** 09/30/2014

Description: DELINQUENT-NON PAYMENT

Status Code: AC **Effective Date:** 09/04/2003

Description: ACTIVE

Status Code: TI **Effective Date:** 08/15/2003

Description: TEXAS LICENSE ISSUED

Status Code: PR **Effective Date:** 03/31/2003

Description: APPLIED FOR RELICENSURE

Status Code: CRB **Effective Date:** 09/07/2001

Description: BOARD CANCELLED BY REQUEST

Status Code: IA **Effective Date:** 08/31/2000

Description: INACTIVE-PRELIM TO BECOMING CN/CR

Status Code: DQ **Effective Date:** 08/17/2000

Description: DELINQUENT-NON PAYMENT

Status Code: LI **Effective Date:** 05/19/2000

Description: LICENSE ISSUED

THE INFORMATION IN THIS BOX WAS REPORTED BY THE LICENSEE AND
HAS NOT BEEN VERIFIED BY THE TEXAS MEDICAL BOARD

Gender: FEMALE

***Ethnicity:** WHITE

Race: WHITE

* We are in the process of transitioning from the current ethnic origin values to federal standards for race and Hispanic origin. The transition period will allow time for individuals to submit updated race and Hispanic origin data to the TMB.

Place of Birth: GEORGIA

Current Primary Practice Address:

2529 DEL MONTE DR
HOUSTON , TX 77019

Years of Active Practice in the U.S. or Canada:

The physician reports that he/she has actively practiced medicine in the United States or Canada for **11** year(s).

Years of Active Practice in Texas:

The physician reports that, of the above years he/she has actively practiced in the State of Texas for **8** year(s).

Specialty Board Certification

The physician reports that he/she holds the following specialty certifications issued by a board that is a member of the American Board of Medical Specialties or the Bureau of Osteopathic Specialists:

Specialty Certification: AMERICAN BOARD OF OTOLARYNGOLOGY

Date: 2004

Specialty Certification: AMERICAN BOARD OF OTOLARYNGOLOGY

Date: 2004

Primary Specialty

The physician reports his/her primary practice is in the area of OTOLARYNGOLOGY.

Secondary Specialty

The physician reports his/her secondary practice is in the area of SLEEP MEDICINE.

Name, Location and Graduation Date of All Medical Schools Attended

Name: MEDICAL COLLEGE OF GEORGIA

Location: AUGUSTA, GA

Graduation Date: 1998

Graduate Medical Education In The United States Or Canada

Program Name: UTMB

Location: GALVESTON, TX

Begin Date: 07/1999

Type: RESIDENCY

End Date: 06/2000

Specialty: OTOLARYNGOLOGY

Program Name: STANFORD UNIVERSITY

Location: PALO ALTO, CALIFORNIA

Begin Date: 07/2000

Type: RESIDENCY

End Date: 06/2003

Specialty: OTOLARYNGOLOGY

Program Name: UTMB

Location: GALVESTON, TX

Begin Date: 7/1998

Type: INTERNSHIP

End Date: 6/1999

Specialty: GENERAL SURGERY

Hospital Privileges

The physician reports that he/she has hospital privileges in the following in the State of Texas:

NONE

Utilization Review

The physician did not report whether he/she provides utilization review.

NONE REPORTED

Patient Services

Accessibility: The physician reports that the patient service area is accessible to persons with disabilities as defined by federal law.

Language Translation Services: The physician reports that the following language translation services are provided for patients: SPANISH

Medicaid Participant: The physician reports that he/she **does not** participate in the Medicaid program.

Awards, Honors, Publications and Academic Appointments

Optional Information

The physician may optionally report descriptions of up to five such honors and has reported the following:

Description: OTOLARYNGOLOGY AND FACIAL PLASTIC SURGERY PEARLS OF WISDOM, 2ND EDITION 2006 MCGRAW HILL PUBLISHING COMPANY

Description: OTOLARYNGOLOGY PEARLS OF WISDOM, 3RD EDITION 2011 MCGRAW HILL PUBLISHING COMPANY

Description: OTOLARYNGOLOGY PEARLS OF WISDOM, 2001, BOSTON MEDICAL

PUBLISHING (EDITION)

Description: ALPHA OMEGA ALPHA

Malpractice Information

Section 154.006(b)(16) of the Act requires that: a physician profile display a description of any medical malpractice claim against the physician, not including a description of any offers by the physician to settle the claim, for which the physician was found liable, a jury awarded monetary damages to the claimant, and the award has been determined to be final and not subject to further appeal. The physician has the following reportable claims.

Description: NONE

Criminal History

Self-Reported Criminal Offenses:The physician is required to report a description of (1) "any conviction for an offense constituting a felony, a Class A or Class B misdemeanor, or a Class C misdemeanor involving moral turpitude" and (2) "any charges reported to the board to which the physician has pleaded no contest, for which the physician is the subject of deferred adjudication or pretrial diversion, or in which sufficient facts of guilt were found and the matter was continued by a court of competent jurisdiction."

The physician has reported the following:

Description: NONE

Criminal history information is also obtained by TMB from the Texas Department of Public Safety. Resulting action, if any, will be reported under the TMB Action and Non-Disciplinary Restrictions section above.

Disciplinary Actions By Other State Medical Boards

The physician has reported the following:

Description: NONE

Physician Assistant Supervision

Description: NONE

Advanced Practice Nurse Delegation

To obtain
primary
source
verifications,
click name

To obtain

primary
source
verifications,
click name

Description: NONE

Summary of all License/Permit Types

Issue Date:	Type:
06/22/1998	<u>INSTITUTIONAL PERMIT</u>
05/19/2000	<u>LICENSED PHYSICIAN</u>
07/07/2003	<u>PHYSICIAN TEMPORARY LICENSE</u>

[Contact Us](#) | [Privacy Policy](#) | [Accessibility Policy](#) | [Compact with Texans](#) | [Website Linking Policy](#)

Please contact Pre-Licensure, Registration and Consumer Services at (512) 305-7030 for assistance.

EXHIBIT 5

NO. 323-117290-21

**ERIN JONES, INDIVIDUALLY AND
AS LEGAL REPRESENTATIVE AND
NEXT FRIEND OF JASON JONES
Plaintiff,**

v

**TEXAS HEALTH HUGHLEY, INC.,
d/b/a/ TEXAS HEALTH HUGHLEY
HOSPITAL FT. WORTH SOUTH;
DR. JASON A. SIEDEN;
JOHN DOES #1-5; JANE ROES #1-5;
Defendants**

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IN THE DISTRICT COURT

323RD JUDICIAL DISTRICT

TARRANT COUNTY, TEXAS

**FILED
TARRANT COUNTY
2021 OCT 28 PM 4:19
THOMAS AWILDER
DISTRICT CLERK**

ORDER TO TRANSFER CASE

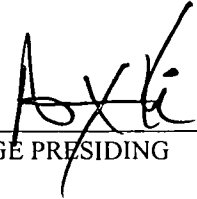
The Court, on its own motion, ORDERS that this matter is to be transferred to a District Court of Tarrant County, Texas with a preference for civil matters.

IT IS THEREFORE ORDERED that this suit is transferred to a District Court of Tarrant County, Texas with a preference for civil matters. On receipt of the of this order, the district clerk of this county is ORDERED to randomly assign a District Court with a preference for civil matters and file and docket the suit in the appropriate court with the appropriate cause number. The district clerk shall notify all parties, the clerk of the transferring court, and, if appropriate, the transferring court's local registry that the suit has been docketed.

The clerk of this Court is ordered to transmit immediately the entire contents of the court file.

The clerk of this Court is ordered to keep a copy of the transferred pleadings and documents.

SIGNED on October 28, 2021.



JUDGE PRESIDING

CAUSE NO: 048329996-21

**ERIN JONES, INDIVIDUALLY AND AS
LEGAL REPRESENTATIVE AND
NEXT FRIEND OF JASON JONES**

§

Plaintiff,

v.

**TEXAS HEALTH HUGULEY, INC.,
d/b/a TEXAS HEALTH HUGULEY
HOSPITAL FT. WORTH SOUTH;
DR. JASON A. SIEDEN;
JOHN DOES #1-5; JANE ROES #1-5;**

Defendants.

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**IN THE DISTRICT COURT OF

TARRANT COUNTY, TEXAS

323rd JUDICIAL DISTRICT**

**AMENDED PETITION FOR EMERGENCY MEDICAL DECLARATORY JUDGMENT
AND EMERGENCY TEMPORARY/PRELIMINARY INJUNCTIVE RELIEF**

COMES NOW, ERIN JONES as Wife of JASON JONES, Plaintiff, by and through undersigned counsel, and files this Petition for Emergency Medical Declaratory Judgment and Emergency Injunctive Relief against Defendants, TEXAS HEALTH HUGULEY, INC., d/b/a TEXAS HEALTH HUGULEY HOSPITAL FORT WORTH SOUTH; DR. JASON A. SIEDEN; JOHN DOES #1-5; JANE ROES #1-5; and for good cause shows the Court the following.

I. INTRODUCTION

1. This is a civil action for Emergency Declaratory and Injunctive Relief brought by the Plaintiff, ERIN JONES, who is the Wife of JASON JONES; who is currently a patient in the Intensive Care Unit at TEXAS HEALTH HUGULEY HOSPITAL FORT WORTH SOUTH

(“Defendants’ Hospital”), who is diagnosed with COVID-19 and intubated.

2. The physicians caring for Mr. Jones at Defendants’ Hospital have taken a “wait and see” approach towards any further treatment of Mr. Jones. Mr. Jones’s Doctor, Mary Talley Bowden, M.D., has prescribed Ivermectin be administered to Mr. Jones in an effort to save Mr. Jones’ life. The attending doctors at Defendants’ Hospital, despite having no answers of their own, have and continue to refuse to administer Ivermectin to Mr. Jones in contravention of Dr. Bowden’s orders.

3. Mrs. Jones seeks a declaration determining the rights of the parties including that the Defendants be compelled to abide by the Patient/Physician contract and their hypocritic Oath and to “Do No Harm” by withholding treatment to Mr. Jones. Further, the Plaintiff seeks a declaration that the Defendants honor the decisions of, and instructions given by Mrs. Jones, as Wife of Mr. Jones. Further, the Plaintiff seeks an emergency order compelling the Defendants to recognize Dr. Bowden’s medical order and prescription and requiring the Defendants to administer Ivermectin to their mutual patient, Mr. Jones, and comply with Dr. Bowden’s medical orders for further prescriptions for Mr. Jones in his battle with COVID-19. Plaintiff seeks an emergency Order of Specific Performance.

4. Mrs. Jones additionally seeks an order for such other, further and different relief as the Court deems just, equitable and proper.

II. JURISDICTION AND VENUE

5. Mrs. Jones is not seeking monetary or compensatory damages as her cause of action simply relates to the enforcement of Mrs. Jones’ decisions and instruction as Wife of Mr. Jones, and Dr. Bowden’s order and prescription; this Court has subject matter jurisdiction over this matter and the parties.

6. Venue lies in Tarrant County Defendants' primary place of business is in Tarrant County, and the cause of action arose in Tarrant County.

III. PARTIES

7. The Plaintiff, Erin Jones, is a citizen of the United States of America, a resident of the State of Texas, over the age of 18, Wife of Jason Jones, and therefore has standing to bring this Complaint.

8. The Defendant Doctors are hospitalists working at Defendants' Hospital, and who are managing Mr. Jones' care and treatment. Dr Sieden has been served.

9. The Defendant, Texas Health Huguley, Inc., d/b/a Texas Health Huguley Hospital has been served.

IV. STATEMENT OF FACTS

10. On September 23, 2021, Mr. Jones was diagnosed with COVID-19.

11. On September 28, 2021, Mr. Jones was taken by ambulance to Defendants' Hospital and admitted.

12. From September 28, 2021 through October 7, 2021, he was treated in accordance with the Defendants' Hospital's COVID-19 protocol, which included steroids and antibiotics.

13. On October 7, 2021, Mr. Jones' condition worsened to such an extent that he was transferred to Defendants' Hospital ICU, where he was sedated, intubated, and placed on a ventilator.

14. Since October 7, 2021, Mr. Jones has been on a ventilator in a medically induced coma, continuing to decline.

15. The Defendant Hospital has exhausted its COVID-19 treatment protocol, and has

no further treatment options for Mr. Jones; his situation is truly “wait and see”.

16. As a 48-year-old male placed on a ventilator, Mr. Jones’ chances of survival have dropped to less than 30%.

17. At this point, there is nothing more the Defendants can do, or will do for Mr. Jones. Defendants have exhausted their course of treatment and COVID-19 procedure in treating Mr. Jones which is unacceptable to Mrs. Jones.

18. Mrs. Jones investigated other forms of treatment for COVID-19.

19. Mrs. Jones requested, as Mr. Jones’ Wife, that Defendants administer Ivermectin pursuant to its dosage schedule.

20. Mrs. Jones offered to sign a release thereby releasing Defendants, their agents, assigns, any third parties acting on its behalf, and any doctors acting on their behalf, from any and all liability in administering the Ivermectin to Mr. Jones.

21. Despite the aforementioned, Defendants refused and are unwilling to administer the Ivermectin to Mr. Jones.

22. Mr. Jones is on death's doorstep; there is no further COVID-19 treatment protocol for Defendants to administer to Mr. Jones; Mrs. Jones does not want to see Mr. Jones die, and she is doing everything she can to give her husband a chance to live.

23. Mrs. Jones sought the medical advice of Mary Talley Bowden, M.D., with regard to Mr. Jones’ prior medical history, current medical condition, and the usage of Ivermectin in treating COVID-19 and its after effects.

24. Dr. Bowden supports the use of Ivermectin to treat Mr. Jones and has prescribed Ivermectin to him.

25. Defendants refuse to administer and comply with Dr. Bowden’s prescription.

26. On October 25, 2021 at approximately 8 PM Plaintiff submitted an Emergency Application for Temporary to Judge Alex Kim in accordance with Tarrant County Local Rule . At 7:55 AM on October 26, Judge Alex Kim signed and filed an Order Granting the Temporary Restraining Order. Defendants refused to follow the order.

27. Mrs. Jones seeks a declaratory judgment declaring that Defendants follow Dr. Bowden's order and prescription to administer the protocol contained in the attached exhibit Prescription to their mutual patient, Mr. Jones; and a declaration that Defendants comply with the wishes and directives of Mrs. Jones, as Wife of Mr. Jones. Mrs. Jones has no other option but to bring the instant declaratory judgment civil action.

V. CAUSE OF ACTION

As and for a Cause of Action Against Defendants, Mrs. Jones alleges as follows:

28. Repeats and realleges each and every allegation previously made as if restated herein.

29. Mrs. Jones is the Wife of Mr. Jones.

30. Mr. Jones is a patient at Texas Health Huguley Hospital Fort Worth South, with very little chance of survival.

31. Mr. Jones has been diagnosed with COVID-19 and is currently in the Intensive Care Unit at Texas Health Huguley Hospital Fort Worth South; he is only breathing with the assistance of a ventilator.

32. Despite requesting that Defendants administer Ivermectin to Mr. Jones based on her authority as Mr. Jones's Wife, and Dr. Bowden's order and prescription, Defendants have refused and are unwilling to do so.

33. Despite Mrs. Jones' offer to sign a full release, releasing and relieving Defendants

from any and all liability concerning the administration of Ivermectin to Mr. Jones, Defendants have refused and are unwilling to do so.

34. Despite Defendants exhausting its COVID-19 protocol with nothing left to treat Mr. Jones, Defendants refuse to administer Ivermectin to Mr. Jones based on upon Dr. Bowden's order and prescription.

35. As a result of Defendants' refusal to administer the Ivermectin to Mr. Jones pursuant to Dr. Bowden's order and prescription, Mr. Jones, through his Wife, Mrs. Jones, has been damaged.

36. Mrs. Jones does not have an adequate remedy at law to enforce her authority as Wife of Mr. Jones, and/or Dr. Bowden's order and prescription.

37. Plaintiff alleges that Defendants have without justification breached their express and/or implied contract with Plaintiff and Mr. Jones in failing to provide proper medical care and have breached their collective obligation and oath to "do no harm" as it relates to Defendants' unjustified refusal to administer medical and pharmaceutical therapy to Mr. Jones in an effort to save his life which has been ordered by Dr. Bowden.

38. Defendants have violated Texas and Federal Law by denying Mr. Jones his legal right to make rational treatment decisions and choices, individually and through his Wife, Mrs. Jones. Defendants have further unlawfully ignored instructions clearly expressed by the Plaintiff, Mr. Jones's legally authorized representative, thereby violating his right to exercise informed consent to accept and/or decline proposed treatment.

39. Unless such conduct is enjoined and restrained, there is a substantial likelihood that such conduct, to wit: refusal to administer Ivermectin, will continue and Mr. Jones will lose all chance to preserve his life creating irreparable loss, damage and injury for which there is no

adequate remedy at law.

40. Mrs. Jones does not have an adequate remedy at law to enforce her authority as Wife of Mr. Jones and/or Dr. Bowden's order and prescription.

41. Mrs. Jones has not made any prior applications for the relief requested herein.

42. It is Mrs. Jones' belief that she has made out a cause of action for declaratory judgment.

VI. RELIEF SOUGHT

Based on the facts and the law, Mrs. Jones is entitled to a declaratory judgment from this Court, declaring and enforcing her authority as Wife of Mr. Jones and Dr. Bowden's order and prescription to administer Ivermectin to Mr. Jones.

Mrs. Jones respectfully requests that this Court enter an order declaring that Defendants comply with (1) her reasonable requests as Mr. Jones's Wife; and (2) Dr. Bowden's order and prescription to administer Ivermectin to their mutual patient, Mr. Jones.

WHEREFORE, Mrs. Jones respectfully requests that this Court Order the following:

(A) Enter a judgment in favor of Mrs. Jones on the Complaint in its entirety and against the Defendants;

(B) Pursuant to Mrs. Jones's valid authority as Wife of Mr. Jones, that the Defendants comply with Dr. Bowden's order and prescription to administer Ivermectin to their mutual patient, Mr. Jones;

(C) Award Mrs. Jones all relief allowed by law and equity, including, but not limited to, declaratory, preliminary and permanent injunctive relief; and

(D) A judgment granting Mrs. Jones such other, further and different relief that the

Court deems just, equitable and proper.

Respectfully submitted,

/s/ Jerri Lynn Ward
Jerri Lynn Ward
Texas State Bar #20844200
1510 Texas Avenue South
College Station, TX 77840
(512) 302-1103
Email: jward@garloward.com

/s/ Ralph C. Lorigo (pro hac
vice pending)
Ralph C. Lorigo
New York State Bar # 1563105
101 Slade Avenue
West Seneca NY 14224
(716) 824-7200
Email: rlorigo@lorigo.com
ATTORNEYS FOR PLAINTIFF

EXHIBIT

PRESCRIPTION



BreatheMD
OPTIMAL AIRWAY HEALTH™

Prescription Form

Date: 10/22/21. Patient: Jason Jones DOB 12/4/1972

Ivermectin 3mg. Give 21 tablets per NGT qD, Dispense 210 tablets, Refill:2

Calcitriol 0.25mcg per NGT QD, Dispense: #30, Refill:2

Melatonin 12mg per NGT QHS , Dispense: #30, Refill:2

Fluvoxamine 50mg per NGT BID, Dispense #60, Refill:2

Cyproheptadine 8mg per NGT TID, Dispense #90, Refill2

Zinc 100mg per NGT QD, Dispense #30, Refill: 2

Famotidine 80mg per NGT BID, Dispense #60, Refill 2

Avorstatin 80mg per NGT QD, Dispense #30, Refill 2

Flutamide 250mg per NGT TID, Dispense #90, Refill 2

Spirolactone 100mg per NGT BID, Dispense #60, Refill 2

Finasteride 10mg per NGT QD, Dispense #30, Refill 2

Nitazoxanide 500mg per NGT BID, Dispense #60, Refill 2

IV Infusions Recommended:

- Methylprednisolone 80mg IV bolus then 40mg IV BID
- Vitamin C 25mg IV BID x 3 days
- Thiamine 200mg IV BID
- Therapeutic Plasma Exchange

Prescriber:

Mary Talley Bowden, MD

Tx license: K9770

NPI: 1699858282

3600 Kirby Dr. Suite F

Houston, TX 77098

713-492-2340

713-206-8988 (cell)

Automated Certificate of eService

This automated certificate of service was created by the eFiling system. The filer served this document via email generated by the eFiling system on the date and to the persons listed below. The rules governing certificates of service have not changed. Filers must still provide a certificate of service that complies with all applicable rules.

Jerri Ward on behalf of Jerri Ward
Bar No. 20844200
jward@garloward.com
Envelope ID: 58702693
Status as of 11/1/2021 9:19 AM CST

Associated Case Party: THETEXAS HEALTH HUGULEY HOSPITAL FT WORTH SOUTH

Name	BarNumber	Email	TimestampSubmitted	Status
Joshua D.Ross		jross@canteyhanger.com	11/1/2021 8:45:27 AM	SENT
Scharli Branch		sbranch@canteyhanger.com	11/1/2021 8:45:27 AM	SENT

Case Contacts

Name	BarNumber	Email	TimestampSubmitted	Status
Beth Parlato		bparlato@parlatolaw.com	11/1/2021 8:45:27 AM	SENT
Ralph Lorigo		rlorigo@lorigo.com	11/1/2021 8:45:27 AM	SENT
Julie Sherman		jsherman@canteyhanger.com	11/1/2021 8:45:27 AM	SENT

048-329996-21

FILED
TARRANT COUNTY
11/1/2021 1:04 PM
THOMAS A. WILDER
DISTRICT CLERK

CAUSE NO: 048329996-21

**ERIN JONES, as Wife of
JASON JONES,**

Plaintiff,

v.

**TEXAS HEALTH HUGULEY, INC.,
d/b/a TEXAS HEALTH HUGULEY
HOSPITAL FT. WORTH SOUTH;
DR. JASON A. SIEDEN;
JOHN DOES #1-5; JANE ROES #1-5;**

Defendants.

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**IN THE DISTRICT COURT OF

TARRANT COUNTY, TEXAS

323rd JUDICIAL DISTRICT**

**SECOND AMENDED PETITION FOR EMERGENCY MEDICAL DECLARATORY
JUDGMENT
AND EMERGENCY INJUNCTIVE RELIEF**

COMES NOW, **ERIN JONES as Wife of JASON JONES**, Plaintiff, by and through undersigned counsel, and files this Petition for Emergency Medical Declaratory Judgment and Emergency Injunctive Relief against Defendants, **TEXAS HEALTH HUGULEY, INC., d/b/a TEXAS HEALTH HUGULEY HOSPITAL FORT WORTH SOUTH; DR. JASON A. SIEDEN; JOHN DOES #1-5; JANE ROES #1-5;** and for good cause shows the Court the following.

I. INTRODUCTION

1. This is a civil action for Emergency Declaratory and Injunctive Relief brought by the Plaintiff, ERIN JONES, who is the Wife of JASON JONES; who is currently a patient in the Intensive Care Unit at TEXAS HEALTH HUGULEY HOSPITAL FORT WORTH SOUTH (“Defendants’ Hospital”), who is diagnosed with COVID-19 and intubated.

(“Defendants’ Hospital”), who is diagnosed with COVID-19 and intubated.

2. The physicians caring for Mr. Jones at Defendants’ Hospital have taken a “wait and see” approach towards any further treatment of Mr. Jones. Mr. Jones’s Doctor, Mary Talley Bowden, M.D., has prescribed Ivermectin be administered to Mr. Jones in an effort to save Mr. Jones’ life. The attending doctors at Defendants’ Hospital, despite having no answers of their own, have and continue to refuse to administer Ivermectin to Mr. Jones in contravention of Dr. Bowden’s orders.

3. Mrs. Jones seeks a declaration determining the rights of the parties including that the Defendants be compelled to abide by the Patient/Physician contract and their hypocritic Oath and to “Do No Harm” by withholding treatment to Mr. Jones. Further, the Plaintiff seeks a declaration that the Defendants honor the decisions of, and instructions given by Mrs. Jones, as Wife of Mr. Jones. Further, the Plaintiff seeks an emergency order compelling the Defendants to recognize Dr. Bowden’s medical order and prescription and requiring the Defendants to administer Ivermectin to their mutual patient, Mr. Jones, and comply with Dr. Bowden’s medical orders for further prescriptions for Mr. Jones in his battle with COVID-19. Plaintiff seeks an emergency Order of Specific Performance.

4. Mrs. Jones additionally seeks an order for such other, further and different relief as the Court deems just, equitable and proper.

II. JURISDICTION AND VENUE

5. Mrs. Jones is not seeking monetary or compensatory damages as her cause of action simply relates to the enforcement of Mrs. Jones’ decisions and instruction as Wife of Mr. Jones, and Dr. Bowden’s order and prescription; this Court has subject matter jurisdiction over this matter and the parties.

6. Venue lies in Tarrant County Defendants' primary place of business is in Tarrant County, and the cause of action arose in Tarrant County.

III. PARTIES

7. The Plaintiff, Erin Jones, is a citizen of the United States of America, a resident of the State of Texas, over the age of 18, Wife of Jason Jones, and therefore has standing to bring this Complaint.

8. The Defendant Doctors are hospitalists working at Defendants' Hospital, and who are managing Mr. Jones' care and treatment. Dr Sieden has been served.

9. The Defendant, Texas Health Huguley, Inc., d/b/a Texas Health Huguley Hospital has been served.

IV. STATEMENT OF FACTS

10. On September 23, 2021, Mr. Jones was diagnosed with COVID-19.

11. On September 28, 2021, Mr. Jones was taken by ambulance to Defendants' Hospital and admitted.

12. From September 28, 2021 through October 7, 2021, he was treated in accordance with the Defendants' Hospital's COVID-19 protocol, which included steroids and antibiotics.

13. On October 7, 2021, Mr. Jones' condition worsened to such an extent that he was transferred to Defendants' Hospital ICU, where he was sedated, intubated, and placed on a ventilator.

14. Since October 7, 2021, Mr. Jones has been on a ventilator in a medically induced coma, continuing to decline.

15. The Defendant Hospital has exhausted its COVID-19 treatment protocol, and has

no further treatment options for Mr. Jones; his situation is truly “wait and see”.

16. As a 48-year-old male placed on a ventilator, Mr. Jones’ chances of survival have dropped to less than 30%.

17. At this point, there is nothing more the Defendants can do, or will do for Mr. Jones. Defendants have exhausted their course of treatment and COVID-19 procedure in treating Mr. Jones which is unacceptable to Mrs. Jones.

18. Mrs. Jones investigated other forms of treatment for COVID-19.

19. Mrs. Jones requested, as Mr. Jones’ Wife, that Defendants administer Ivermectin pursuant to its dosage schedule.

20. Mrs. Jones offered to sign a release thereby releasing Defendants, their agents, assigns, any third parties acting on its behalf, and any doctors acting on their behalf, from any and all liability in administering the Ivermectin to Mr. Jones.

21. Despite the aforementioned, Defendants refused and are unwilling to administer the Ivermectin to Mr. Jones.

22. Mr. Jones is on death's doorstep; there is no further COVID-19 treatment protocol for Defendants to administer to Mr. Jones; Mrs. Jones does not want to see Mr. Jones die, and she is doing everything she can to give her husband a chance to live.

23. Mrs. Jones sought the medical advice of Mary Talley Bowden, M.D., with regard to Mr. Jones’ prior medical history, current medical condition, and the usage of Ivermectin in treating COVID-19 and its after effects.

24. Dr. Bowden supports the use of Ivermectin to treat Mr. Jones and has prescribed Ivermectin to him.

25. Defendants refuse to administer and comply with Dr. Bowden’s prescription.

26. On October 25, 2021 at approximately 8 PM Plaintiff submitted an Emergency Application for Temporary to Judge Alex Kim in accordance with Tarrant County Local Rule . At 7:55 AM on October 26, Judge Alex Kim signed and filed an Order Granting the Temporary Restraining Order. Defendants refused to follow the order.

27. Mrs. Jones seeks a declaratory judgment declaring that Defendants follow Dr. Bowden's order and prescription to administer the protocol contained in the attached exhibit Prescription to their mutual patient, Mr. Jones; and a declaration that Defendants comply with the wishes and directives of Mrs. Jones, as Wife of Mr. Jones. Mrs. Jones has no other option but to bring the instant declaratory judgment civil action.

V. CAUSE OF ACTION

As and for a Cause of Action Against Defendants, Mrs. Jones alleges as follows:

28. Repeats and realleges each and every allegation previously made as if restated herein.

29. Mrs. Jones is the Wife of Mr. Jones.

30. Mr. Jones is a patient at Texas Health Huguley Hospital Fort Worth South, with very little chance of survival.

31. Mr. Jones has been diagnosed with COVID-19 and is currently in the Intensive Care Unit at Texas Health Huguley Hospital Fort Worth South; he is only breathing with the assistance of a ventilator.

32. Despite requesting that Defendants administer Ivermectin to Mr. Jones based on her authority as Mr. Jones's Wife, and Dr. Bowden's order and prescription, Defendants have refused and are unwilling to do so.

33. Despite Mrs. Jones' offer to sign a full release, releasing and relieving Defendants

from any and all liability concerning the administration of Ivermectin to Mr. Jones, Defendants have refused and are unwilling to do so.

34. Despite Defendants exhausting its COVID-19 protocol with nothing left to treat Mr. Jones, Defendants refuse to administer Ivermectin to Mr. Jones based on upon Dr. Bowden's order and prescription.

35. As a result of Defendants' refusal to administer the Ivermectin to Mr. Jones pursuant to Dr. Bowden's order and prescription, Mr. Jones, through his Wife, Mrs. Jones, has been damaged.

36. Mrs. Jones does not have an adequate remedy at law to enforce her authority as Wife of Mr. Jones, and/or Dr. Bowden's order and prescription.

37. Plaintiff alleges that Defendants have without justification breached their express and/or implied contract with Plaintiff and Mr. Jones in failing to provide proper medical care and have breached their collective obligation and oath to "do no harm" as it relates to Defendants' unjustified refusal to administer medical and pharmaceutical therapy to Mr. Jones in an effort to save his life which has been ordered by Dr. Bowden.

38. Defendants have violated Texas and Federal Law by denying Mr. Jones his legal right to make rational treatment decisions and choices, individually and through his Wife, Mrs. Jones. Defendants have further unlawfully ignored instructions clearly expressed by the Plaintiff, Mr. Jones's legally authorized representative, thereby violating his right to exercise informed consent to accept and/or decline proposed treatment.

39. Unless such conduct is enjoined and restrained, there is a substantial likelihood that such conduct, to wit: refusal to administer Ivermectin, will continue and Mr. Jones will lose all chance to preserve his life creating irreparable loss, damage and injury for which there is no

adequate remedy at law.

40. Mrs. Jones does not have an adequate remedy at law to enforce her authority as Wife of Mr. Jones and/or Dr. Bowden's order and prescription.

41. Mrs. Jones has not made any prior applications for the relief requested herein.

42. It is Mrs. Jones' belief that she has made out a cause of action for declaratory judgment.

VI. RELIEF SOUGHT

Based on the facts and the law, Mrs. Jones is entitled to a declaratory judgment from this Court, declaring and enforcing her authority as Wife of Mr. Jones and Dr. Bowden's order and prescription to administer Ivermectin to Mr. Jones.

Mrs. Jones respectfully requests that this Court enter an order declaring that Defendants comply with (1) her reasonable requests as Mr. Jones's Wife; and (2) Dr. Bowden's order and prescription to administer Ivermectin to their mutual patient, Mr. Jones.

WHEREFORE, Mrs. Jones respectfully requests that this Court Order the following:

(A) Enter a judgment in favor of Mrs. Jones on the Complaint in its entirety and against the Defendants;

(B) Pursuant to Mrs. Jones's valid authority as Wife of Mr. Jones, that the Defendants comply with Dr. Bowden's order and prescription to administer Ivermectin to their mutual patient, Mr. Jones;

(C) Award Mrs. Jones all relief allowed by law and equity, including, but not limited to, declaratory, preliminary and permanent injunctive relief; and

(D) A judgment granting Mrs. Jones such other, further and different relief that the

Court deems just, equitable and proper.

Respectfully submitted,

/s/ Jerri Lynn Ward
Jerri Lynn Ward
Texas State Bar #20844200
1510 Texas Avenue South
College Station, TX 77840
(512) 302-1103
Email: jward@garloward.com

/s/ Ralph C. Lorigo (pro hac
vice pending)
Ralph C. Lorigo
New York State Bar # 1563105
101 Slade Avenue
West Seneca NY 14224
(716) 824-7200
Email: rlorigo@lorigo.com
ATTORNEYS FOR PLAINTIFF

VERIFICATION

STATE OF TEXAS §
TARRANT COUNTY §

Before me, the undersigned notary, on this day personally appeared ^{ET JT} ~~{name of affiant}~~ ^{Erin Jones}, the affiant, whose identity is known to me. After I administered an oath, affiant testified as follows:

“My name is Erin Jones. I am capable of making this verification. I have read the Second Amended Petion. The facts stated in it are within my personal knowledge and are true and correct.”

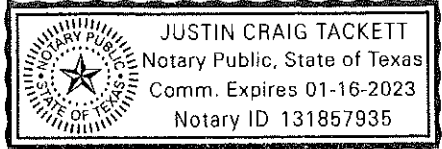
[Signature]
~~{Name of affiant}~~ ^{Erin Jones} ET JT

Sworn to and subscribed before me by ^{JT ET Erin Jones} ~~{name of affiant}~~ on Nov. 1st, 2021.

[Signature]

Notary Public in and for
the State of Texas

My commission expires: 1-16-23



CERTIFICATE OF SERVICE

I hereby certify that on the 1st day of November 2021, I electronically served the foregoing Second Amended Petition through the E-filing system to the following participant:

Mr. Joshua D. Ross
Cantey Hanger L.L.P.
600 W. 6th St. Ste. 300
Fort Worth, Texas 76102

EXHIBIT

PRESCRIPTION



BreatheMD
OPTIMAL AIRWAY HEALTH™

Prescription Form

Date: 10/22/21. Patient: Jason Jones DOB 12/4/1972

Ivermectin 3mg. Give 21 tablets per NGT qD, Dispense 210 tablets, Refill:2

Calcitriol 0.25mcg per NGT QD, Dispense: #30, Refill:2

Melatonin 12mg per NGT QHS , Dispense: #30, Refill:2

Fluvoxamine 50mg per NGT BID, Dispense #60, Refill:2

Cyproheptadine 8mg per NGT TID, Dispense #90, Refill2

Zinc 100mg per NGT QD, Dispense #30, Refill: 2

Famotidine 80mg per NGT BID, Dispense #60, Refill 2

Avorstatin 80mg per NGT QD, Dispense #30, Refill 2

Flutamide 250mg per NGT TID, Dispense #90, Refill 2

Spirolactone 100mg per NGT BID, Dispense #60, Refill 2

Finasteride 10mg per NGT QD, Dispense #30, Refill 2

Nitazoxanide 500mg per NGT BID, Dispense #60, Refill 2

IV Infusions Recommended:

- Methylprednisolone 80mg IV bolus then 40mg IV BID
- Vitamin C 25mg IV BID x 3 days
- Thiamine 200mg IV BID
- Therapeutic Plasma Exchange

Prescriber:

Mary Talley Bowden, MD

Tx license: K9770

NPI: 1699858282

3600 Kirby Dr. Suite F

Houston, TX 77098

713-492-2340

713-206-8988 (cell)

Automated Certificate of eService

This automated certificate of service was created by the eFiling system. The filer served this document via email generated by the eFiling system on the date and to the persons listed below. The rules governing certificates of service have not changed. Filers must still provide a certificate of service that complies with all applicable rules.

Jerri Ward on behalf of Jerri Ward
Bar No. 20844200
jward@garloward.com
Envelope ID: 58719833
Status as of 11/1/2021 1:12 PM CST

Associated Case Party: THETEXAS HEALTH HUGULEY HOSPITAL FT WORTH SOUTH

Name	BarNumber	Email	TimestampSubmitted	Status
Joshua D.Ross		jross@canteyhanger.com	11/1/2021 1:04:00 PM	SENT
Scharli Branch		sbranch@canteyhanger.com	11/1/2021 1:04:00 PM	SENT

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Ralph Lorigo		rlorigo@lorigo.com	11/1/2021 1:04:00 PM	SENT
Julie Sherman		jsherman@canteyhanger.com	11/1/2021 1:04:00 PM	SENT

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REPORTER'S RECORD
CAUSE NO. 342-329996-21
Volume 1 of 3 Volumes

ERIN JONES, Individually and) IN THE DISTRICT COURT
as Legal Representative and)
Next Friend of Jason Jones,)
Plaintiff,)
V) TARRANT COUNTY, TEXAS
TEXAS HEALTH HUGULEY, INC.,)
d/b/a TEXAS HEALTH HUGULEY)
HOSPITAL FT. WORTH SOUTH;)
DR. JASON A. SEIDEN;)
JOHN DOES #1-5; JANE ROOES #1-5)
Defendant.) 342nd JUDICIAL DISTRICT

AMENDED PETITION FOR EMERGENCY MEDICAL DECLARATORY JUDGMENT
AND EMERGENCY TEMPORARY/PRELIMINARY INJUNCTION RELIEF
(F: 11/1/21)

On the 1st day of November 2021, the following
proceedings came on to be heard in the above-entitled and
numbered cause before the Honorable Kimberly Fitzpatrick,
Judge presiding, via Zoom Videoconferencing, held in Fort
Worth, Tarrant County, Texas:

Proceedings reported by Machine Shorthand.

HOLLY BISHOP, TEXAS CSR NO. 3095
OFFICIAL COURT REPORTER
342ND DISTRICT COURT
100 N. Calhoun Street, 5th Floor
Tom Vandergriff Civil Courts Building
Fort Worth, Texas 76196
817.884.2712

A P P E A R A N C E S

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MS. JERRI LYNN WARD (Via Zoom)
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MS. SCHARLI BRANCH (Via Zoom)
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APPEARING FOR THE DEFENDANT

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8 DEFENDANTS' EXHIBITS

9	No.	Description	ADMITTED	VOL.
10	9	Medical Staff Bylaws of	86	
11		Texas Health Huguley Hospital		
12	10	Medical Staff Rules and Regulations	86	
13		of Texas health Huguley Hospital		

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P R O C E E D I N G S

(November 1, 2021, 2:00 p.m.)

THE COURT: Let me call Cause No.
048-329996-21.

If you would go ahead and state your
appearance for the record.

MS. WARD: Jerry Lynn Ward for the plaintiff.

MR. LORIGO: Ralph Lorigo, Your Honor, for
the plaintiff.

THE COURT: Okay.

MR. ROSS: Joshua Ross, Cantey Hanger, for
the defendants collectively, Your Honor.

THE COURT: All right. If you're not
speaking, I need you to stay on mute, please.

And I think Holly already told you, no part
of these proceedings are allowed to be recorded by law.

MS. WARD: Judge, Mr. Lorigo is going to be
lead counsel, but there's a pending motion pro hac vice.

THE COURT: Is there a response to that? Was
it opposed?

MR. ROSS: It was not opposed.

THE COURT: All right. Then I'll go ahead
and sign the order granting it.

All right. I did read the books that had
been dropped off here, so I don't need you guys to start from

1 scratch.

2 My understanding is that there was a TRO that
3 was signed back on October 26th. It looks like the patient
4 is currently being administered Ivermectin right now; is that
5 right?

6 MR. ROSS: No, Your Honor.

7 THE COURT: No? All right. What's going on,
8 then, as far as that's concerned?

9 MR. LORIGO: The patient hasn't received it,
10 Your Honor. I believe that order was never put into effect.
11 I believe that's why we're here today in front --

12 THE COURT: What do you mean it wasn't put
13 into effect?

14 MR. ROSS: The TRO was granted. It was
15 served late Wednesday afternoon. Early Thursday, I filed a
16 motion to -- an emergency motion to dissolve the TRO.

17 Before we had an opportunity to have it
18 heard, Judge Kim transferred it downtown, and then when we
19 had a hearing on the -- on my motion to dissolve, plaintiffs
20 agreed to dissolve the TRO with the agreement that we would
21 accelerate the timeline with which we had the TI hearing.
22 That's, I think, a pretty succinct procedural history.

23 MS. WARD: Your Honor, may I correct one
24 thing that -- the order was delivered to the treating
25 physician in the hospital the day -- that morning or noon,

1 the day that it was signed by Judge Kim. It was formally
2 served the next day.

3 THE COURT: So you purposely -- Mr. Ross, the
4 hospital purposely didn't follow the TRO?

5 MR. ROSS: That is correct.

6 THE COURT: Why?

7 MR. ROSS: Well, I think a lot of the reasons
8 why are -- will come to light in this hearing.

9 THE COURT: That's -- that's crazy to me.

10 All right. You guys have two hours. So you
11 have till 4:00. I need you to be very efficient with your
12 time. I see you have a bunch of exhibits here in the books.
13 So I don't need an opening, so go ahead and call your first
14 witness.

15 MR. LORIGO: Your Honor, my doctor isn't
16 available at this point in time. This thing has moved a
17 number of times. So Dr. Kory -- we have Dr. Kory's
18 affidavit. I can go through the affidavit with Your Honor,
19 but we have his affidavit with all of his exhibits. But this
20 thing has moved three different times now, and I don't have
21 Dr. Kory available. He's --

22 THE COURT: Was that your only witness?

23 MR. LORIGO: Well, I have the plaintiff, the
24 wife, Your Honor, so she can testify.

25 THE COURT: When is Mr. Kory available?

1 MR. LORIGO: He told me he would text me,
2 just let me know if he would be available at some point this
3 afternoon, but I'm just not sure. I had him available this
4 morning, and I --

5 THE COURT: Who objected to the visiting
6 judge?

7 MR. ROSS: Plaintiff.

8 THE COURT: Yeah, I mean, that's your own
9 doing, as far as that's concerned, when you objected to the
10 time.

11 I mean, what -- is he going to be -- you say
12 you don't know when he's going to be available this
13 afternoon, you're waiting on a text?

14 MR. LORIGO: I do not know when he's going to
15 be available.

16 THE COURT: Okay.

17 MR. LORIGO: I wasn't sure if this was just
18 going to be a motion, if you were going to take testimony. I
19 had him available this morning in case there was questions
20 that needed to be answered, but we have all of the papers, we
21 have all of the exhibits. It's an emergency preliminary
22 injunction motion.

23 I've done many of these on oral argument
24 without testimony, and whatever Your Honor tells me is
25 obviously what I will do, but I just don't have him available

1 now.

2 THE COURT: Well, you guys -- normally on the
3 TRO, that's when we'll hear from the lawyers, but on actual
4 TIs, we take evidence.

5 I mean, I don't know how -- are you from
6 New York?

7 MR. LORIGO: Yes.

8 THE COURT: All right. I mean, in this part,
9 we would take evidence and then make a ruling.

10 What I'm happy to do, we can take whatever
11 evidence you want, and then if Mr. Kory calls you, great; if
12 not, then we can -- you can have leave or whatever to get him
13 to give evidence, if you like.

14 So is Mr. Kory, is that the one who would be
15 administering the Ivermectin?

16 MR. LORIGO: No. Dr. Kory's expert testimony
17 is about Ivermectin itself.

18 THE COURT: All right.

19 MR. LORIGO: The doctor that prescribed the
20 medication is Dr. Bowden. And so --

21 THE COURT: Is that doctor here?

22 MR. LORIGO: No.

23 THE COURT: Okay. And so is that doctor
24 going to actually be administering it?

25 MR. LORIGO: No. What we've asked for in

1 these papers, Your Honor, is that the hospital administer the
2 Ivermectin. It's simply the crushing of these pills and
3 putting it in the feeding tube. We've had that order many,
4 many times, but that's what we are asking for.

5 THE COURT: In Texas?

6 (Talking simultaneously.)

7 MR. LORIGO: Actually administer it pursuant
8 to the prescription.

9 THE COURT: In Texas or no?

10 MR. LORIGO: We've had it in Texas, Your
11 Honor.

12 THE COURT: Which district?

13 MR. LORIGO: Pete Lopez, the Peter Lopez
14 case. Let me tell you. There's at least --

15 (Talking simultaneously.)

16 MR. ROSS: That was in Harris County, I
17 believe, Judge.

18 MR. LORIGO: Harris County?

19 THE COURT: And what?

20 MR. ROSS: And the facts are quite different,
21 but that's --

22 THE COURT: What's the difference, just
23 briefly?

24 MR. ROSS: I believe the physician in that
25 case was a physician in the hospital that was credentialed by

1 the hospital.

2 MR. LORIGO: No, that's not the case.

3 The physician there was a veteran -- a VA
4 doctor. They attempted to move him from that hospital to the
5 Veteran's Hospital, but they weren't able to do that. And
6 the judge in that situation ordered the hospital administer
7 the Ivermectin. So it wasn't a doctor that had privileges at
8 the hospital.

9 THE COURT: Okay. So do you have a medical
10 professional that's willing to administer it?

11 MR. LORIGO: I don't at this point in time,
12 Your Honor. I do not.

13 THE COURT: What's the legality in having
14 their own person coming in and administer it at the hospital?

15 MR. ROSS: CMS, conditions of participation,
16 this is kind of what I was getting at. They don't allow
17 that. The physician that wrote this purported prescription
18 is not credentialed at the hospital.

19 She's an ear, nose and throat doctor in
20 Houston. She's not vetted by our facility. There's no
21 record that she's seen this patient, that she's evaluated or
22 examined the patient at all. And the federal government says
23 that you have to have a medical staff, credentialed
24 professionals that exercise their own independent medical
25 judgment to prescribe medications in a facility. Therefore,

1 if my hospital --

2 THE COURT: Repeat that last sentence
3 again.

4 MR. ROSS: The CMS, conditions of
5 participation, which I added as Exhibits 23 through 26 in my
6 binders, do not allow the hospital to administer a medication
7 in accordance with an order or a prescription from a
8 physician who is not credentialed and vetted by our hospital.
9 If the hospital gave the prescription, it would be violating
10 federal law.

11 MR. LORIGO: That's not what I've ever run
12 across before, it's not what happened in the case we just
13 talked about. So --

14 THE COURT: This is for Medicare and
15 Medicaid.

16 MR. LORIGO: Yes, that's true.

17 THE COURT: So what does that have to do --
18 is this guy, is he getting Medicaid or Medicare?

19 MS. WARD: No.

20 MR. ROSS: It's conditions of participation,
21 Your Honor, so the hospital has to have those things in
22 order to --

23 THE COURT: Where is that in this exhibit
24 that you're reading from so I can go to it? What section is
25 it?

1 MR. ROSS: 42 CFR --

2 THE COURT: What? 24, 25, or 26.

3 MR. ROSS: Title 42.

4 THE COURT: All right. 42, where? I'm on it.

5 MR. ROSS: 492.11 --

6 THE COURT: Hold on. 492, what page are you
7 on?

8 MR. ROSS: I'm -- I'm looking at my
9 exhibits.

10 THE COURT: Okay. Well, I'm looking at the
11 exhibits that you provided to me. I see 48.22 and Exhibit
12 20 -- which one is it? 25?

13 MR. ROSS: 23 through 26.

14 THE COURT: All right. I'm in Exhibit 23
15 through 26. 23 is not -- I don't think that's what you're
16 referring to. It says a hospital must be in compliance with
17 the federal laws. It's one page. Exhibit 24 is 482.22, 25
18 is 482.13, 26 is 482.23.

19 MR. ROSS: And there should be a 482.22,
20 conditions of participation.

21 THE COURT: Where at?

22 MR. ROSS: I have it at -- I have it in my
23 binder as 23. I'm looking at my binder, which has two 23s --

24 MS. BRANCH: It's Exhibit 24.

25 THE COURT: All right. I'm at 24. I see

1 482.22.

2 MR. ROSS: Yes, 482.22.

3 THE COURT: Okay. And what page on it?

4 MR. ROSS: So the -- I mean, it's the
5 first -- the relevant sections, pertinent sections, is really
6 just on the first page. Hospital must have an organized
7 medical staff that operates under bylaws approved by the
8 governing body.

9 THE COURT: Where does it say anything about
10 administering medicine that -- do you have something
11 specifically on that? This just looks like general
12 credentialing to get, like, Medicare and Medicaid.

13 MR. ROSS: Well, it's not general
14 credentialing to get Medicare and Medicaid. It's what the
15 hospital has to have in order to be a facility that
16 participates in Medicare.

17 THE COURT: Okay. Well, that's not what
18 we're talking about here.

19 MR. ROSS: But it is what we're talking -- I
20 mean --

21 THE COURT: All right. Well, where does it
22 talk about the medicine?

23 MR. ROSS: Well --

24 THE COURT: Where does it talk about that you
25 have to -- you have to be on staff with the hospital in order

1 to administer medicine?

2 MR. ROSS: Well, part of that is in the
3 bylaws and rules and regulations of the hospital --

4 THE COURT: I just asked you where in these
5 exhibits from the federal government, where is it what you're
6 saying?

7 MR. ROSS: It doesn't say that express --

8 THE COURT: Okay. Well, don't tell me it
9 says something it doesn't say then.

10 So where in the bylaws are you now going to?

11 MR. ROSS: Well, I have a witness that's
12 prepared to testify about the bylaws.

13 THE COURT: Where in the exhibit?

14 MR. ROSS: The bylaws are Exhibit 9, the
15 rules and regs are Exhibit 10.

16 THE COURT: Tell me exactly where in 9 and
17 10 -- so you're telling me that 23 through 26, none of that
18 says that?

19 MR. ROSS: Well, I'm not -- I'm saying that
20 it -- I don't think it says expressly what you're saying. It
21 sets forth --

22 THE COURT: What I'm asking you is, where --
23 what violation is it to have whoever it is that is treating
24 the patient at Huguley work with a physician that they're
25 co-working on and that that physician wants to administer a

1 drug and that person says, no, that that's not allowed; the
2 other doctor that's at Huguley says no?

3 MR. ROSS: Well, the conditions of
4 participation set forth what the federal law is required for
5 the hospital to have. The hospital's bylaws and rules and
6 regulations are set forth in accordance with the Medicare
7 conditions of participation.

8 The bylaws and the rules and regulations of
9 the hospital have requirements for physicians that practice
10 patient care in the hospital.

11 THE COURT: Okay.

12 MR. ROSS: They have to be credentialed.
13 They have to be vetted. They have to be subject to the
14 disciplinary or the oversight of the medical staff.

15 THE COURT: Okay.

16 MR. ROSS: In this case, the physician that
17 issued a purported prescription is in Houston and is an
18 otolaryngologist that is otherwise completely unqualified to
19 care for a severely-ill COVID patient, and she's not
20 credentialed in our hospital. It goes against our bylaws,
21 which go against federal law.

22 THE COURT: Okay. Do you have somebody
23 that's willing -- where is it somewhere that says -- do you
24 have somebody that would come in and administer the
25 medication to them or no?

1 MR. LORIGO: Yes.

2 THE COURT: Yes, a doctor?

3 MR. LORIGO: It would be a nurse practitioner
4 who would operate under the doctor's orders.

5 And he's incorrect. What he's saying -- the
6 bylaws may say one thing, but the federal statute that he
7 points to certainly says something else. It talks about
8 telemed specifically, and it allows it be done through the
9 hospital. And that's what it specifically says. You can
10 laugh all you want, but that's what it says.

11 THE COURT: What is the reason why, if they
12 have somebody that's willing to administer it, to come in and
13 they're obviously waiving any liability against the hospital,
14 why is it not allowed for them to do that?

15 MR. ROSS: Well, there's a lot of reasons,
16 and one reason would be that I think it will -- I don't
17 think, it doesn't matter what I think, I'm not a doctor. But
18 I have one here to testify to the Court that it may very well
19 result in patient harm.

20 THE COURT: Okay. But -- all right. But if
21 they're not administering it and they're waiving liability on
22 it...

23 MR. ROSS: Whoever these practitioners are,
24 we don't know who they are. The hospital -- where are --

25 THE COURT: I mean, you say you don't know

1 who they are. They're licensed under the State of Texas,
2 right? You can go on the Texas State Medical Board and see
3 if they're in good status or not.

4 I mean, I don't think -- I mean, that makes
5 no sense to me. If you were telling me it was some kind of
6 person that wasn't licensed, but, I mean, you're talking
7 about a licensed physician in the State of Texas, right?

8 MR. ROSS: Purportedly.

9 THE COURT: I mean, yes or no. Purportedly?
10 I mean, you can go on the Texas State Medical Board and look
11 up their licensure.

12 MR. ROSS: She's not here to testify --

13 THE COURT: Okay.

14 MR. ROSS: -- how she came to this
15 prescription.

16 THE COURT: Okay.

17 MR. ROSS: I mean, she is not credentialed in
18 our facility.

19 THE COURT: Okay. So where -- you're going
20 to need a doctor to testify if -- if they have someone here.
21 So what I'm willing to do is, if you want to reschedule, we
22 can go ahead and take what testimony we can right now, and
23 then get Dr. Kory on -- is it Wednesday? Is the nurse
24 practitioner going to testify?

25 MR. LORIGO: That's -- I could have that

1 happen through Dr. Bowden. That's one of the fall-back
2 positions, if the hospital or Your Honor was not willing to
3 order the hospital to administer it, the fall-back position
4 would be that we have a nurse practitioner under Dr. Bowden's
5 authority to obtain emergency privileges and go in -- all
6 that needs to be done is these pills get crushed and put into
7 the feeding tube.

8 THE COURT: I'm not going to order a doctor
9 whose against administering it to order it themselves. If
10 you have someone that can administer it and -- I would be
11 inclined to look at that, but I'm not inclined to have
12 somebody who's adamantly against that, I mean, I -- I'm just
13 not. But if you guys have somebody, then I would consider
14 that after I hear the testimony.

15 MR. LORIGO: I understand, Your Honor, and
16 that would be fine. But it would generally be a nurse
17 practitioner under the doctor's orders --

18 THE COURT: Okay.

19 MR. LORIGO: -- that he would send into the
20 hospital. This way the location, it doesn't take hours to go
21 back and forth to the hospital. That's the whole issue here.

22 THE COURT: All right. So what -- let's go
23 ahead and hear the testimony of what you have right now and
24 we'll take it from there.

25 I guess the only time that I could reconvene

1 the hearing would be Wednesday morning. I don't know if
2 y'all have that available. If you can't get them on the
3 phone today, then I would need to probably do it Wednesday.

4 MR. LORIGO: What time works for you, Your
5 Honor, Wednesday morning?

6 THE COURT: Actually, I have some time in the
7 afternoon. I could do after 1:00 or -- it depends on how
8 much we have left. I've got a few things in the morning, but
9 if it's just an hour or so that we need to get done, I could
10 do that at 9:00 or we could do it in the afternoon.

11 (Talking simultaneously.)

12 MR. LORIGO: -- an interim order until we get
13 the testimony on Wednesday morning?

14 THE COURT: It depends on what I hear. I
15 can't tell you without -- what I hear right now. I need to
16 hear the testimony.

17 Mr. Ross, what did you say?

18 MR. ROSS: I have a setting in Dallas County
19 that afternoon, but I'm free in the morning.

20 THE COURT: What time is your setting at?

21 MR. ROSS: 2:00.

22 THE COURT: Okay. Would 9:00 work then?

23 MR. ROSS: Yes.

24 THE COURT: Depending on what we have, we may
25 need to do it at 8:30. I just don't know. I know I had to

1 already move my 10:00 once because I was in trial last week,
2 so depending on what we have, I mean, go ahead and mark 8:30
3 for now and we'll go from there.

4 All right. Go ahead. If you don't have
5 Dr. Kory, who do you have that's available to testify right
6 now?

7 MR. LORIGO: I have the spouse, the wife,
8 Erin Jones.

9 THE COURT: All right. Ms. Jones, if you
10 would, take yourself off mute.

11 All right. If you would, raise your right
12 hand.

13 (Witness sworn.)

14 THE COURT: Can you hear me? You're not
15 coming through. Your sound is not coming through.

16 Holly, can you hear her?

17 THE REPORTER: No.

18 THE COURT: Ms. Jones, do you have the volume
19 up?

20 MS. JONES: Yes, I do.

21 THE COURT: There you go. Turn it up all of
22 the way. Put your -- you need to be as close as possible to
23 the microphone.

24 THE WITNESS: Okay.

25 THE COURT: All right. Did you hear the

1 oath?

2 MS. JONES: Yes, I did.

3 THE COURT: Is your answer yes?

4 MS. JONES: Yes.

5 THE COURT: All right. Go ahead.

6 Mr. Lorigo, you put yourself on mute.

7 MR. LORIGO: Sorry about that, Your Honor.

8 THE COURT: That's all right. Go ahead.

9 ERIN JONES,

10 having been duly sworn, testified as follows:

11 DIRECT EXAMINATION

12 BY MR. LORIGO:

13 Q. Ms. Jones, you're the spouse of Jason Jones; isn't
14 that correct?

15 A. Yes.

16 Q. And how long have you been married?

17 A. 23 years.

18 Q. And how old is your husband?

19 A. 48.

20 Q. And what does he do for a living?

21 A. He's a Tarrant County Sheriff's Deputy.

22 Q. How long has he been a Tarrant County Sheriff's
23 Deputy?

24 A. For the county, a little over 12 years. He's been
25 in law enforcement for 28.

1 Q. Okay. So -- and he's 48 years old at the present
2 time?

3 A. Yes.

4 Q. And what's his overall health before he got
5 COVID?

6 A. Before COVID, he was pretty healthy. He was
7 over -- he's a little overweight, but we were working on
8 getting healthy. We had just joined a gym.

9 Q. All right. So approximately when was he diagnosed
10 with COVID?

11 A. He was diagnosed from a lab on September 23rd.

12 Q. And when was he hospitalized?

13 A. September 28th.

14 Q. And what protocol did the hospital administer for
15 him?

16 A. In the ER? Just a steroid at the time.

17 Q. And when was he placed on a ventilator?

18 A. October 7th.

19 Q. So October 7th. So he's now 25 days in the ICU in
20 an induced coma on that ventilator; is that correct?

21 A. Yes.

22 Q. Are you allowed to visit him at the hospital?

23 A. Yes.

24 Q. And so have you been there on a regular basis to
25 monitor his condition?

1 A. Yes.

2 Q. And what is his condition? What -- what has
3 happened since he's been in that hospital since 28th to the
4 time he was vented through today, what's been his
5 condition?

6 A. Pretty much no change, is what I get.

7 Q. So -- so he hasn't gotten better, correct?

8 A. Correct.

9 Q. And what did they tell you when they placed him on
10 the ventilator? What was the reasons to place him on a
11 ventilator on October the 7th?

12 A. I was called early that morning, so by the time I
13 got to him, I only had just a second to see him, and I guess
14 he was just having trouble breathing.

15 Q. And so do you know what the ventilator settings are
16 at the current time?

17 A. As of today, yes.

18 Q. What are the vent settings?

19 A. He was at 75 percent oxygen on the vent, and the
20 PEEP number was 14.

21 Q. The PEEP number was 14?

22 A. Uh-huh. Yes.

23 Q. Did they tell you that that's an extremely high
24 number?

25 A. I've -- yes, I knew it was a high number, but

1 because of -- he's had now two collapsed lungs, and they say
2 they need it to keep the lung open.

3 Q. So the PEEP is actually the pressure of the machine
4 to push the air into his lungs; isn't that correct?

5 MR. ROSS: Objection, leading, and lack of
6 foundation.

7 THE COURT: Repeat the question.

8 Q. (By Mr. Lorigo) So you understand what the PEEP,
9 what that setting is all about?

10 A. It's to keep --

11 THE COURT: That objection is overruled.

12 Go ahead.

13 MR. LORIGO: Pardon me?

14 THE COURT: When your question was rephrased,
15 I overruled the objection.

16 Go ahead.

17 Q. (By Mr. Lorigo) So --

18 THE COURT: You can answer. Go ahead.

19 A. Yes. To keep the lung open.

20 Q. (By Mr. Lorigo) And so what do they tell you about
21 his condition? What -- what do they tell you about his
22 likelihood -- the likelihood of getting out of this
23 situation?

24 A. I haven't heard a likelihood. They just told me
25 this process just takes weeks, and so I was -- I did this

1 because he couldn't get the tracheotomy last week, and I
2 asked what happens if he can't get that. And he said --
3 Dr. Seiden said we would have to have a different kind of
4 conversation. And I asked the nurse later that day, and she
5 said he would be put on Hospice.

6 Q. So they talked to you about putting him on
7 Hospice?

8 A. Just the one time.

9 Q. So have you -- have you talked to the hospital
10 about administering Ivermectin to your husband?

11 A. Yes. They said no.

12 Q. When did you first talk to them about that?

13 A. I don't have an exact date, but it was, like, in
14 the second week that he was on the ventilator.

15 Q. And what's the hospital's answer to placing him on
16 Ivermectin?

17 A. No.

18 Q. So have you provided any of the information, the
19 studies and that type of documentation, to the hospital with
20 regard to that request?

21 A. I have it, but I asked for a meeting with the
22 doctors and I was denied the meeting with the doctors. And
23 then I later found out that everything goes through the one
24 doctor.

25 Q. So have you been able to sit and talk with that

1 doctor?

2 A. Not sit and talk, no. He called, like, today and
3 asked if I had any questions about a chest tube for him
4 today.

5 Q. Have they ever given you an opportunity to actually
6 face-to-face sit down and have a conversation about your
7 husband utilizing Ivermectin?

8 A. Not utilizing Ivermectin, no.

9 Q. So do they sit down and talk to you about what
10 they're -- what they're going to do for your husband, what is
11 being done on a daily basis and what they expect will be
12 accomplished?

13 A. No. It's just the wait and see is what -- and it
14 just takes weeks. That's what I know.

15 Q. So that's essentially the position you've been in
16 since essentially October 7th, is a wait-and-see situation,
17 correct?

18 A. Yes.

19 Q. And he's not getting any better, is he?

20 A. No.

21 Q. And so you -- it's your request, as his spouse,
22 that he be administered Ivermectin; is that the case?

23 MR. ROSS: Objection, leading.

24 A. Yes.

25 THE COURT: Sustained.

1 Q. (By Mr. Lorigo) So what are you requesting of this
2 Court?

3 A. I would like to see him given the Ivermectin to see
4 if it would improve his health with no...

5 Q. So how many children do you have?

6 A. Six kids.

7 Q. You have six children?

8 A. Yes.

9 Q. And is your husband the sole support of your
10 family?

11 A. Yes.

12 MR. ROSS: I have no other questions, Your
13 Honor.

14 THE COURT: Okay. Mr. Ross?

15 MR. ROSS: Yes, Judge, thank you.

16 CROSS-EXAMINATION

17 BY MR. ROSS:

18 Q. Ms. Jones, with respect to your husband's medical
19 history, you mentioned that it's a -- that he's a little
20 overweight, correct?

21 A. Yes.

22 Q. Is he also a former smoker?

23 A. Yeah. He quit about 15 years ago.

24 Q. Does he have sleep apnea?

25 A. He's not been diagnosed with that, no.

1 Q. Did he have a stroke six years ago?

2 A. Yeah, a TIA one.

3 Q. And you testified that he first tested positive for
4 COVID on September 23rd, correct?

5 A. Yes.

6 Q. And that he was hospitalized on September 28th,
7 correct?

8 A. Yes.

9 Q. But that's actually the day he was hospitalized at
10 Huguley; is that right?

11 A. Yes.

12 Q. Before then he was at a different facility, was he
13 not?

14 A. The same day, yes.

15 Q. What other facility did he go to?

16 A. Harris Southwest.

17 Q. And that's a different hospital within the Texas
18 health system, correct?

19 A. Yes.

20 Q. And at Harris Southwest, did your husband refuse
21 the COVID protocol there?

22 A. The Remdesivir, yes.

23 Q. And did he discharge from Harris Southwest against
24 medical advice?

25 A. Yeah, he left.

1 Q. Against medical advice, correct?

2 A. Yes.

3 Q. And when he left one hospital, after refusing care
4 and leaving against medical advice, he subsequently went to a
5 different hospital which was Huguley, right?

6 A. I took him back to our doctor in between, yes.

7 Q. When you say "our doctor," what doctor was that?

8 A. We go to the Total Care there in Crowley.

9 Q. Does your husband have a primary care physician?

10 A. That's just who we go to.

11 Q. So it's -- is that kind of like a doc-in-the-box
12 type of place?

13 A. I guess.

14 Q. Do you know what I mean by that? Does he have a
15 doctor that he goes to every year for a physical?

16 A. No, we just use Total Care.

17 Q. When he was -- when he got to Huguley on September
18 28th, were you there when he was first admitted?

19 A. Yes, shortly after the ambulance brought him in.

20 Q. Did he tell the staff, the medical staff or the
21 nursing staff at Huguley that he didn't get along with his
22 doctor at Harris Southwest?

23 A. Well, because they were pushing that protocol and
24 he didn't want it.

25 Q. So the answer was, yes, right, he didn't get along

1 with his doctor at Harris Southwest?

2 A. Yes.

3 Q. And it was because they were recommending a certain
4 mode of treatment that he disagreed with, right?

5 A. Yes.

6 Q. Did you agree with him leaving against medical
7 advice, or did you want him to stay there?

8 A. I agreed with it because I couldn't be there with
9 him to advocate for him if need be. They didn't allow
10 visitors.

11 Q. In the petition --

12 THE COURT: Wait, I want to make sure that
13 got on the record. The reason is because they didn't allow
14 visitors; is that what you said?

15 THE WITNESS: Yes.

16 Q. (By Mr. Lorigo) Because he was COVID positive, you
17 couldn't be a visitor, correct?

18 A. Yes.

19 Q. Okay.

20 THE COURT: But I want to be sure I
21 understood earlier, you said that she is allowed to visit him
22 at the new place; is that right?

23 THE WITNESS: Yes, I can visit him.

24 THE COURT: Go ahead.

25 MR. ROSS: I'm sorry, Judge. I don't

1 mean to --

2 THE COURT: Go ahead.

3 Q. (By Mr. Ross) You alleged in your pleadings, there
4 have been some amended pleadings that were filed today, but
5 it's been consistent in all of the pleadings, whether you've
6 seen them or not, that your husband was, quote, treated in
7 accordance with Huguley's COVID-19 protocol. Did you know
8 that that's what you've alleged?

9 A. The protocol for the Remdesivir?

10 Q. What I'm asking you is, you have alleged, you've
11 represented to the Court that your husband is being treated
12 at Huguley consistent with the hospital's COVID-19 protocol.
13 Is that your understanding?

14 A. Yes.

15 Q. Okay. When he got to Huguley, they wanted to give
16 him Remdesivir there as well, did they not?

17 A. Yes.

18 Q. And he refused it at Huguley as well, didn't he?

19 A. Yes.

20 Q. They wanted to give him Actemra, A-C-T-E-M-R-A, and
21 he refused that; is that correct?

22 A. I don't know about that one.

23 Q. Okay. If his medical records suggest that he
24 refused Actemra, which is a monoclonal antibody treatment,
25 that's approved for use for treating COVID, would you have

1 any dispute with that?

2 A. I don't know about that one.

3 Q. So at Huguley, he is, again, refusing a plan of
4 care and a mode of treatment, and he gets worse, correct?

5 A. Yes.

6 Q. And on October 7th he's intubated and he's put on a
7 ventilator?

8 A. Yes.

9 Q. He had a collapsed lung, what's called in Medison,
10 a pneumothorax on the right side, correct?

11 A. Yes.

12 Q. And then on Friday morning of last week, around
13 5:00 in the morning, did you get a call from Dr. Seiden?

14 A. Yes.

15 Q. And did Dr. Seiden tell you that he had -- that
16 your husband had experienced a collapsed lung on his left
17 side?

18 A. Yes.

19 Q. And then what is it -- what is your understanding
20 that Dr. Seiden did in response to that?

21 A. He put in the chest tubes.

22 Q. And was it your understanding that if Dr. Seiden
23 had not done that, that your husband would have passed
24 away?

25 A. Yes.

1 Q. So you understand, then, that Dr. Seiden, who
2 you're suing, rushed to the hospital about 4:30 in the
3 morning last Friday, to save your husband's life, correct?

4 A. Yes.

5 Q. You have testified and what this whole proceeding
6 is about is trying to get your husband Ivermectin. When did
7 that conversation first kind of -- with you, when did you
8 start considering that this is what you wanted?

9 A. That was about the second week, because they told
10 me in the second week that if he didn't get trached by the
11 third week, then we would have different conversations. And
12 I --

13 Q. What did you -- I'm sorry, I cut you off. Go
14 ahead?

15 A. Go ahead.

16 Q. Where did you hear about Ivermectin?

17 A. I've heard stories. I've read testimonies
18 online.

19 Q. So you did your own research on the Internet?

20 A. Yeah, and I looked at, like, the nih.gov, and it
21 was approved from what it looked like.

22 Q. All right. Did you try to get Ivermectin
23 prescribed by a physician at Total Care?

24 A. Yes.

25 Q. Where they -- you did?

1 A. Yes.

2 Q. And so when did you go to Total Care in Crowley for
3 purposes of Ivermectin?

4 A. Before he even went to the hospital.

5 Q. And so -- before he went to Huguley Hospital?

6 A. Yes.

7 Q. Your husband went to Total Care before he was
8 hospitalized and asked for Ivermectin?

9 A. Yes.

10 Q. And what -- was he prescribed Ivermectin?

11 A. No.

12 Q. Were you told why not?

13 A. They just didn't prescribe it.

14 Q. And that has nothing to do with Huguley Hospital,
15 correct?

16 A. Correct.

17 Q. Has nothing to do with Dr. Seiden or any other
18 doctor at Huguley?

19 A. No.

20 Q. It has nothing to do with any of the nurses or the
21 administration at the hospital, correct?

22 A. Correct.

23 Q. Where he goes for, essentially, his primary care
24 also wouldn't prescribe him the Ivermectin, right?

25 A. Yes.

1 Q. Have you -- since he's been at Huguley Hospital,
2 have you gone back to Total Care to see if a doctor there
3 will prescribe it to be given to him in the hospital?

4 A. No.

5 Q. Why haven't you done that?

6 A. I just figured they would say no.

7 THE COURT: Why would -- Mr. Ross, I'm just
8 curious, would that make a difference, because you just said
9 to me that they have to be credentialed at the hospital.

10 MR. ROSS: I don't think legally it makes a
11 difference in --

12 THE COURT: Okay. I'm just wondering, then,
13 if -- you know, we have a limited time. What I just
14 understood you to say, if she can go to Total Care and get
15 the doctor to prescribe it, is that possible?

16 MR. ROSS: I'm getting to why I asked the
17 question.

18 THE COURT: Oh, okay. All right. Go
19 ahead.

20 Q. (By Mr. Ross) Ms. Jones, the physician that
21 prescribed your husband Ivermectin is this Mary Bowden in
22 Houston; is that correct?

23 A. Yes.

24 Q. Have you ever met Dr. Bowden?

25 A. I did a telehealth medicine with her.

1 Q. So have you ever met her in person?

2 A. No.

3 Q. So you did a telehealth medicine with Dr. Bowden,
4 correct?

5 A. Yes.

6 Q. How did you find Dr. Bowden?

7 A. Online.

8 Q. Where online did you find her?

9 A. From the FLCCC website.

10 Q. And the FLCCC is the Front Line COVID-19 Critical
11 Care Lines, correct?

12 A. Yes.

13 Q. And Dr. Bowden is one of many physicians that pop
14 up on that website for people who go there to look for
15 prescriptions for Ivermectin; is she not?

16 A. Yes.

17 Q. And is that how you found her?

18 A. Yes.

19 Q. And did you have to pay her money to get your
20 prescription?

21 A. I paid for the telehealth visit.

22 Q. How much did you have to pay her?

23 A. Does that make a difference?

24 Q. How much did you have to pay her, Ms. Jones?

25 A. It was like \$170.

1 Q. Now, the telehealth visit with Dr. Bowden, was it
2 just you and her?

3 A. Yes.

4 Q. Was your husband on the telehealth visit at all?

5 A. No.

6 Q. Did you even do the telehealth visit in the
7 hospital?

8 A. Not in his hospital room, no.

9 Q. Did you provide Dr. Bowden a single page of your
10 husband's medical records?

11 A. No.

12 Q. Did you ask Dr. Bowden what authority that she has
13 under Texas law to write a prescription for a patient she's
14 never seen or examined?

15 A. No.

16 Q. Did she represent to you that she had that
17 authority?

18 A. No.

19 Q. Did you do any independent investigation to
20 determine whether she's qualified to care for your husband
21 and issue prescriptions?

22 A. Just researched online.

23 Q. In your research, did you see that she's an ear,
24 nose and throat doctor?

25 A. Yes.

1 Q. Did she ever represent to you that she had clinical
2 competence to care for severely-ill and hospitalized COVID
3 patients?

4 A. No, we didn't.

5 Q. The prescription for Ivermectin that was issued by
6 Dr. Bowden, that was on October 22nd, correct?

7 A. Yes.

8 Q. And along with Ivermectin, there's a whole host of
9 other medications on that prescription form; is that right?

10 A. Yes.

11 Q. Did Dr. Bowden explain to you what was on that
12 prescription form, why those prescriptions were indicated and
13 why the dosages were what they were for a patient she hadn't
14 seen or examined?

15 A. I just told her whatever else she thought that he
16 would need for the treatment.

17 Q. Would it be fair to say, Ms. Jones, that the sole
18 reason that you consulted with Dr. Bowden was for the purpose
19 of getting Ivermectin?

20 A. Yes.

21 (A pause in the proceedings.)

22 THE COURT: Do you have additional questions
23 for this witness?

24 MR. ROSS: Just a few, Your Honor. I'm just
25 looking at my notes. I'm sorry.

1 Q. (By Mr. Ross) Ms. Jones, on -- late last week --
2 I'm sorry, we talked about Friday. Earlier today, were you
3 contacted by Dr. Seiden?

4 A. Yes.

5 Q. And what was the situation that occurred earlier
6 today that he called about?

7 A. He wanted to add another chest tube, and I had
8 reservations about it.

9 Q. He wanted to add another chest tube because your
10 husband's left lung collapsed again, correct?

11 A. Collapsed again, no. I wasn't aware of that.
12 Like, I spoke with the doctor that was on call two times this
13 weekend, and he was okay with watching that pneumothorax.
14 And he told me yesterday it was shrinking.

15 Q. But Dr. Seiden today called you and said we've got
16 to put another chest tube in, right?

17 A. Yes.

18 Q. Is it your understanding that without that
19 intervention, your husband would die?

20 A. Not at the moment, no.

21 Q. When you said you had reservations about another
22 chest tube, what were your reservations?

23 A. Because I asked about his stats and what they were
24 in comparison to why he needed the other chest tubes.

25 Q. And did someone tell you to ask those questions of

1 Dr. Seiden?

2 A. No. I asked him. I asked him of the doctor this
3 weekend while I was there in person with him.

4 Q. Did you, to your knowledge, ever sign any contract
5 with anybody at the hospital or Dr. Seiden or any other
6 doctor, where it is stated in the contract that it is a
7 breach if his health providers refuse to give a medication
8 that you want?

9 A. I'm sorry, can you repeat that?

10 Q. Sure. To your knowledge, did you ever sign a
11 contract, or enter into any contract, you or your husband,
12 with anybody at the hospital, any of the nurses or any of the
13 doctors that are caring for him, where it states in the
14 contract that it is a breach of the contract if they don't
15 give your husband the medication that you want?

16 A. I didn't sign a contract.

17 THE COURT: What exhibit is that, if it
18 exists?

19 MR. ROSS: It's -- there is not an exhibit.

20 THE COURT: Okay.

21 MR. ROSS: Thank you, Ms. Jones.

22 I'll pass the witness.

23 THE COURT: Any additional questions for this
24 witness?

25 MR. LORIGO: Yes.

REDIRECT EXAMINATION

1
2 BY MR. LARIGO:

3 Q. So Ms. Jones, you said that you wanted your husband
4 to get Ivermectin; is that correct?

5 A. Yes.

6 Q. And where did you do the research about Ivermectin?
7 How thorough was that?

8 A. Well, it was just online, and I saw where it had
9 been asked to be accepted on the nih.gov website.

10 Q. So how much time did you spend doing that
11 research?

12 A. We've done research even before he went into the
13 hospital just looking at different things.

14 Q. And did your husband also -- was he in agreement
15 that Ivermectin would be an alternative remedy for him?

16 A. Yes.

17 Q. And so when you went looking for Dr. Bowden, you
18 were looking for somebody to prescribe Ivermectin; isn't that
19 correct?

20 MR. ROSS: Objection, leading.

21 THE COURT: Sustained.

22 Q. (By Mr. Lorigo) So when you went looking for
23 Dr. Bowden, what was the purpose?

24 A. I was looking for a prescription for the
25 Ivermectin.

1 Q. And so you found her where? Where did you find her
2 name?

3 A. Through the FLCCC website.

4 Q. And is that where you gained most of your
5 information with regard to Ivermectin?

6 A. Yes.

7 Q. And when you talked to Dr. Bowden, how long did you
8 talk to her, first of all?

9 A. I don't know, maybe 40, 45 minutes.

10 Q. And what kind of questions did she ask you?

11 A. She just asked what kind of care he was getting,
12 what he was getting for the COVID treatment.

13 Q. Did she ask you about his past medical condition,
14 what kind of health he was in?

15 A. Yes.

16 Q. Did you give her that information?

17 A. Yes.

18 Q. And did she ask you, as you said, for his current
19 medical situation?

20 A. Yes.

21 Q. Did you provide that information to her?

22 A. Yes.

23 Q. And based on those conversations, did she -- did
24 she agree to prescribe the Ivermectin?

25 A. Yes.

1 Q. And that is what you were looking for; isn't that
2 correct?

3 A. Yes.

4 Q. So she wrote the prescription on -- I believe it's
5 October 22nd?

6 A. Yes.

7 Q. And along with Ivermectin -- now, in terms of the
8 dosage, how did she arrive at the dosage for Ivermectin?

9 A. On his weight.

10 Q. So did you give her -- did she ask you how much he
11 weighed?

12 A. Yes.

13 Q. And did she tell you that that's how, in fact, it
14 would be prescribed?

15 A. Yes.

16 Q. And what about the other items that she has in the
17 prescription, what did she tell you about those?

18 A. That they would compliment the Ivermectin.

19 Q. And did she tell you what effect the Ivermectin
20 would have on your husband?

21 A. I'm sorry?

22 Q. Let me put it this way. Did you ask her whether
23 there was any negative side effects for Ivermectin?

24 A. Right. I don't know of any side effects for it.

25 Q. So did you have that discussion with her, about the

1 fact that there is no serious side effects?

2 A. Yes.

3 MR. ROSS: Objection, that's hearsay and lack
4 of foundation.

5 THE COURT: Sustained.

6 Q. (By Mr. Lorigo) So did you do your own research
7 with regard to the potential side effects of Ivermectin?

8 A. Yes.

9 Q. And did you do that same research with regard to
10 the side effects of Remdesivir?

11 A. Yes.

12 Q. And what did you discover with regard, first of
13 all, to Remdesivir?

14 MR. ROSS: Objection. This is all hearsay,
15 Your Honor, and lack of foundation.

16 MR. LORIGO: I asked her what she discovered
17 in her research of Remdesivir.

18 THE COURT: That's overruled.

19 Go ahead.

20 A. I discovered that it -- there's a possibility that
21 it shuts down the kidneys and affects the liver.

22 Q. (By Mr. Lorigo) And so based on that, was it your
23 determination not to allow the hospital to administer
24 Remdesivir?

25 A. Yes.

1 Q. Did your husband join in that decision?

2 A. Yes.

3 Q. And did you do a similar research with regard to
4 any potential side effects of Ivermectin?

5 A. Yes.

6 Q. And what did you discover there?

7 A. There's not very many side effects to Ivermectin.

8 Q. And so is it still your request of this Court that
9 your husband be provided the medication that's in that
10 prescription by Dr. Bowden?

11 A. Yes.

12 MR. LORIGO: No other questions, Your Honor.

13 THE COURT: You need to go into -- address
14 the liability of the hospital if it's administered.

15 MR. LORIGO: That's fine.

16 Q. (By Mr. Lorigo) So, Ms. Jones, isn't it true that
17 we offered -- you offered the hospital an informed consent
18 and general release if they would administer the
19 prescription?

20 A. Yes.

21 Q. And are you still willing to do that?

22 A. Yes.

23 MR. LORIGO: I think that covers it, Your
24 Honor.

25 THE COURT: All right.

1 Do you have any additional questions for this
2 witness, Mr. Ross?

3 MR. ROSS: No, Judge, I don't.

4 THE COURT: All right.

5 Call your next witness.

6 MR. LORIGO: I don't have Dr. Kory, so I
7 don't have a witness at this point. So I would defer to
8 counsel to allow their witnesses be called out of order, if I
9 may, Your Honor, and then hopefully either later on in this
10 call or possibly Wednesday morning with my doctor.

11 THE COURT: All right. Is it Dr. Seiden?
12 I'm sorry.

13 DR. SEIDEN: Yes, Your Honor.

14 THE COURT: And so if you want to go ahead --
15 I don't want to make you be away from the hospital anymore
16 than you need to.

17 So I guess, Mr. Ross, if you want to go
18 ahead -- my only concern is if Dr. Kory goes on Wednesday
19 morning and you need him to refute any testimony of that,
20 that he be available on both days, so I will leave that up to
21 you.

22 But, I mean, my concern is it's unfair to all
23 of you, I guess, the way it's been transferred around today,
24 so I'm certainly going to be courteous with regard to calling
25 the witnesses at a later date for that reason.

1 So it's up to you, if you want to go through
2 and finish the hour with your witnesses, or we can have them
3 come back on -- but I will have briefer time on Wednesday to
4 finish the hearing.

5 MR. ROSS: Sure. Judge, I think -- I
6 generally like to defer to my docs when I'm having them
7 appear in court, and I think Dr. Seiden would prefer to go
8 today because this has been quite an interference with
9 patient care anyway. So if he can go, then I'll call him.

10 THE COURT: I'm happy for you to go. I don't
11 want to keep you. I don't want to inconvenience you any more
12 than you already are so...

13 DR. SEIDEN: Thank you.

14 THE COURT: Go ahead, Mr. Ross.

15 I need to swear you in. Dr. Seiden, if you
16 can raise your right.

17 (Witness sworn.)

18 THE COURT: All right. Mr. Ross, go ahead.

19 MR. ROSS: Thank you, Judge.

20 DR. JASON SEIDEN,
21 having been duly sworn, testified as follows:

22 DIRECT EXAMINATION

23 BY MR. ROSS:

24 Q. Sir, could you state your name for the record,
25 please?

1 A. Jason Seiden.

2 Q. And do you -- tell the Court what your education is
3 and what your licensure status is?

4 A. I'm a practicing physician by training. I am a
5 pulmonary critical care hospice and palliative care and sleep
6 physician.

7 Q. And so can I call you Dr. Seiden then?

8 A. Yes, sir. Thank you.

9 Q. Dr. Seiden, how are you currently employed, and
10 where are you employed?

11 A. I'm independently employed. I run a practice,
12 private practice of my own, and I have staff privileges at
13 Texas Health Huguley Hospital.

14 Q. Are you at Texas Health Huguley Hospital right
15 now?

16 A. Yes, sir, I'm using one of the conference rooms.

17 Q. And along with the credentials you've already
18 testified about, have you had any other positions at the
19 hospital on the medical staff or otherwise?

20 A. I do. I'm assistant chief of staff of the
21 hospital. I'm also the medical director of the medical
22 intensive care unit.

23 Q. And could you briefly tell the judge where you
24 went -- where you received your medical degree and where you
25 did any training?

1 A. Yes, sir. I went to the Autonomous University of
2 Guadalajara. And I did my internship residency in fellowship
3 through UMDNJ, which is the University of Medicine and
4 Dentistry of New Jersey, Rutgers University.

5 Q. Are you board certified?

6 A. Yes, sir, in pulmonary medicine, critical care
7 medicine, sleep medicine, and hospice and palliative care
8 medicine.

9 Q. In your experience as a board certified
10 pulmonologist and critical care physician, have you had the
11 experience in the last two years or so, I guess, give or
12 take, in caring for patients with COVID?

13 A. Yes, sir. Unfortunately quite too many.

14 Q. Does Texas Health Huguley Hospital have a COVID-19
15 protocol?

16 A. Yes, sir.

17 Q. And who formed that protocol at the hospital?

18 A. We did that collectively as a COVID committee.
19 It's an ad hoc committee with multiple members of both the
20 medical staff, hospital staff and leadership, of which I was
21 one of the members.

22 Q. And if you could briefly describe for the Court,
23 just in the interest of time, what is the COVID-19
24 protocol?

25 A. Yes, sir. So going back to the committee, through

1 that committee, very similar other facilities, we looked at
2 best evidence, best guidelines from governing organizations
3 such as Infectious Disease, Society of America Critic --
4 Society of Critical Care Medicine, as well as the American
5 College of Chest Physicians, the National Institutes of
6 Health and CMS, and formulated our hospital plans to parallel
7 those of the governing bodies.

8 At this time that protocol includes one
9 oxygen support, so a nasal cannula, a high-flow nasal
10 cannula, noninvasive ventilation like a bipap or mechanical
11 ventilation. From a medicine standpoint, that includes
12 Remdesivir, which was discussed earlier; a medication called
13 Actemra, which is an inhibitor of interleukin.

14 We use Dexamethasone and antibiotics in
15 selected cases. And those are the medications that are
16 recommended and approved by those governing agencies I -- I
17 referenced just a short while ago.

18 Q. It is Ivermectin a part of Texas Health Huguley's
19 COVID protocol?

20 A. No, sir.

21 Q. What do you understand Ivermectin to be?

22 A. Ivermectin is an anti-helminthic. It's been around
23 about 35 years, originally developed by Merck. It works
24 through chloride ion channels and it vertebrates on
25 helminths, or worms, parasites, and that's been its effective

1 and only labeled indication from since its inception 35-plus
2 years ago.

3 Q. Is there a single authoritative body, such as any
4 of the ones that you've just testified or identified through
5 your testimony or otherwise, to your knowledge, that
6 recommends Ivermectin at any stage in the treatment of
7 COVID-19?

8 A. No, sir, not a single one. The National Institutes
9 of Health, the NIH that Mrs. Jones' referenced, is quite
10 clear, neither for nor against and is not part of any of
11 their paradigm.

12 Q. What do you understand to be the current status of
13 the global medical community, I should say, with respect to
14 the treatment of COVID-19 with Ivermectin?

15 A. Ivermectin is not approved or recommended by any of
16 those governing agencies. I cannot speak intelligently as to
17 all international bodies, because I don't know if there
18 are -- there are countries out there where their National
19 Health Services are utilizing that medication.

20 And I say that partly because Ivermectin is
21 used worldwide. It is the preferred treatment for river
22 blindness, so therefore, it's in widespread use throughout
23 Brazil, Sub-Saharan Africa, India, countries with massive
24 population. And there's a large percentage of the world's
25 population that has taken it for that purpose, but not for

1 COVID-19.

2 THE COURT: Has he read this Office of the
3 Attorney General, was he provided this from Nebraska?

4 MR. ROSS: No, Your Honor, I don't think
5 so -- well, I don't know. I didn't provide it to him.

6 THE WITNESS: No, Your Honor.

7 THE COURT: There's like a 40-page, I don't
8 know, document from the Office of the Attorney General that
9 they provided that -- have you read this, regarding the use
10 of Ivermectin?

11 MR. ROSS: When you say "you," are you
12 talking to me, Judge?

13 THE COURT: Yeah. Have you reviewed this or
14 has he? I would like to get his opinion on it, and that's
15 why I'm asking you.

16 THE WITNESS: I have not reviewed it.

17 THE COURT: Okay. Go ahead.

18 Q. (By Mr. Ross) Along with your position at the
19 hospital and what you've already testified about, kind of
20 generally, specifically are you familiar with the care of
21 Mr. Jones who is at issue in this case?

22 A. Yes, sir.

23 Q. How are you familiar with that care?

24 A. I've been caring for Mr. Jones since his second day
25 in the hospital. He was admitted on September 28th, and I

1 have consulted initially for -- as a pulmonologist on the
2 29th of September and have been caring for him since that
3 time, with rare exceptions such as the weekend when I was not
4 on call and my colleague was on call, it has been myself.
5 And I have had daily dialogue with Mrs. Jones since that
6 time.

7 Q. Now, how would you characterize his clinical status
8 when he first came to the hospital on the 28th, or when you
9 first saw him, I guess?

10 A. So Mr. Jones presented to the hospital with
11 hypoxia, low oxygen levels. Initially, he required very high
12 flow oxygen via his nose, which is called the nasal cannula,
13 high flow nasal cannula. After that time he required bipap,
14 which is again, that noninvasive mask, which is a surrogate
15 for the ventilator. And then ultimately starting October
16 2nd, as discussed earlier, he required the ventilator, where
17 I intubated him, placed him on the ventilator and transferred
18 him to the intensive care unit.

19 Q. Were you present and listening to the examination
20 of Ms. Jones just a few minutes ago?

21 A. Yes, sir, I was.

22 Q. Were there any parts of that kind of summary of her
23 care through the questioning that was inaccurate to your
24 recollection?

25 A. Yes, sir. I actually was writing quite feverishly.

1 There was a statement that he was pretty healthy, and I think
2 you clarified that at the age of 42, he had a stroke or a
3 mini stroke. Presumably diabetic, based upon laboratory
4 values that cover the prior three months. Untreated sleep
5 apnea and obesity, plus hypertension and a former smoker, so
6 I would say he was not necessarily healthy.

7 In the emergency department it was asked of
8 Mrs. Jones, and I can't speak verbatim, the response was he
9 was given just a steroid. In reality, he was offered our
10 entire recommended protocol as supported by the Infectious
11 Disease Society of America to include Actemra, Remdesivir,
12 Dexamethasone and oxygen, as well as prone ventilation.

13 Q. And did he accept or refuse parts of that
14 protocol?

15 A. He refused most of that protocol. He did accept
16 Dexamethasone. He would not comply with the prone
17 ventilation until the two days prior to intubation, October
18 5th. He would wear the oxygen, that is for sure, and took
19 the Dexamethasone, which is the oral steroid, but would not
20 take Remdesivir, Actemra.

21 Q. Did he tell you why he refused that?

22 A. No, sir.

23 Q. Did you have any conversations with Mr. Jones about
24 Ivermectin?

25 A. No, sir.

1 Q. So he didn't ask you for Ivermectin, to your
2 knowledge?

3 A. No, sir. I've never been asked for Ivermectin. My
4 first -- the first time I was ever asked for Ivermectin is
5 through this legal action, litigation. I've never been asked
6 personally about it.

7 Q. There was some discussion about his ventilator
8 settings and what is PEEP values were. What was -- to you,
9 what is the clinical significance of those values?

10 A. So Mr. Jones has required significant support from
11 the ventilator since October 7th. I do want to clarify that
12 over the past 48 hours there has been a reduction in the
13 amount of oxygen that he has required, but he still requires
14 75 percent, as Mrs. Jones referenced.

15 He requires those PEEP values, that is added
16 pressure on exhalation in order to maintain his oxygen level
17 so that he can live.

18 Q. And there was some discussion about collapsed lungs
19 or pneumothorax. What was the situation that occurred Friday
20 and then today?

21 A. Yes, sir. So COVID, we know has an effect on the
22 lining around the lungs, which is called the pleura. And for
23 some reason, that is not well-understood or elucidated, it
24 does cause damage to the pleura, to that sac. And as a
25 result, it can develop rents or tears and collapse down.

1 That is further worsened by the mechanical ventilation that
2 keeps people alive, because it's using air under pressure to
3 help keep them alive.

4 As a result, you can develop pneumothorax,
5 which is the introduction of air into that space between the
6 sac around the lung and the lung itself, squeezing the lung
7 down to complete collapse or near complete collapse.

8 On Friday morning I received a call at 4:00
9 in the morning from the nurse practitioner that Mr. Jones had
10 developed tension pneumothorax. That means so much air in
11 that space and so much collapse, that his structures had
12 shifted across the central part of the chest, and as a
13 result, he was unstable and in the process of actively dying.

14 For that, I emergently placed a chest -- a 24
15 French chest tube, evacuated the air and saved his life.

16 Q. And what happened today? Was it similar to what
17 happened Friday?

18 A. Yes, sir, he had a repeat. So he had a
19 pneumothorax that has been worsening. It got a little better
20 yesterday and significantly worse today, with an associated
21 drop in his oxygen levels and also his blood pressure and
22 heart rate.

23 And as a result, they placed another 24
24 French chest tube, evacuated the air, and once again, saved
25 his life.

1 Q. When -- did you hear Mrs. Jones testify that she
2 had reservations about a chest tube today?

3 A. Yes, sir. Today when I called her for consent --
4 actually, my nurse practitioner called first and she said
5 I'll have to get back to you. And they spoke several minutes
6 later, and then I took the phone to be able to talk to her
7 directly. And she did agree to the chest tube, once we
8 talked about the associated risks and benefits, ratio that
9 favored the benefits of the chest tube, which is to save his
10 life by preventing tension pneumothorax, which I said would
11 occur because of positive pressure ventilation and would kill
12 him if it developed.

13 Q. When you testified that you had not been consulted
14 once by either Mr. Jones before he was ventilated or by
15 Mrs. Jones up until to today about Ivermectin, I just want to
16 clarify, it was through getting sued, this legal procedure
17 and being served, that was the first time you, yourself,
18 heard about Ivermectin from this patient?

19 A. That is correct.

20 THE COURT: I just want to clarify, is he the
21 doctor that's there day to day?

22 MR. ROSS: Yes, Your Honor.

23 THE WITNESS: Yes, Your Honor.

24 THE COURT: You're the one actually -- I
25 thought you were supervising over the -- did you say chief

1 over the unit?

2 THE WITNESS: I'm the medical director, Your
3 Honor, of the of ICU, but I'm also a practicing critical care
4 doctor and I've been caring for Mr. Jones since the 29th of
5 September.

6 THE COURT: Okay. I want to be sure you're
7 the one day to day.

8 All right. Go ahead.

9 Q. (By Mr. Ross) Have you prescribed Ivermectin to
10 Mr. Jones?

11 A. No, sir.

12 Q. Why not?

13 A. Because it is on FDA warning not to be used in the
14 treatment of COVID-19 infection, as well as all of those
15 governing bodies, to which I am a member of the college or
16 read fervently because they are the guiding organizations in
17 the American healthcare, the pillars of American healthcare
18 by very bright individuals.

19 Q. Ms. Jones testified, and, in fact, there was a
20 question from the Court about whether she's presently allowed
21 to visit her husband in the hospital. Do you recall that?

22 A. Yes, sir.

23 Q. And is she allowed to visit her husband in the
24 hospital?

25 A. Every day.

1 Q. Now, why is that significant in the clinical
2 scenario of COVID, that she's allowed to visit him?

3 A. We have made great effort to have a family at the
4 bedside. As you know, during the initial part of this
5 pandemic, most hospitals, to my knowledge, were not allowing
6 that. And we have made a very valiant effort at having that,
7 facilitating it.

8 In fact, up until the point he was on
9 isolation, he no longer is, we helped to provide Mrs. Jones
10 with personal protective equipment each and every day to
11 ensure her safety as she visits, made sure to have a chaplain
12 visit, and made sure to counsel her each and every time I saw
13 her.

14 Q. Why is he no longer on isolation protocol?

15 A. Because he's no longer infectious by Infectious
16 Disease Society and Center for Disease Control. After day 20
17 in the hospital for an acutely-ill patient, you are no longer
18 infectious because you know no longer have viremia or a virus
19 circulating in your body.

20 THE COURT: How long was he in the other
21 hospital?

22 THE WITNESS: Pardon me?

23 THE COURT: How long was he at the other
24 hospital?

25 MR. ROSS: He signed out against medical

1 advice in that first 24 or 48 hours.

2 THE COURT: Okay. Do they have the same
3 protocols -- I know it's a THR hospital, but is it the same
4 protocols at that hospital versus your hospital?

5 THE WITNESS: Yes, ma'am. I can't speak if
6 it's exactly verbatim, but yes, Your Honor.

7 THE COURT: Okay. Thank you.

8 Q. (By Mr. Ross) So the plaintiff is trying to get
9 the Court to force Mr. Jones to get Ivermectin to treat
10 COVID, but he's not being treated anymore for COVID; is that
11 right?

12 A. Yes, sir. He's being supported from the damage
13 caused by COVID. He no longer has active viral replication.

14 And one of this, you know, use of -- or
15 purported use of Ivermectin is to prevent further viral
16 replication or reproduction in the cells, and that very
17 hypothesized mechanism is no longer applicable, as he's no
18 longer deemed to have the virus circulating in his body.

19 Q. So is it your testimony that there's no clinical
20 reason to give it to him, even if it did work to treat
21 COVID?

22 A. That is correct.

23 Q. Is there any clinical -- any possible clinical harm
24 to administer COVID in the manner that was prescribed by this
25 doctor in Houston?

1 A. There were several issues with the manner in which
2 it was prescribed. One, it was prescribed that we place 21
3 or 22 tablets via in an oral gastric tube, basically a
4 feeding tube through the mouth. That is a relatively small
5 tube to crush 21, 22 tablets daily for 10 days, plus the
6 additional medications prescribed.

7 In my quick math, this equals 50 tablets per
8 day crushed finely enough so as not to form a large pill ball
9 in the patient's stomach that would not be absorbed.

10 Two, it's a much greater dose, up to a
11 hundredfold greater dose than is currently FDA recommended
12 and labeled for non-COVID indications of helminthic or
13 parasitic infections.

14 There are side effects of Ivermectin: Four
15 percent tachycardia, four percent radial arrhythmia. Those
16 are -- arrhythmia is irregular heart rhythms. Irregular
17 heart rhythms in someone who is critically ill can have
18 catastrophic consequences.

19 Q. And finally -- I'm about to finish up, Dr. Seiden.
20 Mr. Jones is in the ICU, correct?

21 A. Yes, sir.

22 Q. When patients are in the ICU and when they are
23 severely ill like Mr. Jones, do they require day-to-day or
24 shift-to-shift or even minute-to-minute care?

25 THE COURT: I missed the last part of your

1 question. Do they require what?

2 MR. ROSS: Day-to-day or shift-to-shift or
3 minute-to-minute care?

4 A. Critically-ill patients require minute-by-minute
5 care, if not second-by-second. Things change very, very
6 quickly in the intensive care unit.

7 Q. (By Mr. Ross) So when things change, might that
8 mean like needing to switch the dosage or the frequency of
9 medication?

10 A. All the time. We titrate many things. For
11 patients that are critically ill, particularly patients like
12 Mr. Jones, he was in prone ventilation, on his belly. Most,
13 if not all, of his medications come via the form of
14 intervenous, IV. We provide very little pills.

15 In fact, any oral medication that can be
16 substituted intervenous, by standard practice in the
17 insensitive care unit, we do so.

18 Q. So if there is an injunction that is issued by the
19 Court that requires Mr. Jones to have this prescription
20 issued by Dr. Bowden, and he's in the ICU and something
21 happens clinically that requires a change in the dosage or
22 frequency, is it your understanding that you would have to go
23 back to the Court to get permission to change that?

24 A. Yes, sir, because --

25 THE COURT: How are you doing that right now,

1 Mr. Ross? Right now, he's basically telling you that your
2 client is in violation of a Court order by Mr. Kim. I mean,
3 I don't -- he, right now, is supposed to already be
4 administering this medication.

5 MR. ROSS: The order was dissolved, Your
6 Honor, with plaintiff's agreement. It's not in effect.

7 THE COURT: When did that get dissolved?

8 MR. ROSS: I think it was Friday afternoon,
9 is when the Court took that up on an emergency basis, last
10 Friday afternoon.

11 THE COURT: So when did you get service?
12 Wednesday? What was the day they were provided service?

13 MR. ROSS: Wednesday afternoon, I believe.

14 THE COURT: So Wednesday, Thursday, Friday,
15 until they got -- y'all were in violation?

16 MR. ROSS: That's correct.

17 THE COURT: Okay.

18 MR. ROSS: Including me, Your Honor. It says
19 "attorneys" on the TRO. So I guess I was supposed to go to
20 the hospital and shove pills down this guy's throat.

21 THE COURT: Okay.

22 MR. ROSS: But nevertheless, I'll pass the
23 witness.

24 THE COURT: Go ahead.

25 MR. LORIGO: Okay, Your Honor.

CROSS-EXAMINATION

1
2 BY MR. LORIGO:

3 Q. Doctor, so when was your protocol last updated?

4 A. We updated this about six weeks ago.

5 Q. And has the protocol changed from earlier in the
6 year?

7 A. Yes, sir.

8 Q. What changes were there?

9 A. We have stopped the routine of administration of
10 antibiotic unless there's a reason to believe there's a
11 bacterial infection. We have ensured across the line that
12 Dexamethasone is at a fixed dose of 6 milligrams daily, not
13 twice daily, and that anticoagulation reflects the current
14 recommendations from preferentially utilizing an enoxaparin
15 lovenox at the 0.5 milligram Q12 hours or full dose if
16 they're suspected from involved disease or atrial
17 fibrillation.

18 Q. Did those changes come about by way of
19 recommendations from the FDA?

20 A. Not by the FDA, but by CDC, Americans Society of
21 Critical Care Medicine and American College of Chest
22 Physicians.

23 Q. So tell me about the FDA. Ivermectin is an
24 approved drug; isn't that true?

25 A. Is or is not, sir?

1 Q. It is --

2 A. Yes, sir.

3 Q. -- an approved FDA drug?

4 A. Yes, sir.

5 Q. And it has been approved for how many years?

6 A. 35 years to my knowledge.

7 Q. Have you ever administered or prescribed
8 Ivermectin?

9 A. Yes, sir. I had a case with strongyloidiasis last
10 year.

11 Q. What did you prescribe it for?

12 A. Strongyloidiasis, the patient had strongyloid yeast
13 infection, helminthic infection, worm infection.

14 Q. Was it well tolerated?

15 A. Yes, sir.

16 Q. So do you know how -- the negative effects or the
17 side effects of Ivermectin? Are you aware of those?

18 A. Yes, sir.

19 Q. And what are those?

20 A. Four percent of patients have arrhythmias; three
21 percent will have general constitutional complaints such as
22 flushing; fatigue; headaches at two to three percent; GI
23 upsets at two to four percent; and then patients in selective
24 cases with river blindness, there are significant
25 inflammatory response, which I don't believe is relevant in

1 this case.

2 Q. So the side effects that you just mentioned are
3 fairly -- they're not serious side effects, isn't that
4 correct, in most of the side effects that you just
5 mentioned?

6 A. I would say with the exception of arrhythmia.

7 Q. Tell me about Remdesivir. Does Remdesivir have
8 side effects?

9 A. Yes, sir.

10 Q. So do you know how many studies there were to
11 approve Remdesivir?

12 A. Yes, sir.

13 Q. How many?

14 A. One.

15 Q. And do you know how many patients were in that
16 study?

17 A. Just over a thousand.

18 Q. 1,061 patients; isn't that correct?

19 A. I think it's 1,062.

20 Q. And, yet, Remdesivir was approved, correct?

21 A. Yes, sir.

22 Q. It was approved originally on the emergency basis;
23 isn't that true?

24 A. Just like Aspirin.

25 Q. And wasn't -- didn't the WHO recommend against the

1 use of Remdesivir?

2 A. I am not certain of that answer. Don't know.

3 Q. So tell me this: Have you ever looked at the WHO
4 website in terms of the effects of Remdesivir?

5 A. Yes, sir.

6 Q. And do you know what the adverse effects of
7 Remdesivir are on that WHO site?

8 A. The most commonly reported is renal failure, kidney
9 failure.

10 Q. So if I told you that in less than the last two
11 years, there have been 7,690 adverse effects from Remdesivir,
12 would you agree with that?

13 A. I have no reason to refute it. I have never seen
14 the numbers.

15 Q. And of that, 560 deaths.

16 A. Maybe, don't know.

17 Q. Of that, 945 cardiac disorders from Remdesivir in
18 less than two years.

19 Now, if I go to the same WHO website and look
20 at the adverse effects of Ivermectin, over 30 years there's
21 only 5,695 adverse effects. Would you dispute that?

22 A. I have no reason to refute it.

23 Q. No deaths. None. Zero. And that includes the
24 last two years when Ivermectin has been used around the world
25 for the treatment of COVID.

1 So let me ask you this: You say no agency,
2 none, you went on to say, accepts Ivermectin for use in
3 COVID; isn't that what you said?

4 A. It's not what I said. I said I cannot speak to
5 international bodies, such as foreign countries, ministries
6 of health. In the United States, the Infectious Disease
7 Society for America, Centers for Disease Control, National
8 Institutes of Health, American College of Chest Physicians
9 and the American Medical Association.

10 Q. Well, I want to ask you about the NIH.

11 A. Yes, sir.

12 Q. So isn't it true that in 2020, the NIH took the
13 position against the use of Ivermectin?

14 A. Pardon?

15 Q. In 2020, the NIH took the position against the use
16 of Ivermectin for COVID; isn't that true?

17 A. Yes, sir.

18 Q. But in 2021, they changed their position; isn't
19 that true?

20 A. Yes, sir. They changed their position. We can
21 neither -- we can neither recommend for or against.

22 Q. And what does that mean? Doesn't that mean it's
23 between the doctor and the patient; isn't that what they went
24 on to say?

25 A. There was not enough data for or against. To me

1 that's a neutral decision not endorsing a medicine. That's
2 my interpretation.

3 Q. But they upgraded it from being against the use to
4 this neutral position, correct?

5 A. Correct.

6 Q. And they said it was between the doctor and the
7 patient; isn't that true?

8 A. I don't believe it says that verbatim. You could
9 read that to me. I don't remember that verbatim.

10 Q. So have you looked at table 2e on the NIH website,
11 Characteristics of Antiviral Agents That Are Approved or
12 Under Evaluation For Treatment of COVID?

13 A. I have, sir.

14 Q. And Remdesivir is the first one on that list; isn't
15 that true?

16 A. Yes, sir.

17 Q. And, again, it says, Remdesivir has been associated
18 with renal and liver toxicity, correct?

19 A. Yes, sir.

20 Q. And the second one on that list is Ivermectin;
21 isn't that true?

22 A. Yes, sir.

23 Q. And it says the actual dosage is point 0.2 to 0.6
24 milligrams per kilogram. That's the dosage that's on the NIH
25 website for Ivermectin; isn't that true?

1 A. That is correct.

2 Q. That's the dosage that was prescribed in this
3 particular case; isn't that true?

4 A. That is correct. Again, with --
5 (Talking simultaneously.)

6 A. Can I finish my response?

7 Q. (By Mr. Lorigo) My question -- the same dosage
8 that is prescribed for Mr. Jones is the dosage that is listed
9 on the NIH website, that's my question. Is that true or not
10 true?

11 A. It is true, except the NIH, in the same sentence,
12 reads, we neither recommend for or against its use regardless
13 of the dose.

14 Q. That's not on this chart at all on --

15 A. It is on the column on the right-hand side. I've
16 read it.

17 Q. I'm looking at the column on the right-hand side,
18 and what it says is "generally well tolerated;" isn't that
19 what it says?

20 A. It does. Read the rest of it.

21 Q. I'm reading it. It says "generally well
22 tolerated." It lists some other things, "Dizziness, monitor
23 for potential AEs, minor CYP3A4, generally given on an empty
24 stomach with water; however, administering Ivermectin with
25 food increases bioavailability. A list of critical trials is

1 available here."

2 That's what it says. I'm reading right from
3 it. Do you disagree with that, Doctor?

4 A. I don't disagree with that.

5 Q. So isn't it true that the CDC recommends Ivermectin
6 to every refugee that enters this country?

7 A. It is the policy, I understand now.

8 Q. So and -- and that's because they consider it a
9 safe drug; isn't that the reason they would recommend that
10 across the board without medical examination?

11 A. I don't believe it's based -- the decision to
12 administer it is based upon the safety. The decision to
13 administer is based on and it's been chosen and preferred
14 anti-helminthic agent. It is first line in the United
15 States.

16 Q. But, again, there's no requirement for a physical
17 exam in the CDC's requiring it for the administration of
18 Ivermectin to those refugees, is there?

19 A. There's no recommendation for physical exam before
20 prescribing any medication. The FDA says a medication is
21 approved or not, its indication and its approved dosage form,
22 providing the pharmacology, pregnancy, relevancy, it does not
23 say it's requires a physical exam for any medication.

24 Q. So let's get to the --

25 THE COURT: Hold on. Let me ask a question

1 right quick.

2 Dr. Seiden, that's an interesting point,
3 because I wanted to -- I think Mr. Ross was making that point
4 that the ear, nose and throat doctor hasn't conducted a
5 physical exam of the patient. So are you saying that's not
6 required?

7 THE WITNESS: It's not required by the FDA.
8 It is required by the -- by -- under Tex -- this medical
9 practice, whatever that act is, part of our jurisprudence,
10 that we examine a patient or document our assessment of the
11 patient before prescribing a medication.

12 Q. (By Mr. Lorigo) Are you saying, Doctor, that
13 telemedicine is not allowed in Texas?

14 A. It is allowed when you have a telemedicine meeting
15 with the patient themselves.

16 Q. So, Doctor, telemedicine has become substantially
17 normal in the last year and a half; isn't that true?

18 A. It is true. You have a telemedicine --

19 (Talking simultaneously.)

20 A. Could I finish my response?

21 Q. (By Mr. Lorigo) Yes, you can.

22 A. You have a telemedicine meeting with your patient.
23 You don't have a telemedicine meeting with their spouse
24 somewhere else without the patient involved.

25 Q. Is that what it says in some statute? Are you

1 pointing to some statute that says that?

2 A. When I talk about my standard practice of
3 telemedicine, is to have a telemedicine visit with the
4 patient, same way they would have come to my office. It
5 would have not been a spouse visit, it would have been the
6 patient.

7 Q. You're telling me that's your standard, correct?

8 A. I would venture to say that that's the standard
9 across America, that providers want to see their patient.

10 Q. Do you know that that's any legal standard in the
11 State of Texas?

12 A. I don't, but I do know that under our medical
13 jurisprudence, to which all licensed physicians must submit,
14 you must document before prescribing a medication. There
15 must be supporting documentation. That's the Medical
16 Practice Act in Texas, and I will leave it to my counsel to
17 actually reference the actual source in the Texas Medical
18 Code.

19 Q. But that source actually goes on to say about
20 telemedicine and how it is legal in the State of Texas.

21 A. Correct, it does not say to have a telemedicine
22 meeting with their spouse from a vehicle.

23 Q. It doesn't say that it can't be with someone else
24 providing the information, does it?

25 A. I suspect you could have a telemedicine meeting

1 with their neighbor if you wanted to, but I don't think it's
2 fair for the patient.

3 Q. So how would you be able to have a telemed meeting
4 with the patient if the patient was vented?

5 A. You wouldn't, therefore, you wouldn't have a
6 telemedicine meeting. Remember, the behavior is extremely
7 unusual.

8 Q. So are you telling me that it's your opinion that
9 it is somehow illegal to prescribe medication to someone who
10 is vented, if you're a telemed?

11 A. I would say --

12 Q. Do you know that for a fact, is the question.

13 A. I would not say it's illegal. I would say it's
14 standard practice by bylaws of facilities that you be
15 privileged and in good standing with a facility to prescribed
16 medications.

17 (Talking simultaneously.)

18 A. In fact, I will -- Mr. Lorigo, may I finish my
19 answer?

20 In our facility, in order to prescribe in the
21 intensive care unit, you must be an intensivist in our
22 facility.

23 Q. That's your hospital policy, correct?

24 A. Emergency medicine physicians in our own ER cannot
25 prescribe in our intensive care unit, nor an ear, nose and

1 throat doctor from her office in Houston.

2 Q. And that's your hospital policy, correct?

3 A. Yes, sir, that is our bylaws.

4 Q. That's your bylaws. It's not state law, it's your
5 bylaws.

6 A. That's correct, sir.

7 Q. So tell me this: How many patients do you have at
8 your hospital that are on a vent for 25 days or more?

9 A. At this very moment, three.

10 Q. And what's the percentage of survival, if someone
11 is on a vent for more than 25 days?

12 A. Anecdotally, 85 to 90 percent. That's a moving
13 target, if we look at organizations, but it's in excess of
14 three-fourths or 75 percent.

15 Q. Survive or die?

16 A. Mortality.

17 Q. So 85 to 90 percent of people on a vent this long
18 die. Isn't what happens, unfortunately?

19 A. Yes, sir, unfortunately.

20 Q. And so that means this 48-year-old county sheriff
21 deputy has a 10 to 15 percent chance of living. Isn't that
22 what the odds are at this point?

23 A. It's the unfortunate consequence of unvaccinated
24 poor state of health having --

25 Q. Oh, my God.

1 A. -- COVID and severe respiratory failure.

2 Q. So are you telling me that being vaccinated has
3 any -- any effect whatsoever on this man's treatment?

4 A. No. I'm saying that --

5 Q. That's what I asked you --

6 (Talking simultaneously.)

7 THE COURT: Y'all, we can't get a clear
8 record if you talk over each other, nor can I understand you,
9 which is the sole purpose of you being here, so that I can
10 listen to you.

11 So, if you would, Mr. Lorigo, please re-ask
12 your question.

13 Doctor, please answer his question without
14 talking over him.

15 Thank you. Go ahead.

16 Q. (By Mr. Lorigo) So, Doctor, I'm asking you
17 specifically, does the fact whether a person is vaccinated or
18 not have any change in how you treat them for this disease?

19 A. No, sir.

20 Q. So the fact that he was or wasn't vaccinated
21 doesn't affect his treatment one iota, does it?

22 A. No, sir.

23 Q. So in terms of going on a vent, is that the last
24 resort, is that what you use as a last resort, putting
25 someone on a vent?

1 A. Yes, sir.

2 Q. So you would do your best to try to keep them off
3 the vent using high flow oxygen or some other methodology;
4 isn't that true?

5 A. As I did from September 29th to October 7th.

6 Q. And what caused him to need the vent on October
7 7th?

8 A. Lack of compliance with standard therapy.

9 Q. So what -- do you have somewhere where you could
10 tell me what his oxygen levels were on October 7th when he
11 was vented?

12 A. I can tell you that his respiratory rate was
13 somewhere between 38 and 45. He was in extremis. He was
14 diaphoretic, or sweating excessively, couldn't complete his
15 sentences and had the appearance of someone who was going to
16 die.

17 Q. So at some point, there's a necessity to vent these
18 individuals; isn't that correct?

19 A. For some. For some there isn't.

20 Q. And when they're vented, the goal is to get them
21 off the vent as soon as possible, isn't that true?

22 A. That is correct.

23 Q. And so you've been trying, since October 7th at
24 your hospital, to get him off the vent, now some 25 days. Is
25 that what your testimony is?

1 A. I wouldn't say that I'm trying to get him off the
2 ventilator. I'm trying to reduce his requirements on the
3 ventilator to get him off the ventilator.

4 Q. So has the ventilator, in your opinion, done
5 permanent damage to his lungs at this point?

6 A. No. COVID-19 has done permanent damage to his
7 lungs.

8 Q. So --

9 A. The ventilator is a support method.

10 Q. So what type of permanent damage would you see at
11 this point?

12 A. With acute respiratory distress syndrome, or ARDS,
13 by this point he's in the fibroproliferative, or late
14 fibroproliferative, and/or fibrotic stages of that disease.

15 Q. So would -- now, you mentioned about COVID and
16 these antiviral effects. But you're aware -- or excuse me,
17 Ivermectin and its antiviral effects. But you are aware, are
18 you not, that he has anti-inflammatory effects also; isn't
19 that true?

20 A. Those are hypothesized as a mechanism through the
21 action of the macrophage and cytokines. It's proposed. It's
22 an in vitro assessment of its activity.

23 Q. And it's an anti-inflammatory that would be helpful
24 in terms of his situation at this point in time, would it
25 not?

1 A. That is incorrect, sir.

2 Q. So an anti-inflammatory would not be helpful. Is
3 that what you're testimony is?

4 A. Yes, sir. It is well documented that
5 anti-inflammatories do not reverse fibrosis. That is the
6 reason why anti-inflammatories have shown no effect in any
7 clinical trial to date in the management of pulmonary
8 fibrosis. Zero.

9 Q. So tell me this: Did you study the 65 trials of
10 Ivermectin? Have you looked at any of the trials
11 specifically?

12 A. Yes, sir.

13 Q. What trials have you looked at?

14 A. Three trials from Bangladesh, two trials from
15 Turkey, a trial from Greece, a couple of trials from Mexico,
16 a couple of trials from India and a couple of trials from
17 Brazil.

18 Q. Are you aware that 20 countries around this globe
19 use Ivermectin as their specific treatment for COVID?

20 A. I'm aware that a hundred countries use Ivermectin
21 for management of river blindness or associated worm
22 infestation.

23 Q. That wasn't my question, Doctor.

24 A. I would answer at least 20 countries use it, yes.

25 Q. For COVID, I say. So you were aware that at least

1 20 countries use it for COVID, correct?

2 A. Yes, sir.

3 Q. And you mentioned Bangladesh. Do you know the
4 number of people who died in Bangladesh at this point from
5 COVID?

6 A. No, sir.

7 Q. So if I told you less than 30,000 people died from
8 COVID in Bangladesh, would you -- would you object to that
9 accuracy?

10 A. Can I expand upon my answer or is it a yes or no
11 answer?

12 Q. So there's 160 -- I'll ask you a broader question
13 and you can feel free to expand. There's 160 million people
14 in Bangladesh and they have less than 28,000 deaths from
15 COVID at this point in time.

16 We live in the richest country in the world
17 with hopefully the best medical -- you know, medical
18 profession in the world, and we have twice as many people and
19 25 times the number of deaths. Do you have an explanation
20 for that?

21 A. One, I would inform everyone that reporting bias is
22 present, reporting of adverse events, side effects or
23 mortality and epidemiologic data may be seriously lacking in
24 under developed countries, right? There are people that
25 don't even have birth records, for example, and I have worked

1 in those clinics. That data may not be reported.

2 Going back to the Remdesivir earlier, it's a
3 very similar circumstance. Reporting from developing
4 countries may be significantly under reported.

5 So, for example, Ivermectin side effects may
6 be much greater than is reported, but in a small village in
7 Sub-Saharan Africa it may not be reported at all. The use of
8 Remdesivir is limited to wealthy nations with excellent
9 reporting systems.

10 Q. So you blame that discrepancy and those numbers, 25
11 times the number with only twice the number of people, it's
12 your opinion that's because of under reporting?

13 A. Yes, sir.

14 Q. So let me ask you something, Doctor. You've seen
15 the report from the FDA with the woman with a horse, and the
16 FDA in that report supposedly recommends against Ivermectin.
17 Have you looked at that?

18 A. No, sir, I have not.

19 Q. You have not?

20 In terms of toxicity for Ivermectin, are you
21 aware of any reports about additional toxicity for people who
22 use animal dosage Ivermectin?

23 A. Yes, sir, I am.

24 Q. But those are from the veterinary department of the
25 FDA; isn't that correct?

1 A. I don't think that the department of FDA dispenses
2 any medication. I think that's a governing body.

3 Q. I'm talking about the reports.

4 A. Correct, that is correct.

5 Q. So Ivermectin, as we pointed out on the NIH website
6 and from the CDC, is a well-tolerated drug, even at the .02
7 to .06 milligrams per kilogram, the dosage that was in the
8 prescription; isn't that correct?

9 A. That is correct.

10 Q. Well tolerated.

11 MR. LORIGO: Could I have just a minute, Your
12 Honor?

13 THE COURT: Sure.

14 Q. (By Mr. Lorigo) Just a few more questions, Doctor.

15 So are you aware, Doctor, that we have more
16 deaths in this country from COVID in 2021 than we had in
17 2020?

18 A. Yes, sir.

19 Q. So with all of our experience and with your
20 protocol, do you have an exclamation as to why we would have
21 more death in 2021 than we would have in 2020?

22 A. As with most viruses that become relatively endemic
23 and/or pandemic, there's a significant rise in virulence with
24 subsequent strains generational, and that's what pathogens
25 do.

1 Q. And so in terms of your protocol, has your protocol
2 changed to meet this additional, you know, requirement of
3 COVID-19?

4 A. Yes, sir. We have grown the protocol and adapted
5 the protocol, modified it, revised it in order to keep in
6 line with those governing organizations filled with experts,
7 such as IADSA, CDC and NIH, who do not advocate for the use
8 of Ivermectin.

9 (Talking simultaneously.)

10 Q. (By Mr. Lorigo) I'm sorry. Go ahead.

11 A. And advocate against. And, again, I know that
12 you're going to bring up the NIH. The NIH says we can
13 neither support nor recommend against the use of
14 Ivermectin.

15 Q. And isn't it true that the FDA, when you peel back
16 the onion, the FDA says that there hasn't been sufficient
17 studies. That's what they really say; isn't that true?

18 A. That is correct.

19 Q. They don't say you can't use Ivermectin, do they?

20 A. If you have a statement -- I cannot read it
21 verbatim, because it's not in front of me. There is a
22 statement on the FDA.gov cite recommending not to use
23 Ivermectin in the care of COVID-19.

24 Q. That is from the Veterinary Division. I can pull
25 that out. That is from the Veterinary Division, saying don't

1 use animal medication; isn't that correct?

2 A. I don't know.

3 Q. Okay. So let me ask you a question, Doctor. What
4 we have in terms of the FDA is an approved drug in
5 Ivermectin; isn't that correct?

6 A. That is correct.

7 Q. And so if you were to use Ivermectin for COVID,
8 that would be considered an off-label use; isn't that true?

9 A. That is correct.

10 Q. And is there any prohibition against an off-label
11 use of medication?

12 A. There isn't.

13 Q. And our U.S. Supreme Court has actually held that
14 doctors are allowed to prescribe off label; isn't that
15 true?

16 A. I don't know the Supreme Court's decision.

17 Q. Even the FDA says doctors certainly have the right
18 to prescribe off-label medication; isn't that true?

19 A. That is correct.

20 Q. So let me ask you this series of questions, Doctor.
21 If you had a patient you believed would benefit from an
22 off-label use of medication, would you prescribe that
23 medication?

24 A. If I thought they would benefit, I would be the
25 first to prescribe it.

1 Q. Off label, even if it was off label?

2 A. If I thought they would benefit, I would prescribe
3 it.

4 Q. Thank you, Doctor.

5 MR. LORIGO: I have no more questions.

6 THE COURT: Mr. Ross, do you have additional
7 questions for this witness?

8 MR. ROSS: I do not, Judge.

9 THE COURT: Okay. Do you need him to stay on
10 or can he go back to work?

11 MR. ROSS: At his discretion.

12 THE COURT: Dr. Seiden, it's up to you.
13 You're welcome to log off or you're welcome to watch the rest
14 of the hearing. But if you have something important you need
15 to get back to, you're welcome to go.

16 THE WITNESS: Thank you, Your Honor.

17 THE COURT: Thank you. Thank you for being
18 here.

19 Mr. Ross, did you have any additional
20 witnesses?

21 MR. ROSS: Very quickly. I've have Tandra
22 Cobern who is -- I think she's muted and her camera is off,
23 but I think -- there she is. And that is only for purposes
24 of admitting the bylaws and the rules and regs of the
25 hospital. So if the plaintiff will stipulate to those, then

1 I don't need to call her.

2 MR. LORIGO: I'll stipulate to those, Your
3 Honor.

4 THE COURT: All right. Are those being
5 offered?

6 MR. ROSS: Yes. That would be -- I know
7 you're about to ask me what exhibits they are. I will get
8 you that information in just a second.

9 THE COURT: Neither one of you -- I have lots
10 of exhibits here but nothing has been admitted so far.

11 MR. ROSS: Right. I'm offering Exhibit 9 and
12 10. That's the bylaws and rules and regs of the hospital. I
13 will also offer Exhibits 11 through 26 and ask the Court to
14 take judicial notice. Those are just statutes and
15 regulations that are currently enacted.

16 THE COURT: Hold on. What are the two that
17 are the bylaws?

18 MR. ROSS: 9 is the bylaws, Your Honor, and
19 10 is the rules and regs.

20 THE COURT: 9 and 10 or admitted.

21 (Defendants' Exhibits 9 and 10 admitted.)

22 THE COURT: What are the other numbers?

23 MR. ROSS: 11 through 26, those are
24 provisions from the Texas Occupations Code, Texas
25 Administrative Code and the Code of Federal Regulations.

1 THE COURT: Is this the stuff that allows you
2 to be for the Medicare/Medicaid?

3 MR. ROSS: That's part of the Code of Federal
4 Regulations. The other provisions, summarily, I suppose,
5 answer the questions that were brought up in regard to
6 Dr. Seiden's cross-examination with respect to it being
7 against the law in Texas to practice medicine in the way that
8 Dr. Bowden did in this instance.

9 THE COURT: I didn't hear him say that, so I
10 want to make sure I understand that testimony before he does
11 get off.

12 What did you just say? It's against the law
13 to what?

14 MR. ROSS: Dr. Seiden mentioned that he would
15 leave it up to his counsel to provide the Court with law or
16 regulations with respect to the conduct of Dr. Bowden in this
17 case and what is the standard of care with respect to
18 telemedicine or performing an examination and documentation
19 and such, and those statutory provisions in 11, specifically
20 11 through 26, summarily will provide that to the Court.

21 THE COURT: I want you to show me exactly
22 where it is, because I don't -- so 11 just says a person may
23 practice medicine in the state unless a person holds a
24 license. My understanding is that doctor holds a license,
25 right?

1 MR. ROSS: That's correct.

2 THE COURT: And then No. 12, let's go to it.
3 This is the definition of the Texas Medical Board. This is
4 back from 2018. Has this been updated for telemedicine, this
5 document here?

6 MR. ROSS: 12 --

7 THE COURT: It doesn't even refer to
8 telemedicine.

9 MR. ROSS: 12, not specifically. The purpose
10 of 12 is for the definition of practicing medicine.

11 THE COURT: All right. So then 13 is --

12 MR. ROSS: 13 is the eligibility requirements
13 and what is required to have a license. And the purpose of
14 these was for the legal point of a court, or the judicial
15 system substituting its judgment for that of licensed
16 clinical clinician.

17 The next ones, 14, 15 and 16, as well as --

18 THE COURT: Hold on. Let's go through -- I
19 want to go through this, because I feel like this -- so I
20 don't see anything yet about telemedicine. Which one is
21 that?

22 MR. ROSS: That is -- I have a specific --
23 that's not in there because I was doing research during the
24 cross-examination.

25 THE COURT: I understand but you made a very

1 bold statement about a doctor who's not here to defend
2 herself, so I want to be sure. You claim that she was doing
3 something illegal, so I want to be sure. Where in 11 through
4 16, or which are the ones you asked me to admit?

5 MR. ROSS: 11 through 16.

6 THE COURT: All right. Where in 11 through
7 16 does it say that that doctor has done something illegal or
8 that -- I want to go back.

9 Did Dr. Seiden say that, because that's a
10 very bold statement.

11 MR. ROSS: No, he didn't say that.

12 THE COURT: Okay. But that's what you
13 said.

14 MR. ROSS: Right, and I stand by it.

15 THE COURT: Okay. You stand by it, but you
16 just told me he said that.

17 MR. ROSS: No, no. If I said -- if that's
18 what came out of my mouth, that's not what I meant, what I
19 meant to say that. I don't mean that Dr. Seiden said that.

20 THE COURT: All right. So show me where in
21 these. I'm at Number 14 now. I don't see anything still
22 about telemedicine.

23 MR. ROSS: Well, that's not in this statute.

24 THE COURT: Okay.

25 MR. ROSS: 14 is the grounds for denial or

1 disciplinary action. 15 is the prohibited practice by a
2 licensed physician, and 16 is unprofessional and dishonorable
3 conduct.

4 There are multiple provisions in each of
5 these three that codify it being against the law for a
6 physician to practice medicine inconsistent with the terms of
7 the Texas Medical Practice Act and corresponding regulations
8 in Title 22 of the Texas Administrative Code.

9 THE COURT: Show me where it is. Okay. I
10 get, so far from this hearing, that it's against their policy
11 of their hospital to have a non-credentialed physician
12 administer medication in this circumstance. When he was
13 asked earlier what provision is there for -- that is against
14 a doctor who is licensed by the medical board to administer
15 or to prescribe an off-label medication to a patient via
16 telehealth, is there an answer to that question?

17 MR. ROSS: Yes.

18 THE COURT: Where is that?

19 MR. ROSS: That would be in the conditions of
20 participations, specifically --

21 THE COURT: I'm talking about a law, not a
22 policy from the hospital.

23 MR. ROSS: I'm not -- I am talking about a
24 law. It's going to be 42 CFR.

25 THE COURT: What exhibit, please?

1 MR. ROSS: Whatever 42.22, Judge. I'm sorry.
2 42 CFR --

3 THE COURT: What exhibit? What book? What
4 exhibit?

5 MR. ROSS: I think it's 23 or 24.

6 THE COURT: All right. Just a moment. Let
7 me get there. You said it's 42 what? Oh, the 222?

8 MR. ROSS: Yes, 482.222, Conditions of
9 Participation of Medical Staff.

10 THE COURT: This has to do with
11 Medicare/Medicaid.

12 MR. ROSS: The hospital is a CMS
13 participant --

14 THE COURT: Right.

15 MR. ROSS: -- so they have to follow this
16 law.

17 THE COURT: Okay.

18 MR. ROSS: Telemedicine doctors by federal
19 law, telemedicine physicians have to be credentialed either
20 by the hospital where the care is taking place or a
21 distant-site hospital.

22 There is no evidence, and I'm not aware of
23 any, even by checking the Physicians Public Profile on the
24 Texas Medical Board, that Dr. Bowden is credentialed by a
25 distant-site hospital.

1 According to the bylaws of the hospital, but
2 as well as Texas Occupations Code 164.052, 164.053, she is
3 committing dishonorable conduct and unprofessional conduct
4 against the public, health, safety and welfare of patients by
5 engaging in the practice of medicine in prescribing
6 medications for patients she's not even examined.

7 Not only is it against the law, it's against
8 the standard of care. I do think Dr. Seiden did say that.
9 And it's against the law specifically with respect -- or
10 referring to Texas Occupations Code 165.151.

11 THE COURT: This 482.222 does not say --
12 point me exactly to where it says what you're saying. I'm
13 reading it. This has to do with credentialing of people at
14 the hospital.

15 MR. ROSS: So (a) -- 482.222(a)(3).

16 THE COURT: Okay, just a moment.

17 This says, When telemedicine services are
18 furnished to the hospitals's patients through an agreement
19 with a distant-site hospital, the governing body of the
20 hospital whose patients are receiving telemedicine services
21 may choose, in lieu of the requirements in paragraphs (a)(1)
22 and (a)(2) of this section, to have its medical staff rely
23 upon the credentialing and privileging decisions made by the
24 distant-site hospital when making recommendations on
25 privileges for the individual distant-site physicians...

1 This has to do if they're going to rely on
2 the credentialing part. This is not -- this is not --

3 MR. ROSS: But she's not -- she's not
4 credited. We don't know where she's credentialed --

5 THE COURT: They're not credentialing her at
6 your hospital.

7 MR. ROSS: Correct.

8 THE COURT: Right. So --

9 MR. ROSS: And my own --

10 (Talking simultaneously.)

11 THE COURT: Okay. I don't think this says --
12 all right. Where else would you like me to look?

13 MR. ROSS: Well, I mean, Exhibits 11 through
14 whatever I said, 11 through --

15 THE COURT: You want me to take judicial
16 notice of 11 through 15 for what they said, then I'm happy to
17 do so.

18 All right. Anything else you want to offer
19 at this time?

20 MR. ROSS: No, Your Honor.

21 THE COURT: Okay. Did you have any
22 additional witnesses, Mr. Ross?

23 MR. ROSS: I do not.

24 THE COURT: Do we know, is this lady
25 credentialed at any hospital?

1 MR. ROSS: I do not know.

2 THE COURT: Dr. Bowden or whatever -- who's
3 coming? Dr. -- I'm sorry, that may be way off. Who's
4 actually going to be prescribing the medication?

5 MR. ROSS: Reportedly Dr. Bowden.

6 THE COURT: I'm sorry. Who's prescribing it?

7 MR. LORIGO: It would be Dr. Bowden, through
8 a nurse practitioner that she would have administer the
9 medication, Your Honor.

10 THE COURT: So who is Dr. Kory then?

11 MR. LORIGO: Dr. Kory is just a doctor who is
12 probably the world-renowned doctor with regard to the issue
13 of Ivermectin.

14 THE COURT: Okay. I would rather hear from
15 Dr. Bowden, because my understanding from Dr. -- from what I
16 understand is that if something goes wrong with this patient
17 or there's some issue from minute to minute and you have a
18 telemedicine doctor from, where is it, Houston?

19 MR. LORIGO: Yes.

20 THE COURT: You know, there has to be some
21 discussion about how that's going to go down, as far as the
22 communication between them or whatever.

23 So I'll leave you with that. If they don't
24 have any other witnesses, I mean, I don't -- I would rather
25 hear from Dr. Bowden on that, than I would on Dr. Kory on the

1 use of Ivermectin.

2 MR. LORIGO: For the record, Your Honor, I
3 would have an objection to him putting all of these
4 documents -- I didn't have an objection to him putting in the
5 bylaws, but I do have an objection to anything beyond the
6 bylaws.

7 THE COURT: All he asked me to do was take
8 judicial notice of 11 through 15, which they are codes, I can
9 take judicial notice of those.

10 (Talking simultaneously.)

11 MR. ROSS: 11 through 26, just for the
12 record.

13 THE COURT: I'm sorry. You first said 11
14 through 15.

15 MR. ROSS: If I said that, I'm sorry. 11
16 through 26 are the statutes and the codes. I just wanted to
17 make sure the record is clear.

18 MR. LORIGO: Again, I would --

19 THE COURT: If they're codes and statutes, I
20 mean --

21 MR. LORIGO: If they're codes and statutes, I
22 have no objection, Your Honor.

23 THE COURT: All right. That's fine, I mean,
24 these have to do with --

25 MR. LORIGO: Yeah, that's fine.

1 THE COURT: All right.

2 MR. ROSS: Did -- in addition to that, I'll
3 add Title 22, Texas Administrative Code, 165.1.

4 THE COURT: Is that here?

5 MR. ROSS: It's not here.

6 THE COURT: No, I'm not going to take
7 judicial notice of anything I don't have in front of me.
8 Sorry.

9 If you want to get it and have it for the
10 next part of the hearing, that will be fine.

11 MR. ROSS: All right. I do will so.

12 THE COURT: Like I said, how much time are
13 you needing for Wednesday?

14 MR. LARIGO: From from my perspective, Your
15 Honor, I think I will have Dr. Bowden testify and I would
16 expect it would be 25 minutes, 20 minutes at the most.

17 THE COURT: Okay. Anything else that would
18 happen on Wednesday?

19 MR. LORIGO: Only if Your Honor wanted to
20 hear testimony about Ivermectin from the expert, but I think
21 you have enough documentation, but...

22 THE COURT: And has there been any -- I
23 don't --

24 Dr. Seiden, when a family member wants to go
25 against the medical advice of the treating physician, I mean,

1 I'm sure that's happened to you in the past; what is the
2 protocol for that?

3 THE WITNESS: I don't know if we have a
4 specific protocol, Your Honor, for how to address this if and
5 when. This is an unusual circumstance.

6 THE COURT: Can you guys find out the answer
7 to that before Wednesday?

8 MR. ROSS: I can tell you the answer right
9 now, Your Honor.

10 THE COURT: What is it?

11 MR. ROSS: 42, which is in here, this is
12 going to be Exhibit 25, 42 CFR 482.13, deals with patient's
13 rights. Subsection (b)(1) allows patients and their agents,
14 of course, if they have medical power of attorney, the right
15 to participate in the development and implementation of
16 plans --

17 THE COURT: I'm sorry. What exhibit are you
18 in?

19 MR. ROSS: 25.

20 THE COURT: I'm in 25. What page are you on?

21 MR. ROSS: Page 1, which is 482.13,
22 subsection (b)(1).

23 THE COURT: Just a moment. The patient has
24 the right to participate in the development and
25 implementation of his or her plan of care.

1 Go ahead.

2 MR. ROSS: And then if you'll flip to Page 2,
3 Your Honor, and look at (b) (2) in the last sentence,
4 construed to say that a patient does not have a legal right
5 to demand provision of treatment or services.

6 And I think you will find, Your Honor, and I
7 can find exactly where it will be, but these rules and regs
8 and the bylaws of the hospital mirror that language exactly
9 as federal law requires.

10 THE COURT: So, Mr. Ross, I know there's
11 another case -- it's not -- I'm not sure if it's the same.
12 Is it THR, isn't it, the baby case?

13 MR. ROSS: That's -- you're thinking about
14 Tinsley Lewis, that's Cook Children's and has to do with the
15 advanced directives.

16 THE COURT: Right. Is this -- but same, is
17 that the parent wants care that the hospital deems
18 unnecessary or inappropriate, right?

19 MR. ROSS: Well, in that case the hospital
20 believes that there is sufficient clinical evidence to
21 withdraw care, the family is fighting that.

22 THE COURT: Right, but --

23 MR. ROSS: It's under the Advanced Directives
24 Act which has built-in legal framework for the adjudication
25 of those disputes.

1 THE COURT: What is -- Cook Children's is not
2 a THR hospital, right?

3 MR. ROSS: No, Your Honor, it's not.

4 MS. WARD: Your Honor, may I make one
5 comment, because I've been involved in those cases.

6 THE COURT: Go ahead.

7 MS. WARD: Regardless of the distinctions
8 between Advanced Directives Act and the arguments that
9 counsel has made, that they are still -- that the Courts have
10 still mandated provision of medical care that the doctors
11 don't want -- the doctors object to, so there's still that
12 common element.

13 THE COURT: I mean, I'm somewhat familiar
14 with the case, I just couldn't remember if it was -- which --
15 I guess I didn't realize it's not a THR hospital. But I know
16 in that particular case, it's where the parent wanted the
17 child to stay on the machines that were sustaining her and
18 that -- and so in that regard I wondered how they were
19 handling. I know the child is still on the machines, right?

20 MR. ROSS: Correct.

21 MS. WARD: And on the machines is providing
22 care, as well as all of the things that accompany a person
23 who is on those machines. That's all providing care that the
24 hospital objected to but the courts have not allowed them to
25 discontinue providing care.

1 THE COURT: Okay. All right. We'll convene
2 on Wednesday at 8:30 in the morning. Thank you for y'all's
3 time.

4 MR. LORIGO: If I could just renew my request
5 about the interim to provide the Ivermectin on a interim
6 basis, even if Your Honor were to say it had to be Dr. Bowden
7 to do it.

8 THE COURT: My concern is that why did you
9 voluntarily dissolve the TRO? That would have -- I mean,
10 that's the part I don't know if I have any basis, you
11 dissolved it voluntarily.

12 MS. WARD: I can explain that, because writ
13 of mandamus in a state was entered into, and the -- and they
14 were refusing to give the care anyway, and they indicated
15 that they would continue to refuse giving the care.

16 So we thought that the best course of action
17 was try to get a temporary injunction hearing as soon as
18 possible, because the original hearing was not even
19 scheduled, I think, until text Monday or Tuesday. And so we
20 wanted the medicine sooner rather than later, so we thought
21 we would proceed to hear it.

22 THE COURT: I mean, I'm happy to hear the
23 testimony now, but you don't have the people ready. So, I
24 mean, I don't feel comfortable doing that until I talk to the
25 doctor about it until -- to see what would even be the

1 arrangement.

2 Because, I mean, if Dr. Seiden is going to be
3 still the treating physician, and right now I don't have any
4 testimony from Dr. Bowden how she would be assisting in that
5 treatment. Right now, all I have is that she completed a
6 telemedicine visit. I mean, there's got to be some
7 communication between the two of them, and right now I don't
8 have any testimony on that.

9 MR. LORIGO: And that's certainly what we
10 would advocate for, that there be communication, that she be
11 allowed --

12 THE COURT: Right. But what order could I
13 even sign until you talk to her on how that would work?

14 MR. LORIGO: I understand, Your Honor.

15 THE COURT: I mean, I appreciate the
16 situation of the patient, and I am sorry to have to meet you
17 under these circumstances. I understand it's a very delicate
18 situation for both parties. I mean, if y'all want to try to
19 get something done tomorrow, I can try to fit you in tomorrow
20 if the situation is better for y'all.

21 MR. LORIGO: As soon as we are done, Your
22 Honor, I'm going to call and find out the first availability
23 and then I'm going to let Your Honor know when that is. And
24 maybe if Your Honor could take the 10 or 15 minutes just to
25 hear from Dr. Bowden.

1 THE COURT: I would be happy to do that, but
2 not only that, I would need to see your proposed orders. I
3 would like to see what it is and how that would even work.

4 MR. LORIGO: I understand. We'll put that
5 together.

6 THE COURT: And the release, if that's the
7 case.

8 MR. LORIGO: I am happy -- the release is not
9 a problem. The informed consent and the general release has
10 been offered from the beginning.

11 THE COURT: I understand that, but, I mean, a
12 release can look like a lot of different things, and I don't
13 even know if you've gone over that with Mr. Ross or not.

14 MR. LORIGO: I will attempt to do that
15 between now and the next time we meet, Your Honor.

16 THE COURT: All right. My coordinator -- my
17 regular coordinator is out this week, so if you would call
18 Tracey and just let her know that the judge has directed you
19 to schedule an emergency hearing on getting this resolved,
20 then for whatever reason if the doctor becomes available
21 tomorrow, then she can let me know and we can do it, do the
22 Zoom hearing tomorrow. But, you know, you need to check with
23 Mr. Ross to make sure he's available.

24 MR. LORIGO: I will.

25 THE REPORTER: Your Honor?

1 THE COURT: What? Holly, what do you need?

2 THE REPORTER: I want to make sure that we
3 have what exhibits were actually admitted.

4 THE COURT: Right now I only have 11
5 through -- I'm sorry. Was it 9 and 10 that were --

6 MR. ROSS: 9 and 10, Judge.

7 THE COURT: 9 and 10 are admitted, and I was
8 asked to take judicial notice of 11 through 26. I don't have
9 anything offered by Mr. Lorigo.

10 THE REPORTER: Okay. Thank you.

11 THE COURT: All right. I'll wait to hear
12 from y'all.

13 Thank you.

14 (Adjourned for the day.)

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1 THE STATE OF TEXAS)

2 COUNTY OF TARRANT)

3 I, Holly Bishop, Official Court Reporter in and for the
4 342nd District Court of Tarrant County, State of Texas, do
5 hereby certify that the above and foregoing contains a true
6 and correct transcription of all portions of evidence and
7 other proceedings requested in writing by counsel for the
8 parties to be included in this volume of the Reporter's
9 Record, in the above-styled and numbered cause, all of which
10 occurred in open court or in chambers and were reported by
11 me.

12 I further certify that this Reporter's Record of the
13 proceedings truly and correctly reflects the exhibits, if
14 any, admitted by the respective parties.

15 I further certify that the total cost for the
16 preparation of the Reporter's Record is \$ and was
17 paid by the Defendant.

18 WITNESS MY OFFICIAL HAND this the 3rd day of
19 November 2021.

20 /s/ Holly Bishop
21 HOLLY BISHOP, TEXAS CSR 3095
22 Expiration Date: 07-31-22
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REPORTER'S RECORD
CAUSE NO. 342-329996-21
Volume 2 of 3 Volumes

ERIN JONES, Individually and) IN THE DISTRICT COURT
as Legal Representative and)
Next Friend of Jason Jones,)
Plaintiff,)
V) TARRANT COUNTY, TEXAS
TEXAS HEALTH HUGULEY, INC.,)
d/b/a TEXAS HEALTH HUGULEY)
HOSPITAL FT. WORTH SOUTH;)
DR. JASON A. SEIDEN;)
JOHN DOES #1-5; JANE ROOES #1-5)
Defendant.) 342nd JUDICIAL DISTRICT

AMENDED PETITION FOR EMERGENCY MEDICAL DECLARATORY JUDGMENT
AND EMERGENCY TEMPORARY/PRELIMINARY INJUNCTION RELIEF
(F: 11/1/21)
(CONTINUATION FROM 11/1/2021)

On the 2nd day of November 2021, the following
proceedings came on to be heard in the above-entitled and
numbered cause before the Honorable Kimberly Fitzpatrick,
Judge presiding, via Zoom Videoconferencing, held in Fort
Worth, Tarrant County, Texas:

Proceedings reported by Machine Shorthand.

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P R O C E E D I N G S

(November 2, 2021, 12:05 a.m.)

THE COURT: All right. Let me call Cause No.
048-329996-21.

If you would go ahead, state your appearance
for the record.

MR. LORIGO: Ralph Lorigo on behalf of the
plaintiffs, Your Honor.

MS. WARD: Jerri Ward as local counsel for
plaintiffs.

MR. ROSS: Joshua Ross and Scharli Branch for
the defendants.

THE COURT: Who else is on the call?
Can everybody identify themselves, please, and what your
affiliation is?

MR. ROSS: Your Honor, we have two witnesses
for the plaintiff today. We have Dr. Bowden here as witness
for the plaintiff, and we also have State Senator Bob Hall as
a witness.

THE COURT: Okay. And for Ms. Ross, who is
with you?

MR. ROSS: Dr. Seiden is back on the call
today. Well, he can be. I don't know if he will be
testifying or not. And Tandra Cobern is on, and I will be
calling her.

1 THE COURT: And who is she with?

2 MR. ROSS: She's with the hospital. There
3 may be some other observers.

4 THE COURT: How many observers, please? You
5 need to identify yourself for the record.

6 MS. LEWIS: Mary Lewis, Texas Health Huguley,
7 Director of Risk.

8 THE COURT: Okay.

9 Who is Max Maxwell?

10 MR. ROSS: He's within the general counsel's
11 office for the hospital, Your Honor. I don't know what's
12 going on with his monitor.

13 THE COURT: Okay. He needs to turn his
14 camera on and so does Ms. Cobern. If you're going to
15 participate, you need to be by a camera, please.

16 MR. MAXWELL: Okay, I'll do so.

17 THE COURT: Okay, thank you.

18 Ms. Cobern?

19 Okay, thank you.

20 Go ahead. Yesterday we finished the witness
21 for Ms. Ross. Mr. Lorigo, you were going to call some people
22 today to finish your side since they weren't available due to
23 scheduling yesterday.

24 MR. LORIGO: Okay. Thank you, Your Honor. I
25 would like to call Mary Talley Bowden, Dr. Bowden.

1 THE COURT: Okay. Dr. Bowden, if you would,
2 please, raise your right hand.

3 (Witness sworn.)

4 THE COURT: Okay. Please go ahead.

5 MARY TALLEY BOWDEN, M.D.

6 having been duly sworn, testified as follows:

7 DIRECT EXAMINATION

8 BY MR. LORIGO:

9 Q. Dr. Bowden, thank you for your appearance, by the
10 way, today.

11 So can you please give us your medical,
12 educational background.

13 A. I graduated from Medical College of Georgia. I did
14 my residency at UTMD. Ear, nose and throat and sleep
15 medicine training at Stanford. Then I finished my training
16 in 2003, moved to Texas. Did private practice for about
17 eight years. Took some time off to take care of my kids, and
18 then I went back into practice about two years ago.

19 Q. So did you have board certifications?

20 A. I'm board certified in otolaryngology and sleep
21 medicine.

22 Q. And so what is the first board certification, what
23 is that?

24 A. Ear, nose and throat.

25 Q. Okay. Thank you.

1 And do you have hospital privileges?

2 A. Yes, at Methodist Hospital in Houston.

3 Q. And are you aware of the situation with regard to
4 Jason Jones?

5 A. Yes.

6 Q. How did you become aware of that situation?

7 A. His wife reached out to me, and I consulted with
8 her via telemedicine.

9 Q. And did you have a phone call with the wife?

10 A. We had a telemedicine call.

11 Q. And tell me what takes place during that call.

12 A. I do a lot of listening, and, you know, we
13 discussed how he got into the situation that he was in. And
14 I told her my views on Ivermectin and my views on
15 hospitalized patients with COVID, and basically I supported
16 her and wanted to help her.

17 Q. So did she give you his past medical history, some
18 of his past medical history? Did she explain that to you?

19 A. He was otherwise healthy, not any significant
20 health.

21 Q. Okay. And for the current situation at the time
22 that you had your conversation, did she give you the current
23 situation of his medical condition?

24 A. Yes. He's on a vent, he's been trached. As an
25 EMT, I know the significance of being trached. And he's

1 failed all of the other measures that they've tried.

2 Q. And have you been involved with COVID patients over
3 the last 18 months?

4 A. I have tested over 80,000 people for COVID. I
5 didn't recently start doing -- getting involved in their care
6 until more recently, but I have been knee deep in COVID since
7 the pandemic began. I never shut my doors. I've been trying
8 to help people from the start.

9 Q. So have you done research into Ivermectin?

10 A. Deep research. I would never prescribe something
11 that I thought could do any harm unless it's completely
12 proven. And I did my research on it back to the FDA
13 clearance, original clearance, to see how those studies were
14 conducted. I did a deep search to see if people were able to
15 kill themselves of COVID and found that it's nearly
16 impossible to kill yourself with COVID, so that gave me the
17 reassurance I needed.

18 Q. So have you reviewed any of the studies, the 65
19 studies that have been done with regard to Ivermectin and the
20 treatment of COVID?

21 MR. ROSS: Objection, assumes facts not in
22 evidence.

23 THE COURT: What articles are we referring
24 to?

25 MR. LORIGO: I have asked her if she reviewed

1 any of the studies. I was going to be more specific.

2 THE COURT: Can you rephrase, then?

3 MR. LORIGO: Yes.

4 Q. (By Mr. Lorigo) Have you had an opportunity to
5 review any of the studies that have been conducted with
6 regard to Ivermectin and COVID?

7 A. Yes.

8 Q. And what studies have you reviewed?

9 A. I don't recall the specifics off the top of my
10 head. I am -- I am working 12 hours a day every day. I have
11 read them all. I've read all of the ones I need to know,
12 I've read enough. I have had personal experience treating
13 patients with Ivermectin, and I've done enough deep research
14 into the toxicity to know that what I'm doing is safe.

15 Q. So how many patients with COVID have you treated
16 thus far?

17 A. Over 2,000.

18 Q. And in terms of those patients, have you prescribed
19 Ivermectin?

20 A. Many times.

21 Q. And how many patients have died that you've treated
22 with Ivermectin?

23 A. Zero. I have documented zero deaths and zero
24 reports of side effects.

25 Q. And do you believe -- is it your medical opinion

1 that Ivermectin is a safe drug to administer to Jason Jones
2 in this situation?

3 MR. ROSS: Objection, lack of foundation.

4 A. Absolutely.

5 THE COURT: Overruled.

6 Q. (By Mr. Lorigo) You can answer the question,
7 Doctor.

8 A. Absolutely. Absolutely. Without a single dose of
9 hesitation.

10 Q. And you also believe that your prescription will,
11 in fact, help Jason Jones given his situation?

12 MR. ROSS: Objection, speculation, lack of
13 foundation.

14 THE COURT: Overruled.

15 Q. (By Mr. Lorigo) You can answer, Doctor.

16 A. Absolutely.

17 MR. LORIGO: No other questions.

18 A. It's what I would give -- if one of my kids was in
19 the same situation, I would give them the Ivermectin. That's
20 how strongly I feel about it.

21 MR. LORIGO: Thank you, Doctor. No other
22 questions.

23 THE COURT: Mr. Ross, questions for this
24 witness?

25 MR. ROSS: Yes, Your Honor.

1 CROSS-EXAMINATION

2 BY MR. BOWDEN:

3 Q. Dr. Bowden, my name is Josh Ross, and I represent
4 the hospital and the other defendants that are involved in
5 this proceeding.6 Would you agree with me that having a medical
7 license does not give a practitioner unconstrained authority
8 to treat patients?

9 A. Can you explain that? I don't understand.

10 Q. Sure. Do you, as a physician, are you under an
11 obligation, a legal and ethical obligation, to limit your
12 practice of medicine to what you are qualified to provide?

13 A. Yes.

14 Q. In fact, are you aware that it's the law in the
15 State of Texas that all physicians recognize the limitations
16 of their ability and shall not offer services outside the
17 provider's scope of practice, or use techniques that exceed
18 their profession --

19 (Talking simultaneously.)

20 A. I'm very aware of that, yes.

21 Q. (By Mr. Ross) Are you -- do you agree that you are
22 bound as a licensed physician to federal and state law in the
23 provision of medical care to patients?

24 A. Yeah, I do. I absolutely do.

25 Q. Do you agree that the federal government passes

1 rules and regulations that govern in the manner in which
2 patient care is provided by physicians in hospitals?

3 A. Yes, I do.

4 Q. Do you understand that hospitals are governed by
5 the Centers for Medicare & Medicaid Services through the
6 conditions of participation?

7 A. I don't take Medicare.

8 Q. That wasn't my question. Do you understand
9 hospitals --

10 A. I don't know. I'm not a hospital.

11 Q. Have you had privileges at hospitals before?

12 A. Yes.

13 Q. And you have privileges at least at one hospital
14 now, correct?

15 A. Yes, but I am not a hospital.

16 Q. Does Methodist Hospital in Houston service Medicare
17 and Medicaid patients?

18 A. I have no idea.

19 Q. Do you understand the hospitals are also governed
20 by authoritative bodies and government agencies such as the
21 Joint Commission and Department of Health & Human Services?

22 A. I don't know. I'm a private practice physician.
23 I'm not a hospital.

24 Q. Fair enough. Do you agree that physicians
25 practicing medicine in hospitals have to be credentialed

1 pursuant to federal law?

2 A. I don't practice in hospitals.

3 MR. LORIGO: Wait a second, Doctor.

4 He's asking questions, Your Honor, calls for
5 a legal conclusion.

6 THE COURT: Sustained.

7 Q. (By Mr. Ross) Dr. Bowden, before you've been
8 allowed to practice medicine in hospitals, did you have to go
9 through a credentialing process?

10 A. Yes.

11 Q. And did that credentialing process involve making
12 an application to a facility to be granted credentials?

13 A. Yes.

14 Q. And those facilities, wherever you've previously
15 applied, did they have criteria with which you had to meet in
16 order to be granted credentials?

17 A. Wasn't on the other side of that credentialing
18 process, I don't know. I just filled out an application.
19 They didn't tell me what the credentialing requirements were.
20 I just filled out the application.

21 Q. Have you ever --

22 A. I wasn't on that side of the process.

23 Q. Have you ever filled out an application for
24 credentials at Texas Health Huguley Hospital in Fort Worth?

25 A. No.

1 Q. You're not credentialed at Texas Huguley Hospital
2 in Fort Worth, are you?

3 A. No, I'm not. But I am licensed in Texas to
4 practice medicine.

5 MR. ROSS: Objection to the nonresponsive
6 portion of that.

7 Q. (By Mr. Ross) Do you have any supervised delegates
8 that are credentialed to practice medicine at Texas Health
9 Huguley Hospital in Fort Worth?

10 A. No, but I am legally allowed to treat Mr. Jones.

11 Q. Okay. We'll get into that representation in a
12 minute.

13 THE COURT: Mr. Ross, please refrain from the
14 sidebar. Please just ask your questions. Thank you.

15 Q. (By Mr. Ross) Are you solely a cash paid physician
16 now, Dr. Bowden?

17 A. Yes.

18 Q. When you were previously credited at a hospital --
19 I'll tell you what. Where you're credentialed currently at
20 Methodist Hospital, what are you credentialed to do?

21 A. I am credentialed to do a lot of things. Do I need
22 to go through every single one, because there's a whole long
23 list of things.

24 Q. No. Are you credentialed to practice neurosurgery
25 at the hospital?

1 A. I am credentialed to operate very close to the
2 brain, so if there is a CFS leak, yeah, I could.

3 Q. Are you credentialed to provide nephrology care
4 care at the hospital?

5 MR. LORIGO: I object, Your Honor. This is
6 far afield.

7 THE COURT: That's sustained.

8 Mr. Ross...

9 Q. (By Mr. Ross) Doctor, are you saying you're
10 credentialed to provide -- let me ask you this: Do you feel
11 like you're qualified to provide critical care of severely
12 ill patients in the ICU in the hospital?

13 (Talking simultaneously.)

14 A. If I (Zoom audio skip) in the ICU, I would be
15 allowed to treat them, yes, absolutely. I would not (Zoom
16 audio skip) I would be absolutely allowed to treat them with
17 my privileges at Methodist. Absolutely.

18 Q. (By Mr. Ross) Would you be allowed to treat
19 patients who are critically ill with COVID Methodist --

20 (Talking simultaneously.)

21 Q. (By Mr. Ross) Let me finish my question, please.

22 A. There would be nothing preventing that.

23 Q. Are you governed by the Texas Medical Practice
24 Act?

25 A. I don't know what that is. You will have to tell

1 me what that is.

2 Q. Would you agree with me that a physician practicing
3 medicine outside the area of that physician's qualifications
4 and specialty is failing to practice medicine in an
5 acceptable and professional manner?

6 A. Not in an emergency situation, no. Not if
7 somebody's life is on the line.

8 Q. Do you agree with me that violating state or
9 federal law connected with the physician's practice of
10 medicine is unprofessional and dishonorable conduct?

11 A. I think I understand what you're trying to say, but
12 I don't think it applies. Yes, not to me, no.

13 Q. Would you agree that writing a prescription or
14 administering a drug or treatment that is nontherapeutic in
15 nature or nontherapeutic in the manner the drug or treatment
16 is administered or prescribed is unprofessional or
17 dishonorable conduct?

18 A. No. There are many uses of off-label drugs, many,
19 many, many uses of off-label drugs. Ivermectin is one of
20 them, and it is not unprofessional or unethical to use it on
21 an off-label fashion.

22 Q. I didn't ask whether it was legal or not --

23 A. Well, I don't know (Zoom audio skip) --

24 Q. Let me finish my question, please.

25 I didn't ask you whether or not prescribing

1 off label is a violation of the law. What I asked is, do you
2 agree that writing a prescription or administering a drug
3 that is nontherapeutic is unprofessional and dishonorable
4 conduct?

5 MR. LORIGO: I'll object, Your Honor.

6 (Talking simultaneously.)

7 MR. LORIGO: She answered the question that
8 he asked. He's just asking it again. He's just being
9 argumentative.

10 THE COURT: She can answer.

11 Mr. Ross, I'm not sure where you're going
12 with this. Also, if you're going to talk over when you make
13 an objection, I'm not going to make a ruling. So if you keep
14 talking after you make an objection, don't expect a ruling
15 unless you're going to pause and allow for me to make a
16 ruling.

17 Also, you guys are talking over each other.
18 You need to be careful for the record.

19 Please let him finish his question, Doctor,
20 so we can have a clear record, and then answer.

21 And, Mr. Ross, if you would let her finish
22 her answer please before you begin the next question. Why
23 don't you restate your question.

24 Q. (By Mr. Ross) Dr. Bowden, I did not ask you
25 whether or not --

1 THE COURT: Again, refrain from the sidebar
2 comment. Just ask your question.

3 Q. (By Mr. Ross) Do you agree that writing a
4 prescription or administering a drug for treatment that is
5 nontherapeutic is unprofessional or dishonorable conduct?

6 A. No, I don't.

7 Q. With respect to Mr. Jones, can you honestly
8 represent to the Court under oath that you established a
9 practitioner/patient relationship with him?

10 A. Yes, I can.

11 Q. You never saw Mr. Jones, correct?

12 A. Correct. I talked to his wife.

13 Q. You never examined Mr. Jones?

14 A. It wouldn't be possible to because he is
15 incapacitated.

16 (Talking simultaneously.)

17 A. Many physicians, many physicians -- let me finish.
18 Many physicians consult on other patients without having seen
19 them. That is common practice without having talked to them.
20 What do you do if somebody has a brain injury? You can't
21 talk to them. What difference does it make? You know all of
22 their information.

23 Q. (By Mr. Ross) You never examined Mr. Jones,
24 correct?

25 A. I -- telemedicine, you can't examine somebody.

1 Q. So the answer is no, you never examined him.

2 A. No, I didn't.

3 Q. Were you provided --

4 (Talking simultaneously.)

5 Q. (By Mr. Ross) Were you provided any of Mr. Jones'
6 medical records?

7 A. No, I was not.

8 Q. Were you aware of what his current --

9 A. I haven't had time to get the medical records. I
10 didn't know about this hearing until 12 hours ago.

11 Q. Have you ever requested his medical records?

12 A. Not yet.

13 Q. When you issued a prescription for this patient
14 that you had never seen or examined, were you aware of what
15 medications that he was on?

16 A. His wife told me what she -- what he was on.

17 Q. What did she tell you?

18 A. Am I allowed to say that? This is not -- HIPPA is
19 okay?

20 THE COURT: I can't advise you on your HIPPA.
21 I mean, I don't -- that's something that you would have to --
22 I don't know if you're looking for legal advice, but, I mean,
23 I can't --

24 THE WITNESS: I don't want to allow -- I
25 don't think I feel comfortable talking about that.

1 THE COURT: That was a question I was going
2 to ask yesterday. If he's incapacitated, is there a power of
3 attorney or what is the situation?

4 MS. WARD: Judge, under Texas law, she is his
5 wife and therefore the deferred decision maker because he
6 cannot communicate.

7 THE COURT: I wanted to know the answer to
8 that. So who is Huguley communicating with for all of the
9 medical decisions at the hospital? Is it his wife?

10 MR. LORIGO: Yes, Your Honor.

11 THE COURT: Dr. Seiden?

12 MR. LORIGO: She's obtaining all of the
13 information freely from the hospital. She hasn't had a
14 problem with that at this point, so she does have the
15 knowledge of what he has. She testified that she's there day
16 to day and contacts the hospital on a regular basis.

17 THE COURT: But is that who they're going to
18 for communication on the treatment, on getting it approved?

19 DR. SEIDEN: Yes, Your Honor.

20 THE COURT: Thank you. Go ahead.

21 Q. (By Mr. Ross) Dr. Bowden, when you issued this
22 prescription to Mr. Jones, were you aware of his acute
23 clinical presentation?

24 A. Yes. Dying.

25 Q. Is that how you would describe his acute clinical

1 presentation?

2 A. Yes.

3 Q. Were you aware of any results of his diagnostic
4 studies that have been recently done?

5 A. He had a collapsed lung. He had just been trached,
6 he had been intubated for weeks.

7 Q. Would it surprise you to know he's never been
8 trached and he's not trached currently?

9 A. Yeah, that would surprise me. He's not trached?

10 Q. He's not trached.

11 Do you have any records of this
12 physician/patient encounter?

13 MR. ROSS: Judge, I don't know if it's me, I
14 could see Dr. Bowden speaking and I couldn't hear a thing.

15 THE COURT: That's the problem with -- when
16 you guys schedule Zoom hearings with this many people. So I
17 don't know what to tell you. I can reschedule the hearing
18 and have it in the courtroom, if you would like.

19 MS. WARD: Judge, she's muted.

20 Dr. Bowden, you need to unmute yourself.

21 THE WITNESS: Oh, sorry. Okay.

22 A. Okay. So whether or not the patient has a
23 tracheostomy does not change my -- would never change my
24 decision to give him Ivermectin. It makes no difference. I
25 assume the wife doesn't understand what a tracheostomy is,

1 which -- but it doesn't change the fact that he's been in the
2 ICU for a very long time and nothing is working and he's a
3 very otherwise healthy man who needs something.

4 Q. (By Mr. Ross) Did you say he's an otherwise
5 healthy man? Did Mrs. Jones convey to you that he's
6 medically obese, that he's had a prior stroke, that he has
7 undiagnosed -- untreated sleep apnea, that he's a former
8 smoker?

9 A. Doesn't matter. Doesn't matter. He still needs
10 Ivermectin.

11 Q. I didn't asked whether it matters. I asked whether
12 she told you that.

13 A. No, she did not tell me that.

14 Q. Do you have records of this physician/patient
15 encounter, Dr. Bowden?

16 A. Yes, I do.

17 Q. And where are those records right now?

18 A. In my computer.

19 Q. Have you provided those records to Mrs. Jones'
20 counsel?

21 A. Not yet.

22 Q. When did you produce those records?

23 A. I would have to look. I don't remember the exact
24 date.

25 (A pause in the proceedings.)

1 THE COURT: Do you have any additional
2 questions for this witness?

3 MR. ROSS: I'm thinking, Your Honor. If I
4 can have just a moment, please.

5 Q. (By Mr. Ross) Dr. Bowden, what is your
6 relationship with the Front Line COVID-19 Critical Care
7 lines?

8 A. Zero.

9 Q. Are you aware that you're listed on their website
10 as a physician source on the page for, quote, How to Get
11 Ivermectin, unquote?

12 A. I have no contractual relationship with FLCCC.

13 Q. I was just wondering if you're aware that you are
14 on their website under the page, quote, How to Get
15 Ivermectin, unquote.

16 A. I was not aware of that, no. I have never seen a
17 page that says (Zoom audio skip) Ivermectin, so no. I don't
18 know about that.

19 THE COURT: Did Erin -- sorry, she just went
20 blank.

21 MR. ROSS: I'm sorry, Judge --

22 THE COURT: I was trying to see if somebody
23 knew if she came on but maybe her screen just went blank.

24 Go ahead.

25 Q. (By Mr. Ross) Your own practice has a website,

1 does it not, Dr. Bowden? Dr. Bowden?

2 A. Yes.

3 Q. Okay.

4 A. Yes.

5 Q. And on that website you advertise telemedicine
6 consults Monday through Friday for \$175, correct?

7 A. No, it's \$190.

8 Q. And your website says, For those with COVID-19 or
9 those who have questions about COVID-19, Dr. Bowden will call
10 you at the time of your appointment and can switch to
11 FaceTime, depending on your preferences. Does that sound
12 right?

13 A. Yes.

14 Q. Can you tell the Court what prescription that you
15 provided or that you made for Mr. Jones?

16 A. Ivermectin.

17 Q. Was there anything else other than Ivermectin
18 prescribed?

19 A. I'm going to say that because of HIPPA, I'm not
20 going to disclose that. I am happy to provide full records
21 if Mrs. Jones would like to release those.

22 Q. Okay. Well, a prescription form dated October
23 22nd, 2021, with your signature on it is in evidence. It's
24 part of the public record in this case, okay?

25 A. Then why are you asking me what I prescribed?

1 Q. Did you prescribe Calcitriol?

2 A. Yes.

3 Q. Did you prescribe Melatonin?

4 A. Yes.

5 Q. Did you prescribe Fluvoxamine?

6 I didn't hear your answer. Did you,

7 Dr. Bowden?

8 A. Yes.

9 Q. Did you prescribe Cyproheptadine?

10 A. No.

11 Q. Cyproheptadine, 8 milligrams per NGT TID, Dispense
12 90, Refill 2 is on this prescription. You didn't prescribe
13 that?

14 A. Okay. I'm going to have to find the
15 prescription.

16 Q. If it's easier, I can share my screen and pull it
17 up for you if you can't find it.

18 A. Whatever you would like to do. Here. Okay. I
19 have it. And basically I prescribed everything on the
20 FLCCS's protocol for patients in the hospital.

21 Q. Are Cyproheptadine and Fluvoxamine together
22 contraindicated?

23 A. No.

24 Q. Do you know if Cyproheptadine is used for the
25 reversal to Fluvoxamine toxicity?

1 A. I prescribed everything on the FLCCC protocol for
2 patients in the hospital because this man is dying.

3 Q. So you didn't --

4 A. And it's what I would do -- that's exactly what I
5 would give my husband.

6 Q. So are you testifying to the Court that you didn't
7 use your independent professional medical judgment for
8 Mr. Jones, you just used a resource of basically a political
9 group?

10 MR. LORIGO: I object, Your Honor. He's
11 mischaracterizing what she answered.

12 THE COURT: She can answer. Overruled.

13 A. I do not consider FLCCC a political group
14 whatsoever. I'm following protocols that have been made by
15 the experts in the field and people that have a wide
16 collection, a great knowledge of treating COVID patients. I
17 have spoken personally to Dr. Joe Morrone about the
18 protocols. I didn't just half-hazardly prescribe. I talked
19 to him, I listened to the webinars. I have no contractual
20 relationship with them, but I do respect them.

21 Q. (By Mr. Ross) Did you prescribe Avorstatin along
22 with Ivermectin for Mr. Jones?

23 A. I prescribed what was on that list, which is
24 according to FLCCC protocol for patients that are in the
25 hospital and dying of COVID.

1 Q. So the answer is yes, correct?

2 A. Yes, it is. I have also prescribed a lot of drugs
3 that -- excuse me. I also prescribed a lot of drugs that may
4 have some interactions, may, but you do that at -- because
5 the benefit outweighs the risk. That is -- that's the heart
6 of medicine. You have to weigh the risk benefit. There may
7 be interactions, but you have to weigh the risk benefit, art
8 of medicine.

9 Q. So did you weigh the risk benefit of Avorstatin --

10 (Talking simultaneously.)

11 A. Yes, I did. I did.

12 Q. (By Mr. Ross) Please let me finish my question,
13 Dr. Bowden.

14 Did you analyze or evaluate the risk benefit
15 of Avorstatin increasing the Ivermectin levels in Mr. Jones'
16 liver to toxic levels.

17 A. I have been unable to find a toxic level for
18 Ivermectin.

19 Q. That's not what I asked.

20 A. So I don't -- well, then, I did not consider that
21 because it is not a concern of mine, no.

22 Q. When you have written prescriptions before -- I
23 can't remember how many times you said you have done it --
24 how much do they differ from this prescription form here for
25 Mr. Jones?

1 A. This is the type of prescription I write for
2 somebody who is dying. I have done many of these.
3 Fortunately, most of my patients are not dying, but the ones
4 that are, I (Zoom audio skip) them because that's what they
5 need.

6 Q. When you testified that you evaluated that risk
7 benefit and safety or potential harm to a patient, how do you
8 administer 50 tablets a day to a critically-ill patient
9 through an oral gastric tube?

10 A. That's not a problem whatsoever.

11 Q. Explain why that's not a problem.

12 A. It's not a problem whatsoever. You can crush them,
13 you can use a liquid form. That's not a problem. That's not
14 a problem. Compound it.

15 Q. Were you aware or do you have any knowledge of
16 Mr. Jones having a low-grade ileus?

17 A. Doesn't matter.

18 Q. So generalized slowing of the bowels because of his
19 underlying diabetes --

20 A. I have a low-grade ileus. Constipation? I don't
21 don't understand what that means.

22 MR. ROSS: I'm just going to object to the
23 nonresponsive testimony, Your Honor.

24 THE COURT: Sustained.

25 Q. (By Mr. Ross) Dr. Bowden, were you told that

1 Mr. Jones had low-grade ileus from underlying diabetes and
2 gastroparesis?

3 A. No.

4 Q. Do you not see any risk --

5 A. It would not change my recommendation.

6 Q. The plaintiff has asked for the Court to order that
7 your prescription be administered to Mr. Jones at Huguley
8 through you or someone acting under your supervision. Do you
9 understand that?

10 A. Yes.

11 Q. Who is going to manage the clinical complications
12 of that therapy, if there are any?

13 A. I am happy to. I am more than happy to go to
14 Dallas to take care of him. I am -- would be -- would not
15 bother me whatsoever. I will.

16 Q. If -- and how would you do that? Are you going to
17 apply for temporary privileges?

18 A. I understand they are going to grant me the ability
19 to do that on an emergency basis.

20 Q. Is that what you've been told by somebody?

21 A. I haven't been told, but that was the hope.

22 Q. How many patients as an ear, nose and throat doctor
23 have you cared for in the ICU with advanced fibrotic acute
24 respiratory distress syndrome?

25 A. I don't know. A hundred.

1 Q. What are the three phases, then, of acute
2 respiratory distress syndrome?

3 MR. LORIGO: I object, Your Honor. This is
4 going well beyond --

5 THE COURT: What's your response, Mr. Ross?
6 I mean --

7 MR. ROSS: I'm trying to get to her
8 qualifications --

9 THE COURT: She said she's treated a hundred
10 patients, she's licensed in the State of Texas, she treats
11 these kind of patients. I mean, you've already gone through
12 all of that. We're not giving her an exam.

13 Q. (By Mr. Ross) What phase of acute respiratory
14 distress syndrome, Dr. Bowden, do you understand Mr. Jones to
15 be in?

16 A. Here's what I would do. I would consult a
17 pulmonologist to handle that portion of his care, which is
18 what any physician would do, which would be a standard of
19 care. But I am the one who has more experience than most in
20 prescribing Ivermectin, which is what makes me more qualified
21 to do it. And I have been prescribing it for hundreds of
22 people, I have treated thousands of COVID patients. This is
23 within my realm. And I have seen excellent results.
24 Excellent.

25 MR. ROSS: Objection to nonresponsive to all

1 of that, Your Honor.

2 THE COURT: Sustained. If you would, answer
3 the question that he's asked, please.

4 Q. (By Mr. Ross) What phase of acute --

5 A. Would you mind repeating the question?

6 Q. Yes, Dr. Bowden. What is --

7 A. I don't know.

8 Q. You don't know what phase of acute respiratory
9 distress syndrome that Mr. Jones is in?

10 A. No. I thought his -- I have not talked to his
11 doctor.

12 Q. Do you know whether Mr. Jones even has COVID
13 anymore?

14 A. I don't know, but I treat long-haul COVID, too. He
15 could have...

16 Q. It's been -- like I said, it's been proposed that
17 you would somehow come to Huguley to administer this
18 medication or someone under your -- acting under the
19 authority of your license. Who do you have currently
20 approved by the Texas Medical Board to act under the
21 authority of your medical license?

22 A. I haven't been in this situation before where I've
23 had to send somebody to a hospital to do this, so I would
24 have to research that.

25 Q. Do you have any advanced practice nurses?

1 A. I will go to Dallas and administer it myself, if I
2 have to, if that's what it takes to save this guy's life, I
3 will do it myself.

4 MR. ROSS: Objection, nonresponsive.

5 THE COURT: Overruled.

6 Q. (By Mr. Ross) Do you have any advanced practice
7 nurses that are practicing under your supervision?

8 A. No.

9 Q. So would it be your understanding, then, that you,
10 yourself, would be the one that would come up here to --

11 A. I'm happy to.

12 Q. -- take care of Mr. Jones?

13 A. I'm happy to.

14 Q. Well, I understand you're happy to, but I'm
15 wondering if it's your understanding that that's what you
16 would do.

17 A. Yes.

18 Q. There would be someone operating -- or practicing,
19 sorry, under your delegation, it would be you, correct?

20 A. If I can find somebody to do it, I will do that,
21 but if I can't, then I will do it because his life is
22 important.

23 MR. ROSS: I'll pass the witness.

24 THE COURT: Any additional questions for this
25 witness?

1 MR. LORIGO: Yes.

2 REDIRECT EXAMINATION

3 BY MR. LORIGO:

4 Q. So, Doctor, you said you had conversations with
5 Dr. Joe Varon; is that correct?

6 A. Uh-huh, yes.

7 Q. And who is he? Can you tell the Court who that
8 is?

9 A. He is a critical care physician in Houston.

10 Q. And what hospital does he practice at?

11 A. United Methodist Hospital.

12 Q. In Houston, correct? And is it true to your
13 knowledge that he uses the protocol that you have prescribed
14 in this situation?

15 A. Yes, we've talked about it on the phone.

16 Q. And has he talked to you about the results of using
17 that protocol?

18 A. Yes.

19 Q. And what are the results that he's been able to
20 talk to you about using that protocol for COVID patients?

21 MR. ROSS: Objection, hearsay.

22 THE COURT: Response?

23 A. He said --

24 THE COURT: Hold on. Just a moment, Doctor.
25 Do you have a response to the objection?

1 Q. (By Mr. Lorigo) So have you been able to confer
2 with Dr. Varon on any of your patients specifically?

3 A. I haven't needed to, but I've talked to him about
4 his success.

5 Q. So tell me, Doctor, given the circumstances that
6 you've heard from counsel, are you still of the opinion that
7 Ivermectin will benefit Jason Jones?

8 A. Absolutely.

9 Q. And is it true that in order to obtain a nurse
10 under your control, that could be accomplished through a
11 nursing agency; isn't that the case?

12 A. I believe so.

13 Q. And you're willing to do that in this situation;
14 isn't that true?

15 A. Yes, I'm willing to go up there myself if I need
16 to.

17 Q. But you're also, if available, you're willing to
18 obtain a nurse from a nurse agency that's qualified and allow
19 her to do it under your direction, correct?

20 A. Yes, absolutely.

21 MR. LORIGO: No other questions, Your Honor.

22 THE COURT: Any additional questions,
23 Mr. Ross?

24 MR. ROSS: Briefly.

25 RECROSS-EXAMINATION

1 BY MR. ROSS:

2 Q. Dr. Bowden, is there medications that cures
3 fibrosis?

4 MR. LORIGO: Object, Your Honor. That's
5 not -- object, Your Honor. That's not anything we asked on
6 redirect.

7 THE COURT: Mr. Ross?

8 MR. ROSS: Well, I mean, she testified she
9 doesn't know what phase of ARDS that the patient is in. For
10 later in the hearing, I want to ask if she knows if there's
11 medications that treat fibrosis for late stage acute
12 respiratory distress syndrome.

13 MR. LORIGO: This is recross and it should be
14 subject to redirect.

15 THE COURT: Sustained. Go ahead.

16 MR. ROSS: I don't have any further
17 questions, Judge.

18 THE COURT: Do you have any additional
19 witnesses?

20 MR. LORIGO: Yes, Your Honor.

21 Thank you, Doctor.

22 I would like to now call Senator Bob Hall.

23 THE COURT: What's the purpose of the
24 testimony, please?

25 MR. LORIGO: So his testimony, Your Honor,

1 would be with regard to the Texas Medical Freedom Act,
2 section -- Chapter 490.

3 THE COURT: Okay.

4 Senator, if you could please raise your right
5 hand, take yourself off mute.

6 (Witness sworn.)

7 THE COURT: All right. Go ahead, please.

8 SENATOR BOB HALL,
9 having been duly sworn, testified as follows:

10 DIRECT EXAMINATION

11 BY MR. LORIGO:

12 Q. Good afternoon, Senator. Can you tell me, Senator,
13 how long you have been a Senator in the State of Texas?

14 A. I was first elected in 2014 and sworn into office
15 in January of 2015.

16 Q. So you were a Senator at the time the Medical
17 Freedom Act was discussed and passed your the house?

18 A. Yes, I was.

19 Q. And can you tell me about that act? What was that
20 about?

21 A. That was an act that came about to give patients
22 the right to try a medicine when they were otherwise
23 expecting to die with the treatment they were currently
24 receiving that was considered to be standard protocol. A
25 number of drugs -- a number of doctors have said that other

1 drugs could be used and the patient should be able to try
2 those when they reach the point that basically they're going
3 to die on the standard treatment that was being given. And
4 it was a -- a choice given to the patient, for them to be
5 able to make the decision.

6 Q. And so does that include medications that are not
7 advocated or formally approved by the FDA?

8 A. That is correct.

9 Q. And so the Medical Freedom Act allows the patient
10 of the fundamental right to request that type of medication;
11 is that true?

12 A. That is true.

13 MR. ROSS: Your Honor, I'm going to object to
14 the leading.

15 THE COURT: Sustained.

16 Q. (By Mr. Lorigo) And that act was passed by the
17 Texas legislature. Do you know approximately when or what
18 year?

19 A. I (Zoom audio skip) in the session of 2015.

20 Q. And so it's been in effect since 2015, and it's
21 currently the law in the State of Texas; isn't that
22 correct?

23 A. That is correct.

24 Q. And, Senator, let me ask you, have you had other
25 situations with regard to hospital patients who have sought

1 this Medical Freedom Act?

2 A. Yes, I have.

3 Q. And what are those situations? Are they -- can you
4 tell me situations that are specifically related to COVID?

5 A. Yes. I've had -- I've had many a call from -- from
6 the spouse whose patient -- whose husband or wife, mostly the
7 wife that calls, and tells us it's the husband in the
8 hospital, wanting to treat them other than the standard
9 government issued give them Remdesivir and put them on the
10 ventilator and see if they live. They very well have seen
11 other people with the therapeutics recommended by the
12 Association of American Physicians and Surgeons, which
13 include Hydroxychloroquine, Ivermectin, Finasteride and
14 several other drugs being successfully used. And when they
15 approach the hospital about why don't you try these, they
16 will be told, well, that's not in our protocol, we don't do
17 that.

18 Q. Is it your belief, Senator, that having debated
19 this bill, having been in the senate when the bill was
20 passed, that this bill gives those patients that right to an
21 informed consent to use that type of medication?

22 A. Absolutely. There is --

23 MR. ROSS: Objection --

24 (Talking simultaneously.)

25 THE COURT: Just a moment.

1 Go ahead, Mr. Ross.

2 MR. ROSS: Objection, that calls for a legal
3 conclusion, and I would ask for a cite to this law.

4 THE COURT: Mr. Lorigo, do you want to
5 rephrase your question?

6 MR. LORIGO: So it is Chapter 490, it is HB
7 No. 661. It was passed in 2015. It is The Access to
8 Investigational Treatments for Patients With Severe Chronic
9 Disease, is the name of the statute, and with regard to his
10 objection, the Senator helped create the law, so certainly he
11 knows the purpose of the statute. He helped create it.

12 THE COURT: Go ahead and ask your question
13 again.

14 Q. (By Mr. Lorigo) So, Senator, do you believe that
15 the Medical Freedom Act that you were present for when it was
16 debated and that was enacted in 2015, do you believe that
17 that Medical Freedom Act gives patients the right to choose
18 this type of medication in this type of situation?

19 A. Absolutely, I do. That was the -- that was the
20 main intent behind the law, to make sure that patients had
21 the right to participate in decisions being made for them,
22 and when there was the experimental drug or any other drug
23 that was available, could be used if the patient chose to do
24 so, wanted it done.

25 Q. Thank you, Senator.

1 MR. LORIGO: Your Honor, I ask that the
2 statute be -- the Court take judicial notice of the statute
3 that's been passed in the State of Texas.

4 I have no other questions.

5 THE COURT: Mr. Ross, what -- I see you threw
6 your hands up, but what does that mean? Do you have an
7 objection?

8 MR. ROSS: I do need to object to taking
9 judicial notice of a statute that's not been cited. I
10 don't -- do we have a location in the code, in Texas law,
11 where this statute is -- supposedly exists?

12 MR. LORIGO: I will get it for you, Your
13 Honor.

14 THE COURT: Okay. Do you have any additional
15 witnesses?

16 MR. LORIGO: No other witnesses, Your
17 Honor.

18 THE COURT: Mr. Ross, did you have any
19 additional witnesses?

20 MR. ROSS: I do, Your Honor.

21 THE COURT: Go ahead.

22 MR. ROSS: I will call Tandra Cobern.

23 THE COURT: You guys have about 10 minutes
24 left, so I just want to make sure, is this going to be brief?
25 She was available yesterday, wasn't that right?

1 MR. ROSS: Yes, Your Honor, she was and I
2 will keep it very brief.

3 THE COURT: All right. Go ahead.

4 DIRECT EXAMINATION

5 BY MR. ROSS:

6 Q. Ms. Cobern, are you there?

7 A. Yes, sir.

8 Q. Can you state your name and what your title is,
9 please?

10 A. My name is Tandra Cobern. I'm the Southwest
11 Regional Director for Medical Staff Services and the Medical
12 Staff Quality Director for Texas Health Huguley.

13 Q. Does Texas Health Huguley have bylaws and rules and
14 regulations?

15 A. Yes, sir.

16 Q. Do they mirror the Centers for Medicare & Medicaid
17 Services, conditions of participation?

18 A. Yes, sir.

19 Q. Can a noncredentialed physician practice medicine
20 at Texas Huguley Hospital?

21 A. No, sir.

22 Q. The plaintiffs have submitted a proposed order to
23 the Court requesting the Court to, I guess, give Dr. Bowden
24 emergency privileges. Is there such a thing as emergency
25 privileges?

1 A. Not emergency privileges. They're called temporary
2 privileges.

3 Q. And how does temporary privileges work and what
4 types of situations is that for?

5 A. It's for an important patient care need, treatment,
6 or service. So it's for -- normally for physicians that want
7 to go ahead and get on staff that they want to get on prior
8 to going through all of the committees, and they want to
9 become a member of our medical staff and continue providing
10 service after the (Zoom audio skip) privileges.

11 Q. Is there still some vetting process for even
12 temporary privileges?

13 A. Yes, sir. We have to verify that -- obviously
14 their current licensure, that they have professional
15 liability insurance, current competence, their training and
16 the NPDB, which stands for the National Practice Data Bank,
17 which let's us know about any malpractice claims or any other
18 issues.

19 Q. The specific patient in this case is in the ICU; is
20 that right?

21 A. Yes.

22 Q. Are there any limitations to the types of providers
23 that can even be granted temporary privileges for a patient
24 such as Mr. Jones?

25 A. Our MICU is a closed unit, which means that our

1 hospitalists admit all patients to the hospital, they take
2 care of only medical needs for the patient in the ICU, and
3 the intensivist is responsible for the care of the patient.
4 So anybody, any consultant we have on the case, are to treat
5 within their scope of practice, their scope of privilege is
6 granted at Texas Health Huguley.

7 Q. Is there any situation where a otolaryngologist
8 would be given temporary privileges at Texas Health Huguley
9 for Mr. Jones?

10 A. They could be given privileges for otolaryngology
11 only.

12 Q. But not for severely ill critical care?

13 A. That's correct.

14 MR. ROSS: Pass the witness.

15 CROSS-EXAMINATION

16 BY MR. LORIGO:

17 Q. So tell me this: Have you had people admitted on
18 an emergency basis? Have you had physicians admitted on an
19 emergency basis?

20 A. We have given temporary privileges, yes, sir.

21 Q. When was the last time that happened?

22 A. I -- I am not sure of the date. We generally try
23 not to give temporary privileges often, but, of course, if
24 they meet the criteria, they are granted temporary
25 privileges.

1 Q. And the criteria is current license, liability
2 insurance and competence, correct?

3 A. Competence, training, and also a national
4 practitioner data bank. So if someone is board certified in
5 their field, that should show competence, right?

6 A. We would obtain a professional reference attesting
7 to the practitioner's competence.

8 Q. So you could, if provided the current license, the
9 liability policy, and you reviewed the database, you could
10 then make the determination of competency and temporarily
11 approve a physician to be able to have privileges at your
12 hospital; could you not?

13 A. Yes, sir, if they met all of the criteria and they
14 were functioning within their privileges.

15 MR. LORIGO: I have no other questions, Your
16 Honor.

17 THE COURT: Okay. Any additional questions
18 for this witness?

19 MR. ROSS: No, Judge. Thank you.

20 THE COURT: All right. Any additional
21 witnesses on either side?

22 MR. LORIGO: Not for the plaintiffs, Your
23 Honor.

24 THE COURT: All right. Go ahead.

25 MR. ROSS: Not from the defense. Sorry.

1 THE COURT: This is what I'm going to do.
2 I'm going to allow her to apply for a privilege at Huguley.

3 You're going to need to get that -- go
4 through that step for Dr. Bowden to administer it or somebody
5 that's approved in accordance with the law.

6 She's going to need to -- the wife is going
7 to need to execute a release based on the -- the prescription
8 being administered to her husband.

9 I'm not sure of the legality on that,
10 Mr. Ross, as far as, I guess, if the husband lives but has a
11 complication.

12 MR. LORIGO: So we would provide an informed
13 consent and a release with regard to anything and everything
14 that would happen as a result of the administration of
15 Ivermectin.

16 THE COURT: I'm just thinking through, if,
17 let's say he lives and there's a side effect or something
18 like that, if he's not waiving his own --

19 MR. LORIGO: I would provide -- I've
20 provided -- I have a release form, Your Honor, that I can
21 provide to Mr. Ross. It's an informed consent and a release
22 of the hospital, its doctors, the agents, everyone associated
23 with the hospital with regard to any ramifications that occur
24 as a result of the administration of the Ivermectin.

25 THE COURT: I know, but you're not answering

1 my question. So let's say he lives, right, and there's
2 a side effect. She can't release for him, that's my worry.

3 MR. LORIGO: Well, it's my understanding
4 under your Texas law that she does have that legal right if
5 given time, Your Honor.

6 THE COURT: I don't know, I'm asking
7 Mr. Ross.

8 Mr. Ross, do you know the legality on that?

9 MR. ROSS: No, I don't, Your Honor, and I
10 wouldn't be comfortable with it without knowing with
11 certainty.

12 THE COURT: Yeah, I know. I need you guys to
13 research that. So if for some reason there's an issue with
14 regard to the Ivermectin, he lives and he wants to go sue
15 Dr. Seiden or Huguley, is the wife's release sufficient, what
16 happens in that scenario.

17 MS. WARD: My understanding as a health law
18 attorney is that she does have the right to act for him and
19 to provide a release for him; and furthermore, if you look at
20 Chapter 74.155 of the Texas Civil Practice & Remedies Code,
21 the hospitals and doctors have been given almost complete
22 immunity for anything that arises from COVID treatment, and
23 practically have to be Dr. Mengele putting bags over people's
24 heads and putting sandflies in it to even rise to the level
25 of having a lawsuit against these hospitals and doctors for

1 anything that arises from treatment of COVID.

2 THE COURT: I would like you guys to
3 cooperate in crafting of the order, is what I'm saying. So I
4 want the order -- your order I saw is not sufficient. It
5 doesn't even go into the evidence. If you would, you need to
6 revise your order. It needs to be way more detailed than it
7 is, and it also needs to -- put in the language for
8 Dr. Bowden to go through that process at Huguley and for
9 there not to be unreasonable delay in approving her for this
10 purpose, the very limited purpose of just treating this one
11 patient and then with this -- with what we've discussed. And
12 from there, you know, there needs to be language in there
13 about her willing to be there on the emergency treatment or
14 whatever else that you guys can foresee that she may need to
15 be there for.

16 My concern, Dr. Bowden, is if you come in and
17 administer the medicine and you're gone and something
18 happens, how are they going to be able to get ahold of you,
19 what's going to be the process then, who's going to be
20 responsible for anything else that may come up? So some
21 thought needs to be put into crafting that. And there needs
22 to be language in there about the release, and I want the
23 release attached as an exhibit.

24 MR. LORIGO: I fully understand, Your
25 Honor.

1 THE COURT: All right. Once you get all of
2 that, I don't know when you guys can get that to me, but
3 Mr. Ross, due to the sensitive nature of the patient and
4 hanging on here, you know, I want you to be very cooperative
5 in getting this order done quickly.

6 MR. ROSS: I think I understand what the
7 Court's order is, and I'll represent that we'll do our best
8 to comply with what the order is if drafted right.

9 THE COURT: What he's provided so far, I've
10 already reviewed, is not sufficient. So I really don't think
11 it goes into what we discussed yesterday, if she is allowed
12 to come in and administer this, there's no discussion there.
13 To me, it leaves a lot of confusion on what happens after she
14 comes in and administers the medicine.

15 (Talking simultaneously.)

16 THE COURT: Go ahead, Mr. Ross.

17 MR. ROSS: Well, I just -- you know, I can
18 see the faces on my clients here, and I just want to make
19 sure this is covered. If the order is requiring Dr. Bowden
20 or contemplates that Dr. Bowden will be applying for
21 temporary privileges, if in the medical staff's review they
22 decide not to accept those privileges, I'm concerned about
23 what the effect has on the Court's intent.

24 THE COURT: I don't know. I mean, I'm
25 trying -- my understanding from Ms. Cobern is as long as

1 she's licensed, as long as she's in good standing, she has
2 malpractice insurance, there shouldn't be an issue.

3 Now, I don't know what they could come up
4 with in response. The intent is for her to come in and
5 administer this one medication while, you know, he's a
6 patient there. If they don't want her there for any other
7 purpose, I don't know how they would limit that.

8 (Talking simultaneously.)

9 THE COURT: Temporary privilege, I don't
10 know, is giving her more power than just coming in on this
11 one patient, I don't know. That's why I'm asking you to be,
12 you know, cooperative and making sure that it's something
13 that protects your clients and also allows her to administer
14 the medication to the patient.

15 MR. LORIGO: So what I would ask, Your Honor,
16 while the order is being determined, can Dr. Bowden apply
17 immediately, right now, so that we can get some of that out
18 of the way? She can provide obviously --

19 THE COURT: Yeah, tell her to go ahead and
20 apply. Either that, or I guess there would be some kind of
21 Rule 11 agreement between you and Mr. Ross on how that
22 procedure would go.

23 MR. LORIGO: I would like her to be able to
24 apply immediately, Your Honor.

25 THE COURT: Okay. Well, I mean, you can go

1 ahead and apply. I mean, that doesn't --

2 MR. LORIGO: I understand.

3 THE COURT: My order doesn't affect her
4 applying.

5 So do you understand exactly? The order
6 needs to be extremely detailed. It needs to go into that I'm
7 allowing it, but she needs to apply. If she needs to be
8 given permission to go in, that, you know, that that won't be
9 withheld. If there's a problem, I guess, with that part, you
10 guys need to come back and let me know right away.

11 How quickly, Ms. Cobern, does that process
12 occur?

13 MS. COBERN: It's an electronic application
14 process. So we just need to get certain information from
15 her. Most of it is web checks and, of course, how quickly
16 her malpractice carrier gets back with us and her
17 professional reference.

18 THE COURT: So 24 hours typically?

19 MS. COBERN: I would say if we can get -- it
20 usually takes more than 24 hours to get temp privileges.
21 Once we do that, there are four signatures that we have to
22 get. We have to get her activated in our EMR. I mean, we
23 will, of course, work as quickly as we can to get everything
24 into place, but I do --

25 THE COURT: I don't know, that's why I'm

1 asking you. So let's say she didn't go through the process
2 of getting temporary privileges, I mean, this can't be the
3 first time someone wanted to be administered a prescription
4 and the hospital wouldn't allow it. What have y'all done in
5 the past?

6 MS. COBERN: We've not had this particular
7 situation happen before. Usually it's --

8 THE COURT: Go ahead. I'm sorry.

9 MS. COBERN: Usually it's physicians wanting
10 to go ahead and start practicing prior to them being fully
11 credentialed. So generally to get temp privileges, depending
12 on the, again, how quickly her professional -- her
13 malpractice carrier gets us the information, how quickly her
14 professional reference, and, of course, how quickly she
15 completes the Texas application. Because we can't do
16 anything until she sends that application back to us. Once
17 we get that, then we immediately, we'll be able to start
18 working on it.

19 THE COURT: So is there some solution, other
20 than her going through the temporary privilege process and
21 Dr. Seiden not having to administer? She can't administer it
22 without having a privilege?

23 MS. COBERN: That's correct. Yes, ma'am.

24 THE COURT: Is that because of your Medicare
25 credentialing?

1 MS. COBERN: That's because the bylaws which
2 are based off of our -- the Joint Commission Standards which
3 are based off of the CMS conditions of participation.

4 THE COURT: Okay. What you can write in the
5 order is that, you know, she's going to have so many hours,
6 or whatever, that y'all can agree on to get that done after
7 she receives everything from Dr. Bowden. Not you, but
8 whatever the -- whoever is handling it.

9 Okay. Anything else?

10 Anything else, Mr. Ross, that you foresee
11 needs to be in the order?

12 MR. ROSS: Other than what's been discussed,
13 I'm sure I'll think of something the minute we get off of
14 this Zoom call, but not off the top of my head.

15 THE COURT: Dr. Bowden, is there a time frame
16 here, which -- I mean, I know that he's extremely urgent, as
17 far as, like, getting you in there to get the medication
18 administered?

19 DR. BOWDEN: Time is of the essence. I mean,
20 it's hard to say, but --

21 THE COURT: How quickly could you get those
22 things to them?

23 DR. BOWDEN: We can get it today.

24 THE COURT: I'm sorry. How quickly could you
25 get those items to Ms. Cobern?

1 DR. BOWDEN: I plan on immediately applying
2 after we get off of this.

3 THE COURT: Okay. I guess, you guys, let me
4 know if you run into any issues along the way, but the order
5 needs to be very, very specific to just this patient and just
6 this situation.

7 MS. WARD: Your Honor, one housekeeping
8 matter. I presented the order for the pro hac vice today
9 with the correct cause number and just wanted to make sure
10 that got signed so that Mr. Lorigo is officially in the
11 documents as counsel.

12 THE COURT: Yes, that's -- yes. You should
13 get a copy of it.

14 Okay. All right. Let me know if you have
15 any issues, otherwise, I'll look out for your order.

16 MR. LORIGO: Thank you, Judge. Thank you for
17 your time today.

18 THE COURT: Thank you.

19 (End of proceedings.)
20
21
22
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25

1 THE STATE OF TEXAS)

2 COUNTY OF TARRANT)

3 I, Holly Bishop, Official Court Reporter in and for the
4 342nd District Court of Tarrant County, State of Texas, do
5 hereby certify that the above and foregoing contains a true
6 and correct transcription of all portions of evidence and
7 other proceedings requested in writing by counsel for the
8 parties to be included in this volume of the Reporter's
9 Record, in the above-styled and numbered cause, all of which
10 occurred in open court or in chambers and were reported by
11 me.

12 I further certify that this Reporter's Record of the
13 proceedings truly and correctly reflects the exhibits, if
14 any, admitted by the respective parties.

15 I further certify that the total cost for the
16 preparation of the Reporter's Record is \$ and was
17 paid by the Defendant.

18 WITNESS MY OFFICIAL HAND this the 3rd day of
19 November 2021.

20 /s/ Holly Bishop
21 HOLLY BISHOP, TEXAS CSR 3095
22 Expiration Date: 07-31-22
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REPORTER'S RECORD
CAUSE NO. 342-329996-21
Volume 3 of 3 Volumes

ERIN JONES, Individually and) IN THE DISTRICT COURT
as Legal Representative and)
Next Friend of Jason Jones,)
Plaintiff,)
V) TARRANT COUNTY, TEXAS
TEXAS HEALTH HUGULEY, INC.,)
d/b/a TEXAS HEALTH HUGULEY)
HOSPITAL FT. WORTH SOUTH;)
DR. JASON A. SEIDEN;)
JOHN DOES #1-5; JANE ROOES #1-5)
Defendant.) 342nd JUDICIAL DISTRICT

AMENDED PETITION FOR EMERGENCY MEDICAL DECLARATORY JUDGMENT
AND EMERGENCY TEMPORARY/PRELIMINARY INJUNCTION RELIEF
(F: 11/1/21)
(CONTINUATION FROM 11/1/2021)

EXHIBITS

On the 1st day of November 2021, the following
proceedings came on to be heard in the above-entitled and
numbered cause before the Honorable Kimberly Fitzpatrick,
Judge presiding, via Zoom Videoconferencing, held in Fort
Worth, Tarrant County, Texas:

Proceedings reported by Machine Shorthand.

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MEDICAL STAFF BYLAWS

OF

TEXAS HEALTH HUGULEY HOSPITAL

Approved April 16, 2021

TEXAS HEALTH HUGULEY HOSPITAL

MEDICAL STAFF BYLAWS

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1.0 DEFINITIONS

Each of the following terms shall have the meaning indicated when used in these Medical Staff Bylaws and Rules and Regulations:

- 1.1 **Advanced Practice Professionals (APPs):** Allied Health Professionals required by the Board of Directors to obtain Clinical Privileges prior to practicing in the Hospital. These include Physician Assistants (PA), Nurse Anesthetists (CRNA), Nurse Practitioners (NP), Nurse Midwives, Clinical Nurse Practitioners, Registered Nurse First Assistants (RNFA) and Physician residents-in-training.
- 1.2 **Adverse Action:** Includes reducing, restricting, suspending, revoking, or denying Clinical Privileges or Membership at the Hospital.
- 1.3 **Allied Health Professionals ("AHPs"):** A person qualified through education and/or training to provide care to patients in the Hospital in a discipline which is needed and approved by the Board of Directors.
- 1.4 **AOA:** American Osteopathic Association.
- 1.5 **Ancillary Services:** Includes the Department of Physical Therapy, Department of Radiology, Department of Pathology, Department of Pharmacy, the Cardio-Pulmonary Department and all of the non-clinical units of the Hospital including Plant Services, the Nutrition Center, Materials Management and Patient Business Services.
- 1.6 **Application:** Define as (1) An Application for Appointment to Membership on the Medical Staff ("Application for Appointment"), (2) an Application for Reappointment to Membership on the Medical Staff ("Application for Reappointment") or (3) an Application for Clinical Privileges at the Hospital ("Application for Clinical Privileges). Only Individuals eligible to receive an Application as provided in these Bylaws and Rules and Regulations shall be provided an Application.
- 1.7 **Applicant:** A qualified individual who submits an Application.
- 1.8 **Appointment:** Appointment of a Physician, Dentist or Podiatrist to Membership on the Medical Staff
- 1.9 **Board of Directors ("Board"):** The governing body which has the responsibility and authority for the overall management, functioning and operation of the Hospital.
- 1.10 **Business Day:** Shall refer to Mondays through Fridays, excluding weekends and national holidays.
- 1.11 **Bylaws:** The Medical Staff Bylaws of Texas Health Huguley Hospital.
- 1.12 **Certificates:** Collectively, the term shall include DEA Certificate and Texas DPS Certificate.
- 1.13 **Chief Executive Officer or CEO:** The individual appointed by the Board of Directors as the representative of the Board of Directors responsible for the overall management and functioning of the Hospital.
- 1.14 **Clinical Privileges ("Privileges"):** The authorization granted by the Board of Directors to a Practitioner to perform specified procedures or otherwise participate in patient care within specified limits at the Hospital.
- 1.15 **Complete Application:** An Application meeting the requirements of The Joint Commission and

these Bylaws which is suitable and ready for processing in accordance with these Bylaws.

- 1.16 **Corrective Action:** Any action, including a Professional Review Action, which adversely affects Membership and/or Clinical Privileges.
- 1.17 **Day:** Shall refer to calendar days unless otherwise specified.
- 1.18 **DEA Certificate:** Drug Enforcement Administration Controlled Substances Registration Certificate.
- 1.19 **Dentist:** A person duly licensed to practice dentistry by the Texas State Board of Dental Examiners.
- 1.20 **Department:** A part of the Medical Staff, formally recognized by the Board of Directors as a part of the organization of the Medical Staff, which is comprised of Members with the same medical specialty or related medical specialties or similar Clinical Privileges.
- 1.21 **Department Chair:** The Member of the Medical Staff duly elected to be responsible for the administration of a Department.
- 1.22 **Disciplinary Action:** Any action, including Revocation/Surrender, Suspension, Restriction, Public Reprimand, Administrative Penalty Order or Professional Review Action which adversely affects a Physician's license, permit, or certification.
- 1.23 **Ex-Officio:** Holding Membership on a committee or other body of the Medical Staff by virtue of, or because of, another office or position.
- 1.24 **Good Standing:** A Member of the Medical Staff not having Membership or Privileges adversely affected.
- 1.25 **He:** Whenever the term "he" is used in these Bylaws, it shall mean "she", as the context requires. Whenever the term "his" is used in these Bylaws, it shall mean "hers", as the context requires.
- 1.26 **Health Care Quality Improvement Act:** The federal act codified at 42 U.S.C. " 11101 et seq., that, among other things, encourages reasonable professional review actions.
- 1.27 **Hearing Panel:** The ad hoc committee selected to conduct a hearing regarding a proposed Professional Review Action in accordance with these Bylaws.
- 1.28 **Hospital:** Texas Health Huguley Hospital.
- 1.29 **Joint Commission:** The Joint Commission.
- 1.30 **Medical Executive Committee ("MEC"):** The governing body of the Medical Staff of the Hospital.
- 1.31 **Medical Practice Act:** The state statute codified at Tex. Rev. Civ. Stat. Ann. art. 4495b which regulates the practice of medicine in the State of Texas.
- 1.32 **Medical Staff:** Shall have the same meaning as Organized Medical Staff.
- 1.33 **Medical Staff Bylaws:** Shall have the same meaning as "Bylaws" unless otherwise indicated, when the term "Bylaws" or the term "Medical Staff Bylaws" is used herein.

- 1.34 Medical Staff Membership:** Being a Member of the Medical Staff.
- 1.35 Medical Staff Office:** The Hospital's Medical Staff Office.
- 1.36 Medical Staff Officers:** The President of the Medical Staff, Vice President of the Medical Staff, Assistant Vice President of the Medical Staff and the Immediate Past President of the Medical Staff.
- 1.37 Member or Medical Staff Member:** A Physician, Dentist or Podiatrist with Medical Staff Membership at the Hospital.
- 1.38 Membership:** Shall have the same meaning as "Medical Staff Membership."
- 1.39 National Practitioner Data Bank ("Data Bank"):** The clearinghouse established in accordance with the Health Care Quality Improvement Act.
- 1.40 Negative Recommendation:** A recommendation of the Credentials Committee or the Medical Executive Committee or a recommendation or a determination of the Board of Directors that an Applicant's request for Membership or Privileges be denied, in whole or in part, or a recommendation of the Credentials Committee or the Medical Executive Committee or a recommendation or a determination of the Board of Directors that a Member's Medical Staff Membership and/or Privileges be Adversely Affected.
- 1.41 Non-Member:** A Practitioner who is not a Member of the Medical Staff but who is accountable to the Board of Directors, and governed under these Bylaws, Rules and Regulations, and policies developed and adopted by its voting Members and approved by the Board of Directors."
- 1.42 Organizational Performance Improvement Plan:** Written hospital-wide plan that guides and promotes a systematic, multidisciplinary approach to performance improvement efforts.
- 1.43 Organized Medical Staff:** The collective group of Physicians, Dentists, and Podiatrists who have been granted and hold Medical Staff Membership. The Organized Medical Staff is accountable to the Board of Directors, and is governed under these Bylaws, Rules and Regulations, and policies developed and adopted by its voting Members and approved by the Board of Directors.
- 1.44 Performance Improvement Committee:** Any committee of the Medical Staff, including, but not limited to, Centralized Performance Improvement Committee and/or its subcommittees, any Department committee or any subcommittee of a Department conducting performance improvement activities.
- 1.45 Podiatrist:** A person duly licensed to practice podiatry by the Texas State Board of Podiatric Medical Examiners.
- 1.46 Physician:** A person duly licensed to practice medicine by the Texas State Board of Medical Examiners.
- 1.47 Practitioner:** A person granted Clinical Privileges by the Board of Directors.
- 1.48 President of the Medical Staff:** The Member of the Medical Staff elected to be the chair of the Medical Executive Committee and to act as the presiding Member of the Medical Staff.
- 1.49 Privileges:** Shall have the same meaning as "Clinical Privileges."

- 1.50 Proctoring:** The monitoring and observation of patient care provided by a Member by any other Member(s).
- 1.51 Professional Review Action:** An action or recommendation of a Professional Review Body resulting from a Professional Review Activity.
- 1.52 Professional Review Activity:** An activity of the Hospital to determine whether Medical Staff Membership and/or Clinical Privileges of an Applicant, Member and/or Practitioner should be modified or denied.
- 1.53 Professional Review Body:** The Hospital Board of Directors, or any committee of the Hospital or the Medical Staff which conducts Professional Review Activities or assists the Board of Directors in conducting Professional Review Activities.
- 1.54 Reappointment:** The Appointment of a Member to the Medical Staff immediately following a prior Appointment.
- 1.55 Rules and Regulations:** The Rules and Regulations adopted by the Medical Staff.
- 1.56 Service:** Shall have the same meaning as "Department."
- 1.57 Subject:** A Member or Practitioner who is under investigation or professional review, or who is receiving a fair hearing, according to the provision of these Bylaws or Rules and Regulations.
- 1.58 Written Notice:** Shall mean notice in writing, including delivery by fax, e-mail, or letter, and effective on the date received.

2.0 NAME AND FUNCTION OF THE MEDICAL STAFF

2.1 Name of the Medical Staff

The Physicians, Dentist and Podiatrists granted Medical Staff Membership at the Hospital shall be known, collectively, as the Medical Staff of Texas Health Huguley Hospital.

2.2 Purpose of the Medical Staff

The Medical Staff shall organize and function to provide a structure for Practitioners to furnish medical care and treatment to patients at the Hospital. Individual Practitioners shall, in accordance with the requirements of these Bylaws, provide medical care and treatment for patients at the Hospital. Individual Members of the Medical Staff shall participate in the organization and functioning of the Medical Staff.

2.3 Function of the Medical Staff

The Medical Staff shall:

- 2.3.1 Develop and implement policies and procedures regarding the medical care and treatment of patients in the Hospital;
- 2.3.2 Assist in developing and implementing policies and procedures for Appointment and Reappointment and granting of Clinical Privileges;
- 2.3.3 Monitor the quality of patient care provided in the Hospital by evaluating the performance and activities of each Practitioners in providing care and treatment to patients;
- 2.3.4 Participate in assessing and monitoring the quality of care that occurs at the various levels within the organization as part of the Organizational Performance Improvement Plan (OPIP). As more specifically described in the Rules and Regulations, assist in Performance Improvement functions;
- 2.3.5 Review and make recommendations regarding Applications for Appointment, Applications for Reappointment, and Applications for Clinical Privileges;
- 2.3.6 Make recommendations regarding, and participate in, Professional Review Activities and Professional Review Actions, as necessary;
- 2.3.7 Report the results of Professional Review Activities, including performance improvement activities, and Professional Review Actions, to the Board of Directors;
- 2.3.8 Assist the Hospital in complying with reporting requirements, including, but not limited to, those regarding Professional Review Actions and all other applicable laws, Rules and Regulations and requirements of all accreditation organizations;
- 2.3.9 Develop, review, enforce and maintain Medical Staff Bylaws and Rules and Regulations and other policies and procedures, as necessary, for the organization and orderly functioning of the Medical Staff;
- 2.3.10 Provide opportunities for education and training to Members, Practitioners and others participating in the care and treatment of patients at the Hospital;

- 2.3.11 Provide an orderly and systematic means to identify, discuss and resolve issues regarding the Medical Staff and/or Members and/or the Hospital with the Board of Directors and the Chief Executive Officer; and
- 2.3.12 The Medical Staff, its committees, and its individual members are each an integral part of the patient safety evaluation system (PSES) of Texas Health Huguley and the Medical Staff is committed to full participation in patient safety initiatives and organizations with the Hospital.
- 2.3.13 Accomplish such other purposes described in these Bylaws.

3.0 ORGANIZATION OF THE MEDICAL STAFF

3.1 Officers of the Medical Staff

3.1.1 Officers

The officers of the Medical Staff shall be the:

- i. President of the Medical Staff;
- ii. Vice President of the Medical Staff;
- iii. Assistant Vice President of the Medical Staff; and
- iv. Immediate Past President of the Medical Staff.

The officers of the Medical Staff shall also be the members of the Medical Executive Committee. The President of the Medical Staff, Vice President of the Medical Staff and Assistant Vice President of the Medical Staff shall be nominated and confirmed as provided in these Bylaws and the Rules and Regulations. The election or Appointment of each officer of the Medical Staff shall be subject to the approval of the Board.

3.1.2 Qualifications, Election, Term, Removal and Vacancies

- 3.1.2.1 An officer must be a Member of the Medical Staff in good standing in the Active Category.
- 3.1.2.2 The procedures for Medical Staff Officer nomination, election and removal are set forth in Section 7.0 of the Rules and Regulations.
- 3.1.2.3 The Nominating Committee shall forward their recommendations to the Medical Executive Committee.
- 3.1.2.4 The Medical Executive Committee shall forward the nominees to the Medical Staff for a vote.
- 3.1.2.5 The Nominating Committee will count all votes and forward the results to the Medical Executive Committee.
- 3.1.2.6 Medical Staff Officers may be removed from office by a two-thirds vote of the Medical Executive Committee or a petition signed by at least fifty percent of the Active Medical Staff or a majority vote of the Board of Directors present at the meeting.
- 3.1.2.7 Each Medical Staff officer shall serve a term of two (2) years or until his successor is confirmed by the Medical Staff and is approved by the Board of Directors.

3.2 Departments of the Medical Staff

- 3.2.1 The Medical Staff shall be organized in accordance with the Rules and Regulations subject to Board approval.
- 3.2.2 Each Department shall have a Chair. The Chair of each Department shall be a Member of the Department in the Active Category, shall have certification by an appropriate specialty board or affirmatively established comparable competence through the credentialing process and shall have duties as outlined in Section 2.11 of Rules and Regulations.
- 3.2.3 Removal of a Department Chair may be initiated by either (a) a majority vote of the Medical Executive Committee acting on its own initiative or (b) a petition signed by a two-thirds vote of the Members of the Department of the Active category or (c) a majority vote of the Board of Directors acting on its own initiative. A removal under either (a) or (b) is subject to approval by the Board of Directors. Removal of a Medical Staff Officer is covered under Section 3.1.2.v.

3.3 Medical Staff Meetings

Meetings of the Medical Staff shall be held no less than twice a year. These meetings may be rescheduled as necessary. The Medical Staff office shall notify Medical Staff Members no later than fourteen (14) calendar days in advance of all meeting dates. The last meeting of the year shall be the annual meeting of the Medical Staff.

* More specific details concerning the terms of office, qualifications and duties of officers and Department Chair and the procedures for nominating, electing, removing and filling vacancies are set out in the Rules and Regulations.

4.0 COMMITTEES

4.1 General Provisions

4.1.1 Types of Committees

Medical Staff and Departments may utilize standing, special, joint or ad hoc committees to carry-out their responsibilities. The Medical Staff may also utilize and/or be part of joint committees of hospitals affiliated with Hospital or other hospitals or health care systems to accomplish functions common to one or more of such affiliates, hospitals, or health care systems. Subject to the approval of the Board of Directors, the Medical Executive Committee may create Medical Staff and Department committees in addition to those specified in these Bylaws. The Medical Executive Committee and/or the President of the Medical Staff may establish an ad hoc committee of the Medical Staff to perform specified tasks.

4.1.2 Appointment of Medical Staff Committee Members

During the last quarter of the Medical Staff Officers' term, the President of the Medical Staff Elect shall appoint the Members of each Medical Staff Committee unless otherwise provided in these Bylaws. The President of the Medical Staff Elect shall designate the Chair of each Medical Staff Committee from among the Members of each committee unless otherwise provided in these Bylaws.

4.2 Medical Staff Committees

4.2.1 Medical Executive Committee (MEC)

4.2.1.1 Members

The Medical Executive Committee shall consist of the following voting Members: President of the Medical Staff, Vice President of the Medical Staff, Assistant Vice President of the Medical Staff, Immediate Past President of the Medical Staff and the Chair, or in his absence the Vice Chair of each Medical Staff Department. The non-voting Member(s) of the Medical Executive Committee shall be the Chief Executive Officer and/or his designee(s). In addition, others such as the Chief Medical Officer and Chairs of various committees may be invited as guests at the discretion of the President of the Medical Staff and Chief Executive Officer.

4.2.1.2 Duties and Responsibilities

The duties of the Medical Executive Committee shall include, but not be limited to:

4.2.1.2.1 Coordinating the activities and implementing the general policies of the Medical Staff Departments;

4.2.1.2.2 Empowered to act for the Medical Staff in the intervals between Medical Staff meetings subject to the requirements and limitations of these Bylaws.

4.2.1.2.3 Receiving and acting on reports and recommendations of the Credentials Committee; to review credentials and to delineate individual Clinical Privileges; to review recommendations of individuals for Medical Staff membership; to review recommendations for delineated Clinical Privileges for each eligible individual; to review the participation of the Medical Staff in organization performance improvement activities; be the mechanism by which Medical Staff membership may be terminated; and for the fair hearing procedures; and receives and acts on reports and recommendations from Medical Staff committees, clinical Departments, assigned activity groups, other standing or special committees; and

4.2.1.2.4 Making Medical Staff recommendations directly to the Board of Directors for its approval.

4.2.1.3 Authority

4.2.1.3.1 The Medical Staff may delegate the responsibility for adoption and amendment of the Rules, and Regulations and policies to the MEC.

4.2.1.3.2 Any actions taken by the MEC related to amendments shall follow the process set forth in Section 11.0.

4.2.1.3.3 The Medical Staff may remove the authority delegated to the MEC by amending its bylaws, in accordance with Section 11.4.

4.2.2 Credentials Committee

4.2.2.1 Members

The Vice President of the Medical Staff shall serve as chair of the Credentials Committee. The voting Members of the Credentials Committee shall be the Vice President, the Assistant Vice President, the immediate past President and two other past Presidents, and two (2) Members selected by the President of the Medical Staff. These Members may be from any Medical Staff category. If a Member is also a Department Chair, he or she shall not vote on Applicants in their own Department.

4.2.2.2 Duties: The duties of the Credentials Committee shall include, but not be limited to:

4.2.2.2.1 Reviewing all Applications and Requests for Clinical Privileges and requests for advancement and making recommendations to the Medical Executive Committee regarding such Application and requests.

4.2.2.2.2 Evaluating reports made to the Credentials Committee involving patient care concerns, alleged breaches of ethics or

confidentiality or behavior or conduct of Members or consideration of a proposed Professional Review Action and making appropriate recommendations to the Medical Executive Committee;

4.2.2.2.3 Developing and revising guidelines for the credentialing of Medical Staff Members, as needed;

4.2.2.2.3 Review of ongoing and focused professional practice evaluations.

4.2.3 Special Committees

Special Committees shall be appointed as required to properly carry out the duties of the Medical Staff. The composition of a Special Committee shall be determined by its purpose. A Special Committee shall confine its work to the purpose for which it is appointed; shall have only the authority and power of action specifically granted in the charge to the committee; and will automatically cease at the conclusion of its specific charge. Special Committees may be appointed by the President of the Medical Staff or by a Department chair. Such committees will not continue beyond the term of office of the officer who appointed them unless continued by the new officer who succeeds the officer who appointed the Special Committee.

4.3 Committees Other Than Medical Staff Committees

The President of the Medical Staff, in consultation with the Chief Executive Officer, shall select Medical Staff Members to serve on all committees established by the Board of Directors and/or the Hospital which may require representation by the Medical Staff.

4.4 Medical Peer Review Committees

4.4.1 Medical Peer Review Committee Status. The Medical Executive Committee, the Departments, and all Medical Staff and Department committees (whether standing, special, ad hoc, subcommittee, joint committee, Hearing Panel or Professional Review Body), as well as the Medical Staff when meeting as a whole, shall be constituted and operate as a “medical peer review committee,” “medical committee,” and “professional review body,” as such terms are defined by Texas and/or federal law, and are authorized by the Board of Directors through these Medical Staff Bylaws (Bylaws) to engage in Medical Peer Review as defined below. This provision shall also apply to any Hospital or other committees engaged in Medical Peer Review at the Hospital, including the Board of Directors and its committees.

4.4.2 Medical Peer Review Defined. “Medical Peer Review” means the evaluation of medical and health care services, including the evaluation of the qualifications and professional conduct of Members, Practitioners and other individuals holding or applying for Clinical Privileges, and of patient care, treatment, and services provided by them. The term includes but is not limited to:

4.4.2.1 The process of credentialing for initial appointment, reappointment, the granting of Clinical Privileges, and reinstatement from leave of absence;

- 4.4.2.2 The process of issuing an Adverse Action, including but not limited to Corrective Action, and affording procedural rights of review as provided in the Bylaws;
 - 4.4.2.3 Any evaluation of the merits of a complaint relating to a Member or Practitioner, or issuance of a recommendation or action in that regard;
 - 4.4.2.4 Any evaluation of the accuracy of a diagnosis or quality of the patient care, treatment, or services provided by a Member or Practitioner, including but not limited to implementation of the Hospital's Performance Improvement Plan and the review of patient care, treatment, or services by another Practitioner or outside peer reviewer, whether or not a Member of the Medical Staff;
 - 4.4.2.5 A report made to an individual or a committee engaged in Medical Peer Review or to a licensing agency;
 - 4.4.2.6 Implementation of the duties of a committee engaged in Medical Peer Review by a Member, Practitioner, or agent; and
 - 4.4.2.7 "Medical peer review" as defined in the Texas Medical Practice Act and "professional review activity" as defined by the federal Health Care Quality Improvement Act.
- 4.4.3 Agents. The following are considered agents of the Medical Staff and Board of Directors in the following circumstances:
- 4.4.3.1 The Hospital CEO, other members of Hospital administration, Medical Staff Services staff, and all other Hospital department staff supporting Medical Peer Review activities shall be considered agents as applicable when performing authorized functions and responsibilities.
 - 4.4.3.2 Practitioners, whether or not Members of the Staff, and others including outside peer reviewers who are requested by the Medical Executive Committee or another Medical Staff committee, a Department or a committee thereof, or a special or ad hoc committee thereof, or by the Medical Staff or the Board of Directors to review the patient care, treatment or services of another Practitioner, or who do so as an authorized function of the requesting committee, Department, Medical Staff, or Board of Directors shall be considered agents thereof when performing such review in good faith.
- 4.4.4 Any good faith action by an agent or member of the Medical Executive Committee or another Medical Staff committee, a Department or committee thereof, or special or ad hoc committee thereof, or of the Medical Staff or the Board of Directors, when performing authorized functions and responsibilities shall be considered an action taken on behalf of the committee, Department, Medical Staff, or Board of Directors as applicable, not an action taken in the agent or member's individual capacity. This shall include, but not be limited to, actions by the Medical Staff or Department officers, the Chief Medical Officer and other Practitioners serving in medical staff leadership and/or administrative positions, and the Hospital CEO.

5.0 MEDICAL STAFF MEMBERSHIP AND PRIVILEGES

5.1 General Principles

Only Physicians, Dentists and Podiatrists who continuously meet the qualifications and requirements for Medical Staff Membership in these Bylaws and the Rules and Regulations shall be eligible for Membership on the Medical Staff. A Physician, Dentist or Podiatrist shall not be entitled to Membership or Clinical Privileges in the Hospital (including telemedicine from a distant site) merely by virtue of the fact that he is duly licensed in this or any other state, or is a Member of any professional organization, or had in the past or presently has privileges in another hospital. Furthermore, Medical Staff Membership is not synonymous with Clinical Privileges. A Medical Staff Member may hold Membership without Clinical Privileges and a Practitioner may have Clinical Privileges without Membership. Medical Staff membership and Clinical Privileges are explicitly and separately granted by the Board of Directors as defined in these Bylaws. However, to the extent that an Applicant is an otherwise qualified person, neither Membership nor Privileges shall be denied because of an Applicant's sex, race, color, religion, national origin, or other grounds not permitted by law. All Applicants, Members and Practitioners shall abide by the Medical Staff Bylaws, the Rules and Regulations and all Hospital, Medical Staff and Departmental policies/guidelines and procedures.

5.2 Burden of Proof

The Applicant for Membership or Clinical Privileges shall have the burden of producing adequate information to document his competence and qualifications to the satisfaction of the appropriate Department(s), Committees and the Board, and for resolving any doubts about such qualifications. The Applicant shall also have the duty to update information provided on an Application while the Application is pending. Failure to update or any misstatement, misrepresentation, or omission in connection with an Application is grounds for Application denial or corrective action.

5.3 Qualifications for Membership

Every Member at the time of Medical Staff Appointment and continuously thereafter, must demonstrate to the satisfaction of the Medical Staff and the Board, the following minimum, uniformly applied, qualifications:

5.3.1 Licensure: A Member must have, and be able to demonstrate that he has a current unrestricted Texas license to practice medicine, dentistry or podiatry, as applicable.

5.3.2 Competence: A Member who has Clinical Privileges must have current clinical competence, education, training experience and certification in those areas of Clinical Privileges. All such qualification items are more specifically detailed in the Rules and Regulations.

5.3.3 Standards of Conduct:

5.3.3.1 A Member must demonstrate an adherence to recognized standards of conduct and ethics of his profession;

5.3.3.2 He must be able to contribute to the orderly and efficient functioning of the Medical Staff and the Hospital.

5.3.3.3 He must have high personal and professional standards;

5.3.3.4 He must have a satisfactory professional liability record, including past and

pending professional liability claims, suits, settlements and judgments as determined by the Board of Directors;

5.3.3.5 He must work with and relate to other Members, Practitioners, Hospital Administration and staff, patients, visitors, and the community in general, in a cooperative, professional, non-disruptive manner that is essential for maintaining an environment appropriate to quality and efficient patient care.

5.3.4 Health Status: A Member is in sufficiently good physical and mental health to fulfill the obligations of Medical Staff Appointment and is willing to submit to a physical and/or mental examination as requested by the Medical Executive Committee or the Board of Directors.

5.3.5 Professional Liability Insurance: A Member maintains professional liability insurance in the amounts required by and with companies approved by the Board of Directors and in accordance with those other requirements set out in the Rules and Regulations.

5.4 Responsibilities of Members

Each Medical Staff Member shall have the following responsibilities:

5.4.1 Abide by the Medical Staff Bylaws, Rules and Regulations, the Hospital's policies and procedures, regulatory requirements and the professional code of ethics of the Member's profession;

5.4.2 Cooperate fully with all Hospital committee investigations and respond to all Hospital and/or Medical Staff and/or committee inquiries in the time specified;

5.4.3 Discharge all Medical Staff, Department, committee and Hospital responsibilities in a professional, courteous and timely manner in accordance with these Bylaws;

5.4.4 Prepare and complete medical records for all patients admitted or treated by the Member in the Hospital in a timely manner in accordance with these Bylaws, the Rules and Regulations and Hospital policies;

5.4.5 Agree to notify the President of the Medical Staff and Chief Executive Officer via the Medical Staff Office, within 15 days, of any pending actions, proceedings, initial notification of an investigation, or any final action regarding:

5.4.5.1 Professional license to practice from a State Licensing Board (notification must be immediate if license to practice has been suspended or revoked);

5.4.5.2 DEA (notification must be immediate if controlled substance registration has been suspended or revoked);

5.4.5.3 Professional liability insurance coverage (notification must be immediate if professional liability insurance coverage is suspended, cancelled, revoked or there is a lapse in coverage);

5.4.5.4 Membership, status, and/or Clinical Privileges at another facility, voluntary or involuntary.

5.4.6 Agree to notify the President of the Medical Staff and Chief Executive Officer via the Medical Staff Office, within 15 days, of any of the following:

- 5.4.6.1 Federal or State governmental licensing board or agency notification of findings of an investigation or disciplinary action;
- 5.4.6.2 Member's mental or physical health, which could affect the Member's ability to provide quality medical care and treatment to patients;
- 5.4.6.3 Any settlement or jury verdict arising from the Member's clinical and/or professional conduct;
- 5.4.6.4 Any alleged violation of law (other than minor traffic violation);
- 5.4.6.5 Exclusion from governmental payors (i.e.: Medicare, Medicaid, Tricare);
- 5.4.6.6 Any sanctions by the TMF;
- 5.4.6.7 State Medical Board Order, agreement, reprimand, sanction or fine.
- 5.4.7 Retain current clinical competence for all Privileges granted or requested at the Hospital;
- 5.4.8 Perform such other duties and functions as may, from time to time, be delegated by the Board of Directors, Medical Executive Committee or the Medical Staff.

5.5 Qualifications for Clinical Privileges.

Every Practitioner, at the time Clinical Privileges are granted and continuously thereafter, must demonstrate to the satisfaction of the Medical Staff and the Board, the following minimum, uniformly applied, qualifications:

- 5.5.1 Licensure: A Practitioner must have, and be able to demonstrate that he has a current unrestricted Texas license to practice medicine, dentistry or podiatry, as applicable.
- 5.5.2 Competence: A Practitioner must have current clinical competence, education, training experience and certification in those areas of Clinical Privileges. All such qualification items are more specifically detailed in the Rules and Regulations.
- 5.5.3 Standards of Conduct:
 - 5.5.3.1 A Practitioner must demonstrate an adherence to recognized standards of conduct and ethics of his profession;
 - 5.5.3.2 He must be able to contribute to the orderly and efficient functioning of the Medical Staff and the Hospital.
 - 5.5.3.3 He must have high personal and professional standards;
 - 5.5.3.4 He must have a satisfactory professional liability record, including past and pending professional liability claims, suits, settlements and judgments as determined by the Board of Directors;
 - 5.5.3.5 He must work with and relate to Members, Practitioners, Hospital Administration and staff, patients, visitors, and the community in general, in a cooperative, professional, non-disruptive manner that is essential for maintaining an environment appropriate to quality and efficient patient care.

- 5.5.4 **Health Status:** A Practitioner is in sufficiently good physical and mental health to exercise the Privileges requested and is willing to submit to a physical and/or mental examination as requested by the Medical Executive Committee or the Board of Directors.
- 5.5.5 **Professional Liability Insurance:** A Practitioner maintains professional liability insurance in the amounts required by and with companies approved by the Board of Directors and in accordance with those other requirements set out in the Rules and Regulations.

5.6 Responsibilities of Practitioners

Each Practitioner shall have the following responsibilities:

- 5.6.1 Provide continuous care and treatment to patients consistent with that practiced at the Hospital and appropriate to the circumstances;
- 5.6.2 Abide by the Medical Staff Bylaws, Rules and Regulations, the Hospital's policies and procedures, regulatory requirements and the professional code of ethics of the Practitioner's profession;
- 5.6.3 Cooperate fully with all Hospital committee investigations and respond to all Hospital and/or Medical Staff and/or committee inquiries in the time specified;
- 5.6.4 Discharge all Medical Staff, Department, committee and Hospital responsibilities in a professional, courteous and timely manner in accordance with these Bylaws;
- 5.6.5 Prepare and complete medical records for all patients admitted or treated by the Member in the Hospital in a timely manner in accordance with these Bylaws, the Rules and Regulations and Hospital policies;
- 5.6.6 Agree to notify the President of the Medical Staff and Chief Executive Officer via the Medical Staff Office, within 15 days, of any pending actions, proceedings, initial notification of an investigation, or any final action regarding:
 - 5.6.6.1 Professional license to practice from a State Licensing Board (notification must be immediate if license to practice has been suspended or revoked);
 - 5.6.6.2 DEA controlled substances registration (notification must be immediate if controlled substance registration has been suspended or revoked);
 - 5.6.6.3 Professional liability insurance coverage (notification must be immediate if professional liability insurance coverage is suspended, cancelled, revoked or there is a lapse in coverage);
 - 5.6.6.4 Membership, status, and/or Clinical Privileges at another facility, voluntary or involuntary.
- 5.6.7 Agree to notify the President of the Medical Staff and Chief Executive Officer via the Medical Staff Office, within 15 days, of any of the following:
 - 5.6.7.1 Federal or State governmental licensing board or agency notification of findings of an investigation or disciplinary action;
 - 5.6.7.2 Practitioner's mental or physical health, which could affect the Member's ability

to provide quality medical care and treatment to patients;

5.6.7.3 Any settlement or jury verdict arising from the Member's clinical and/or professional conduct;

5.6.7.4 Any alleged violation of law (other than minor traffic violation);

5.6.7.5 Exclusion from governmental payors (i.e.: Medicare, Medicaid, Tricare...);

5.6.7.6 Any sanctions by the TMF;

5.6.7.7 State Medical Board Order, agreement, reprimand, sanction or fine.

5.6.8 Retain current clinical competence for all Privileges granted or requested at the Hospital;

5.6.9 Refrain from transferring responsibility for the care and treatment of patients, including on-call duty, to any Practitioner who has not been granted Clinical Privileges at the Hospital; and

5.6.10 Perform such other duties and functions as may, from time to time, be delegated by the Board of Directors, Medical Executive Committee or the Medical Staff.

5.7 Organized Health Care Arrangement

The Hospital, each Member of the Medical Staff, and each Practitioner at the Hospital will be part of an Organized Health Care Arrangement (OHCA) which is defined as a clinically integrated care setting in which individuals typically receive healthcare from more than one healthcare provider. The OHCA allows the Hospital and Medical Staff Members to share information for purposes of treatment, payment and operations. Under the OHCA, at the time of admission or registration, a patient will receive one Notice of Patient Privacy Practices (NPPP), which will include information about the Organized Health Care Arrangement between the Hospital and Medical Staff.

5.8 Completion of History and Physical Examinations

5.8.1 A medical history and physical examination must be completed no more than thirty (30) days before or twenty-four (24) hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services. The medical history and physical examination must be completed and documented by a Physician, an oral and maxillofacial surgeon, or other qualified licensed individual in accordance with State law and hospital policy. Podiatrists shall complete a podiatric history.

5.8.2 An updated examination of the patient, including any changes in the patient's condition, must be completed and documented within twenty-four (24) hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services, when the medical history and physical examination are completed within thirty (30) days before admission or registration. The updated examination of the patient, including any changes in the patient's condition, must be completed and documented by a Physician, an oral and maxillofacial surgeon, or other qualified licensed individual in accordance with State law and hospital policy.

5.8.3 The content of complete and focused history and physical examination is delineated in the Medical Staff Rules and Regulations.

5.9 Categories

5.9.1 Designations - Medical Staff Membership shall have four (4) categories: Non-Voting, Active, Retired and Honorary. Assignment to Non-Voting and Active categories is based on established criteria using parameters of clinical activity and Medical Staff service.

5.9.2 Non-Voting Category

5.9.2.1 Qualifications:

5.9.2.1.1 Members in the Non-Voting Category must meet qualifications for Members listed in 5.3.

5.9.2.1.2 Non-Voting Members include all initial Appointments to the Medical Staff, and all those who do not meet criteria for Active, Retired or Honorary categories.

5.9.2.2 Rights and Responsibilities

5.9.2.2.1 The responsibilities for Medical Staff Membership provided in Section 5.4;

5.9.2.2.2 Participate in all Medical Staff and Hospital committees and subcommittees, except Medical Executive Committee, Bylaws Committee and Credentials Committee, as assigned;

5.9.2.2.3 Complete proctoring requirements, if any, as set forth in the Rules and Regulations;

5.9.2.2.4 Serve as a proctor for any granted Clinical Privileges, as assigned;

5.9.2.2.5 Participate in the Department of Emergency Medicine on-call roster, as assigned;

5.9.2.2.6 Attend without vote assigned Medical Staff, Department and Committee meetings;

5.9.2.2.7 Attend and/or participate in all Hospital Continuing Medical Educations meetings; and

5.9.2.2.8 Non-Voting Members may not hold Medical Staff and/or Department office.

5.9.3 Active Category

5.9.3.1 Qualifications

5.9.3.1.1 Active Members must have a total of 200 eligible clinical documentations, or 20 hours of eligible Medical Staff service, or a pro-rata combination of both (10 clinical documentations equals 1 hour of Medical Staff service), during the previous twenty-four months;

5.9.3.1.2 Eligible clinical documentations are: History and Physical, Consultations, Discharge Summaries, Operative Reports, Short Stay Summaries, Anesthesia Reports, Cardiac Cath Reports, Cardiopulmonary

Reports, Emergency Room Reports, Pathology Reports, Psychiatric Evaluations, and Radiology Reports;

- 5.9.3.1.3 Medical Staff Departments may request Department specific clinical documentation criteria, subject to Board approval;
- 5.9.3.1.4 Eligible Medical Staff service hours are: Hospital sponsored Medical Directorships, attendance or participation at any meeting of the Medical Staff or Medical Staff Department, Medical Staff committee or sub-committee, Department committee or sub-committee, Hospital committee or sub-committee, Multidisciplinary committee or sub-committee, Hospital sponsored continuing medical education activity, Hearing Panel, Member Proctoring, or preparation for any of the preceding activities;
- 5.9.3.1.5 Initial Appointments to the Medical Staff shall be in the Non-Voting category; however, Members may request Active category before Reappointment once criteria are met;
- 5.9.3.1.6 Once assigned to the Active category, the Member will remain in the Active category until the next Reappointment unless the Member requests a change of membership category;
- 5.9.3.1.7 At Reappointment, Active Members must have met Active category criteria during the previous Appointment period in order to be eligible for Reappointment in the Active category; otherwise, the Member will be considered for Reappointment in the Non-Voting category.

5.9.3.2 Rights and Responsibilities

In addition to all of the Rights and Responsibilities of Non-Voting Members, Active Members shall have the right to:

- 5.9.3.2.1 Be a Member of all Medical Staff committees and sub-committees, including Medical Executive Committee, Credentials Committee and Bylaws Committee;
- 5.9.3.2.2 Attend and vote at all assigned Medical Staff, Department and committee meetings; and
- 5.9.3.2.3 Hold Medical Staff and/or Department office.

5.9.4 Retired Category

Members who have provided long standing service to the Hospital who no longer actively practice but desire to maintain their affiliation with the Hospital, may request Membership in the Retired category. A Member in the Retired category may attend Medical Staff functions and may attend Medical Staff and Hospital continuing education programs. Retired Members are not required to meet qualifications for Membership listed in 5.3, and do not have Rights or Responsibilities except those listed in this paragraph. Retired members are not required to submit a Reappointment Application.

5.9.5 Honorary Category

Members in the Retired Category who have provided extraordinary service to the Hospital may be awarded Honorary Category upon nomination by the Medical Executive Committee and approval by the Board of Directors. A Member in the Honorary Category may attend Medical Staff functions and may attend Medical Staff and Hospital continuing education programs. Honorary Members are not required to meet qualifications for Membership listed in 5.3, and do not have Rights or Responsibilities except those listed in this paragraph. Honorary Members are not required to submit a Reappointment Application.

5.10 Leave of Absence (LOA)

To make it possible for the Medical Staff to track extended periods of clinical inactivity, any Member or Practitioner who is unavailable for duty at the hospital and/or service to the Medical Staff for more than ninety (90) days must request a leave of absence (LOA). During a leave of absence, all Clinical Privileges are suspended, and, if the Practitioner is a Member of the Medical Staff, the Membership category becomes non-voting. A LOA may be requested for up to one year at a time, and may be renewed one time only for up to an additional year. If a Member's term of Appointment expires before the end of the LOA, the Member must submit an Application for Reappointment. The Member or Practitioner must request reinstatement of Membership and/or privileges at the end of the LOA. If the Member does not submit an Application for Reappointment prior to the expiration Membership, or does not submit a request for reinstatement of Membership and/or Privileges at the end of LOA, then the Member or Practitioner will be considered to have voluntarily resigned Membership and/or Privileges.

5.11 Advanced Practice Professionals

- 5.11.1 Advanced Practice Professionals (APPs) are non-physicians who provide a service to physicians in the area of their expertise. Advanced Practice Professionals are defined by the Adventist Health System Verification Methods Document.
- 5.11.2 APPs afforded an opportunity to provide patient services at the Hospital shall do so subject to these Bylaws, the Rules and Regulations, and in accordance with those policies, procedures and rules of the Hospital concerning the delivery of patient care generally and the delivery of care by APPs specifically.
- 5.11.3 Permission to provide patient care within their scope of practice – All decisions with regard to granting, suspending, terminating, discontinuing, reducing, or denying permission of APPs shall be at the sole discretion of the Board of Directors.

5.12 Practitioners Under Hospital Contract

A Practitioner providing patient care services in the Hospital pursuant to a contract with the Hospital must be a Member of the Medical Staff. He must also fulfill all of the obligations of his Medical Staff category unless expressly exempted by the Board. The effect of expiration or termination of a patient care services contract upon a Practitioner's Medical Staff Appointment or Clinical Privileges and any entitlement to procedural rights pursuant to these Bylaws shall be governed by the terms of the contract. If the contract is silent on the matter, then expiration or termination of the contract shall not affect the Practitioner's Appointment or Clinical Privileges, unless:

- 5.12.1 The circumstances of such termination are such that Practitioner's Appointment or Clinical Privileges are affected because of other provisions of these Bylaws and/or the Rules and Regulations; or

5.12.2 The Hospital has entered into other contractual arrangements with another Practitioner pursuant to Section 6.4 of these Bylaws.

5.13 Telemedicine

Telemedicine involves the use of electronic communication from one site to another for the health and education of the patient or health care provider and for the purpose of improving patient care, treatment, and services. Clinical privileges shall be granted to qualified Practitioners to diagnose and treat patients via a telemedicine link as set forth herein. Practitioner's whose involvement with the Hospital is limited to the diagnosis and treatment of patients via telemedicine link will not be Members of the Medical Staff in any category. Applicants for telemedicine privileges shall follow the procedures for the granting of Clinical Privileges as set forth in these Bylaws. It shall be permissible for the Medical Staff to utilize credentialing information from another Joint Commission accredited entity when granting the requested telemedicine privileges.

6.0 APPOINTMENT, REAPPOINTMENT AND CLINICAL PRIVILEGES

6.1 General Information

- 6.1.1 A complete credentialing Application must be submitted by all Applicants for Medical Staff Membership and/or Clinical Privileges.
- 6.1.2 Appointment and Reappointment to Membership on the Medical Staff is a privilege, is made in accordance with these Bylaws and the Rules and Regulations. The Board of Directors shall make all Appointments and Reappointments to the Medical Staff only after the Medical Executive Committee has reviewed an Applicant's eligibility for Membership and provided a recommendation to the Board of Directors. The Board of Directors is responsible for granting, denying, revoking or taking other actions regarding Medical Staff Membership at the Hospital.
- 6.1.3 No person shall have or exercise Clinical Privileges in the Hospital, other than Temporary Privileges, unless he has been granted Clinical Privileges by the Board of Directors. A person granted Clinical Privileges shall only hold and exercise those privileges granted to him pursuant to these Bylaws.
- 6.1.4 An Individual may be granted Membership or Privileges in a Department that is operated pursuant to a contract, which provides for the exclusive provision of services in the Department only if the individual is associated with the group providing that service.
- 6.1.5 No Applicant shall be denied Membership or Privileges on the basis of sex, race, religion, color, national origin, or any other basis prohibited by law.
- 6.1.6 Applications for Appointment, Reappointment and Clinical Privileges shall be made in accordance with the procedures and requirements set forth in the Medical Staff Rules and Regulations.

6.2 Applicant's Responsibility

- 6.2.1 Each Applicant shall be solely responsible for providing a Complete Application, including any additional documents and information which may be requested. Failure of the Applicant, without good cause, to provide a Complete Application in accordance with the Rules and Regulations of the Medical Staff, including any and all additional documents and information requested, no later than forty-five (45) days after initial receipt of the Application in the Medical Staff office, shall cause the Application to become void and further processing shall be discontinued.
- 6.2.2 Falsifying or withholding information in connection with an Application shall void an Application for Appointment, Reappointment or Clinical Privileges, and may provide grounds for termination of Medical Staff Membership and Clinical Privileges.
- 6.2.3 Effect of Withdrawal of Application
 - 6.2.3.1 A Practitioner who withdraws an application for appointment or reappointment, or amends or withdraws a written request for Clinical Privileges, after the application or request has been presented to the Medical Executive Committee but prior to a final decision by the Board of Directors, may not resubmit such application or request for a period of one (1) year from the date of the withdrawal. At the discretion of the President of the Medical Staff and Chief Executive Officer or their designees, this requirement may be waived.

6.2.3.2 If the withdrawal occurred prior to a final decision by the Board of Directors but after being afforded a hearing as set forth in Article 10, the Practitioner may not resubmit such application or request for a period of three (3) years from the date of the withdrawal.

6.2.4 Failure to Process Application. If an application was closed or not processed due to failure of the applicant to provide requested or required information within the timeframe allotted, the Practitioner is not eligible to submit another application for a period of one (1) year following the date of withdrawal from processing. At the discretion of the President of the Medical Staff and Chief Executive Officer or their designees, this requirement may be waived.

6.3 Period of Appointment, Reappointment and Clinical Privileges

6.3.1 Each period of Appointment, Reappointment and Clinical Privileges may be for any period of time not to exceed twenty-four (24) months.

6.4 Hospital Needs and Resources

The Board may decline to accept or have the Medical Staff review Applications for particular Appointment, Reappointment and/or Clinical Privileges on the basis of:

6.4.1 The Hospital's present inability to provide adequate facilities or support services for the Applicant and his patients or requirements or limitations in the Hospital's Medical Staff development plan; or

6.4.2 Existence of a contractual or other arrangement for the provision by Practitioners of professional services of the Hospital-based Physicians of the type being requested which precludes affording particular Clinical Privileges to the Practitioner.

Refusal to accept or review an Applicant's request pursuant to this section shall not constitute a denial of Clinical Privileges and shall not entitle the Applicant to any rights of review. Any portion of the Application which is accepted (e.g., requests for Clinical Privileges that are not subject to a limitation imposed pursuant to this section) shall be processed in accord with these Bylaws.

6.5 Waiver of Requirements

The Board of Directors, following consultation with the Medical Executive Committee, may waive a qualification for Medical Staff membership, Clinical Privileges, and/or a Staff category, but only on a finding that the waiver is in the best interests of the Hospital and the community it serves. Failure to waive a requirement for a particular Practitioner does not entitle the Practitioner to any procedural rights of review under these Bylaws or otherwise.

6.6 Medical Staff Membership or Clinical Privileges Following an Adverse Determination

If a Practitioner has been subject to an Adverse Recommendation or Action as a final decision of the Board of Directors regarding an application for appointment or reappointment, a request for Clinical Privileges, or Corrective Action, resulting in denial or termination of Medical Staff membership and/or all of some Clinical Privileges, the Practitioner may not reapply for a period of five (5) years following the date of the final decision. To be eligible to submit another Application, an Applicant must state, as part of his request for an Application, the basis for the previous adverse determination and why the basis for the decision no longer exists.

6.7 Clinical Privileges

A Practitioner shall exercise only those Clinical Privileges, other than Temporary Privileges, specifically granted to him by the Board of Directors. Privileges granted shall be:

- 6.7.1 Within the scope of the Practitioner's license;
- 6.7.2 In accordance with the requirements of the Joint Commission and/or other accreditation bodies; and
- 6.7.3 In accordance with the requirements of these Bylaws and the Rules and Regulations.

6.8 Application for Clinical Privileges

- 6.8.1 A completed credentialing Application must accompany all Requests for Clinical Privileges. This Application may be combined with an Application for Membership, or submitted without an Application for Membership. The Application for Clinical Privileges is not complete unless the Clinical Privileges requested by the Applicant have been clearly indicated on the Request for Clinical Privileges form(s) and all supporting documents regarding relevant training and experience have been provided.
- 6.8.2 The evaluation of an Applicant's Request for Clinical Privileges, and the granting of Clinical Privileges, shall be based upon an Applicant's education, training, experience, judgment, mental and physical health, demonstrated current clinical competence, peer recommendations, performance improvement and utilization reviews, status of licensure or registration, status of Medical Staff Membership and Clinical Privileges at other health care facilities, and all other information regarding the Applicant's ability to provide quality patient care. Each Applicant shall be responsible for demonstrating his current clinical competence and other qualifications for the Clinical Privileges requested.
- 6.8.3 Requests for Clinical Privileges shall be evaluated and processed in the same manner as Applications for Appointment and Applications for Reappointment.
- 6.8.4 A Medical Staff Member may apply for additional Clinical Privileges at any time. Evaluation and review of such a request shall be evaluated and processed in the same manner as an Application for initial Appointment. The request must be supported by documents regarding additional training and/or experience to justify such request.

6.9 Clinical Privileges for Dentists and Podiatrists

- 6.9.1 Requests for Clinical Privileges

Requests for Clinical Privileges for dentists and podiatrists shall be evaluated and processed in the same manner as Requests for Clinical Privileges for Physicians.
- 6.9.2 The following also applies to the granting of surgical privileges to dentists and podiatrists:
 - 6.9.2.1 Oral surgeons shall have completed a residency program in Oral and Maxillofacial Surgery approved by the American Board of Oral and Maxillofacial Surgery.
 - 6.9.2.2 General dentists shall have completed an Advanced Dental Education Program accredited by the Commission on Dental Accreditation; and
 - 6.9.2.3 Podiatrists shall have completed a residency program approved by the Council

of Podiatric Medical Education.

6.9.3 Each dentist and podiatrist shall be responsible for demonstrating his current clinical competence and other qualifications for the Clinical Privileges requested.

6.10 Clinical Privileges for Advanced Practice Professionals (APP)

6.10.1 Requests for Clinical Privileges for Advanced Practice Professionals shall be evaluated and processed in the same manner as Requests for Clinical Privileges for Physicians with the exception of the following:

6.10.1.1 Drug screen is required on all initial APP applicants;

6.10.1.1.1 Applicant is required to present for a drug screen once requested to do so. If there is reasonable suspicion the applicant or current APP is impaired, he may be drug tested.

6.10.1.1.2 The following are prohibited actions which will result in withdrawal of application and/or voluntary resignation and ineligibility to reapply to Texas Health Huguley for six (6) months:

6.10.1.1.2.1 The illegal use of drugs confirmed by a positive drug test result;

6.10.1.1.2.1.1 If the drug screen comes back confirmed positive for any unauthorized drug (drug for which there is no valid prescription by a medical provider) the application will be considered withdrawn if the applicant is unable to provide an authorized/valid prescription by a medical provider for the identified drug within twenty-four (24) hours;

6.10.1.1.2.1.2 If the drug screen comes back confirmed positive on a current APP for any unauthorized drug (drug for which there is no valid prescription by a medical provider) the APP will be an immediate voluntary resignation if the APP is unable to provide an authorized/valid prescription by a medical provider for the identified drug within twenty-four (24) hours.

6.10.1.1.2.2 Illegal possession, sale, exchange or distribution of drugs on AdventHealth facility premises;

6.10.1.1.2.3 Switching, degrading, diluting, adulterating or attempting to tamper with any sample submitted for a drug or alcohol test, or otherwise interfering or attempting to interfere with the testing process;

6.10.1.1.2.4 The use of alcohol or the possession, transportation and/or distribution with the apparent intent to consume alcohol while on facility property, or sale

of alcohol or intoxicating beverages while on facility property;

- 6.10.1.1.2.5 A positive alcohol test equal to or greater than .04 Blood Alcohol Content as tested in an APP's urine, blood or breath;
- 6.10.1.1.2.6 Refusal to consent or submit to a test for the current illegal use of drugs, controlled substances or alcohol;
- 6.10.1.1.2.7 Refusal by any applicant or APP to release test results to the facility;
- 6.10.1.1.2.8 Refusal by an applicant or current APP to submit to a drug test immediately upon request.

6.10.1.2 Interview with the CMO is not required but may be requested.

6.10.2 Advanced Practice Professionals are eligible to apply for Privileges defined specifically for their education, degree and certification.

6.10.3 Advanced Practice Professionals are not eligible to apply for Membership on the Medical Staff.

6.11 Fair Hearing and Appeal for APPs

6.11.1 APPs are not entitled to the hearing and appeals procedures set forth in the medical staff bylaws. In the event one of these APPs receives notice of a recommendation by the Medical Executive Committee that will adversely affect the APP's exercise of clinical privileges, the APP and the APP's supervising physician, if applicable, shall have the right to meet personally with two physicians and a peer assigned by the President of the Medical Staff to discuss the recommendation. The APP and the collaborating/supervising physician, if applicable, must request such a meeting in writing to the CEO within ten (10) business days from the date of receipt of such notice. At the meeting, the APP and the collaborating/supervising physician, if applicable, must be present to discuss, explain, or refute the recommendation, but such meeting shall not constitute a hearing and none of the procedural rules set forth in the medical staff bylaws with respect to hearings shall apply. Findings from this review body will be forwarded to the affected APP, the MEC and the Board of Directors.

6.11.2 The APP and the collaborating/supervising physician, if applicable, may request an appeal in writing to the CEO within ten (10) days of receipt of the findings of the review body. Two members of the Board of Directors assigned by the chair of the Board of Directors shall hear the appeal from the APP and the collaborating/supervising physician. A representative from the Medical Staff leadership may be present. The decision of the appeal body will be forwarded to the Board of Directors for final decision. The APP and the collaborating/supervising physician will be notified within ten (10) days of the final decision of the Board of Directors. If the decision is adverse to the APP, the APP will not be allowed to reapply for privileges for five (5) years.

6.12 Temporary Privileges

6.12.1 The Chief Executive Officer, or his designee, upon the recommendation of the President of the Medical Staff, the Chair of the Credentials Committee and the appropriate

Department Chair, may grant Temporary Privileges to a qualified Applicant. The Department Chair shall remain responsible for the supervision of an Applicant granted Temporary Privileges.

- 6.12.2 An Applicant's request for Temporary Privileges may be granted only when there is an important patient care, treatment or service need. In these circumstances, there must be verification of, at a minimum, current licensure, professional liability insurance, current competence relevant training or experience, and NPDB query before Temporary Privileges are granted. The Temporary Privileges expire when the patient care, treatment or service need no longer exists.
- 6.12.3 Temporary Privileges shall be granted infrequently and for a period not to exceed one hundred twenty (120) days, not to exceed the pendency of the Application process. Temporary Privileges granted concurrently with a pending Application automatically expire when the Board of Directors either denies or grants the Applicant's Application and Request for Clinical Privileges.
- 6.12.4 Temporary Disaster Privileges may be granted to Physicians or Allied Health Professionals who do not possess Clinical Privileges but may be needed at the Hospital during an emergency (defined as any officially declared emergency, whether it is local, state, or national). The Hospital's Emergency Preparedness Plan must be activated for these privileges to take effect. The Hospital will ensure that the Chief Executive Officer and President of the Medical Staff or their designee(s), during an emergency/disaster, can rapidly credential Physicians and Allied Health Professionals utilizing the Medical Staff policy regarding Credentialing of Physicians and/or Allied Health Professionals in the event of a disaster.
 - 6.12.4.1 Physicians or Allied Health Professionals granted disaster privileges shall be paired with a Practitioner or Hospital Staff member who has appropriate training and experience to make reasonable judgements regarding the clinical competence of the person granted Temporary Disaster Privileges. Practitioners or Hospital Staff members who are paired with the Physicians or Allied Health Professionals shall immediately report any concern regarding the Physician or Allied Health Professional's competence to the President of the Medical Staff, Chief Executive Officer or their designee(s).
 - 6.12.4.2 The Physician or Allied Health Professional's Temporary Disaster Privileges shall be terminated in the event that any information received through the verification process indicates any adverse information or suggests the person may not be capable or qualified to render services. Termination of the Physician or Allied Health Professional's privileges does not entitle the Physician or Allied Health Professional to request a hearing or other due process.
 - 6.12.4.3 When the emergency/disaster situation is under control and/or no longer exists, the Temporary Disaster Privileges granted shall immediately terminate.
- 6.12.5 Locum Tenens are Physicians, Dentists or Podiatrists who temporarily provide an important patient care, treatment or service need, but with sufficient advance notice to allow completion of the credentialing process. Locum Tenens must go through the same credentialing process as other Applicants for Clinical Privileges, but will not be Members of the Medical Staff in any Category.

- 6.12.6 Imposition of special requirements, restrictions on Temporary Privileges, failure to grant Temporary Privileges, failure to grant an extension of Temporary Privileges, or expiration of Temporary Privileges are not considered final Professional Review Actions and do not entitle the Practitioner to any procedural rights of review.

6.13 Special Limited Privileges

6.13.1 Under certain circumstances, Physicians who are neither Applicants for Medical Staff Membership nor Members of the Medical Staff may be granted special limited privileges. Such circumstances may include, but are not limited to, consulting in the care of a medical patient, demonstrating special medical or surgical techniques and/or providing other education or training for Practitioners. However, such Clinical Privileges shall be available only to Physicians who will provide expertise not readily available from the Medical Staff Membership or who have an existing Physician-patient relationship with the patient regarding whom the privileges are requested. For special limited privileges a Medical Staff Member (Sponsor) must submit a written request to the Medical Executive Committee for another licensed Physician to visit the Hospital for the exclusive purpose of demonstrating such special limited privileges to Medical Staff Members. The Member submitting the request shall include justification in support of his request. For consultative privileges, a Medical Staff Member must submit a written request which identifies the patient and the consultant for whom privileges are requested. Special Limited Privileges shall be granted for a period not to exceed 14 days.

6.13.2 Upon a determination by the Medical Executive Committee that such a procedure is needed in the Hospital, the Committee shall, in cooperation with Hospital administration, endeavor to select an appropriate Physician who is willing to instruct the Medical Staff in the selected procedure(s). The Physician specifically requested by the Member or selected by the Medical Executive Committee must be recognized as an expert in performing that procedure.

6.13.3 The visiting Physician must submit the following documentation:

6.13.3.1 Complete curriculum vitae, including training and publications, as well as past and current positions;

6.13.3.2 License to practice medicine in Texas or approval by the Texas Medical Board;

6.13.3.3 Current certificates or permits to prescribe issued by the United States Drug Enforcement Agency (DEA) and the appropriate state agency, unless the consultant, by the nature of their practice, does not prescribe;

6.13.3.4 Professional liability insurance at that level required by the Hospital;

6.13.3.5 A fully positive reference specific to the privileges requested from a Medical Staff Officer or Department Chair at the consultant's primary hospital affiliation who is personally familiar with the consultant's expertise in the Clinical Privileges requested; and

6.13.3.6 Such other documentation as may be requested.

The visiting Physician shall be provided with a complete copy of the Medical Staff Bylaws and the Rules and Regulations, and shall, by exercising special limited privileges pursuant to this Section, abide by and be subject to these Bylaws, the Rules and Regulations, and the policies and procedures of the Hospital.

6.13.4 When appropriate documentation has been received and verified by the Medical Staff

Office, temporary privileges may be granted. Clinical privileges granted under this section shall automatically terminate upon the discharge of the patient(s) for whom the privileges were granted or upon the completion of the educational or training program for which the privileges were granted.

6.13.5 The Sponsor shall be responsible for the performance of the visiting Physician and shall intervene immediately should intervention be judged to be in the best interest of the patient. The Sponsor shall immediately notify the Medical Staff office of any competency or behavioral problems and, in such case, the privileges shall be revoked. Such Clinical Privileges may be revoked with prior notice by any two of the following:

6.13.5.1 The President/CEO of the Hospital (or designee);

6.13.5.2 The President of the Medical Staff (or other Medical Staff officer);

6.13.5.3 The Chair of the Credentials Committee;

6.13.5.4 The Chair of the appropriate Department (or Vice Chair).

Such revocation shall not entitle the visiting Physician to a hearing or other due process described in Article 10 of the Bylaws.

6.13.6 The purpose of this provision is to bring acknowledged clinical expertise to the Hospital for the benefit of instructing the Medical Staff, under the circumstances described herein. Accordingly, it is anticipated that special limited privileges shall only be granted infrequently.

6.14 Emergency Privileges

In a medical emergency, any Practitioner shall be permitted, and shall be assisted by Hospital personnel, to do everything possible to save the life of a patient, or to save the patient from serious harm, to the degree permitted by his license, even if in so doing he may engage in actions beyond the scope of his Clinical Privileges. In so acting, the Practitioner is obligated to summon all available consultative assistance deemed necessary. Emergency privileges terminate automatically on termination of the emergency and do not entitle the Member to any procedural rights of review as a result of termination of the emergency privileges or failure to continue the privileges upon request.

6.15 Request for Change in Clinical Privileges

A Member may submit an Application requesting to change his Clinical Privileges. Such request shall be processed in the same manner as an Application for Clinical Privileges.

6.16 Resignation

The resignation of any Medical Staff Member and/or Practitioner shall become effective on the date agreed upon by the Board of Directors. Resignation shall not relieve the Member and/or Practitioner of the responsibility of completion of medical records as required by the Rules and Regulations. Following a resignation, any Medical Staff Member and/or Practitioner who subsequently desires Membership on the Medical Staff and/or Clinical Privileges shall reapply as an initial Applicant. Prior to the Applicant receiving a request for Application, the Applicant will be required to complete his previous medical records.

7.0 CORRECTIVE ACTIONS, SUMMARY SUSPENSIONS AND AUTOMATIC SUSPENSIONS

7.1 Routine Corrective Actions

Corrective Action against any Practitioner may be imposed whenever the conduct of any Practitioner is considered to be:

- 7.1.1 Lower than the standards of the Medical Staff or Board;
- 7.1.2 Disruptive to the operations of the Hospital or the delivery of patient care;
- 7.1.3 In violation of state or federal law;
- 7.1.4 Detrimental to the quality of patient care at the Hospital;
- 7.1.5 Detrimental to the Hospital's licensure, accreditation or the Hospital's status under any governmental health program;
- 7.1.6 Detrimental to Hospital or Medical Staff efforts to comply with any professional review organization, or utilization review requirements; or
- 7.1.7 In violation of these Bylaws, the Rules and Regulations, or any policies or requirements of the Board, Hospital or Medical Staff or any Department or Committee.

7.2 Summary Suspensions and Emergency Corrective Actions

- 7.2.1 If the conduct of any Practitioner warrants immediate action to prevent imminent danger to the health of patients, employees, or others in the Hospital, or disruption of the orderly operation of the Hospital; or if the Practitioner violates the Bylaws or Rules and Regulations or any other Department or Hospital policy, Emergency Corrective Action may be taken against such Practitioner. Emergency Corrective Action under this section may include summarily suspending all or any portion of such Practitioner's Clinical Privileges, imposition of mandatory consultation requirements, co-admitting requirements, proctoring, supervision requirements or any other action deemed necessary by those individuals having authority to institute an Emergency Corrective Action.
- 7.2.2 The President of the Medical Staff or the person acting in such capacity at the time and the Chief Executive Officer or his designee, acting together, are authorized to impose Emergency Corrective Actions, including summary suspensions of a Practitioner's Clinical Privileges. Emergency Corrective Actions shall be effective immediately. The President of the Medical Staff shall provide the Practitioner with prompt Written Notice of the Emergency Corrective Action in accordance with Section 9.0 and Section 10.0 of these Bylaws. At the time of the Emergency Corrective Action, the chair of the Department to which the affected Practitioner belongs shall assist in the implementation of such action, including assigning the care of a Practitioner's patients in the Hospital to another Practitioner, competent to care for those patients if a summary suspension is imposed.
- 7.2.3 In the case of an Emergency Corrective Action which does not last for a period not longer than thirty (30) days, during which an investigation is being conducted to determine the need for a Professional Review Action, the procedures of Section 10.0 shall not apply. This rule shall apply even when an Ad Hoc Committee is appointed pursuant to Section 8.0 of these Bylaws to investigate the facts to determine whether a Professional Review Action is warranted.

7.3 Automatic Suspensions

- 7.3.1 The Clinical Privileges of any Practitioner shall be automatically and immediately suspended for any one of the following reasons:
- 7.3.1.1 A Practitioner's license to practice is revoked, suspended, voluntarily surrendered or if the Practitioner fails to maintain current licensure.
 - 7.3.1.2 A Practitioner's DEA Certificate is revoked, limited or voluntarily surrendered, unless the Practitioner's privileges do not require maintenance of a DEA Certificate.
 - 7.3.1.3 A Practitioner fails to maintain professional liability insurance in the amount required by the Board of Directors.
 - 7.3.1.4 A Practitioner fails to complete medical records in accordance with requirements and time limits set forth in the Rules and Regulations.
 - 7.3.1.5 A Practitioner fails to provide within thirty (30) days of date of written request the Medical Staff office or designee with any documentation which may be requested in order to maintain complete and current files on all Medical Staff Members and/or Practitioners or fails to comply with any other reasonable request.
 - 7.3.1.6 A Practitioner fails to comply with the requirements imposed on the Hospital or Practitioners by any governmental accreditation body or agency.
 - 7.3.1.7 A Practitioner is convicted of a felony.
- 7.3.2 A Practitioner shall not be entitled to any procedural rights of review for any automatic suspension under this section.
- 7.3.3 The President of the Medical Staff shall notify the Physician by Written Notice, which would include fax or letter, that his privileges are automatically suspended. The Practitioner's Clinical Privileges will not be reinstated until verification has been received of current credentials. If proof of current credentials cannot be verified within thirty (30) days of their automatic suspension, their privileges will be voluntarily and permanently relinquished. Any delinquencies must be current before a Medical Staff Member will be allowed to reapply and they must do so as an initial Applicant.

7.4 Voluntary Agreement

- 7.4.1 Grounds. Whenever the activities or professional conduct of any Practitioner are of such concern that, in the assessment of the President of the Medical Staff or designee, further evaluation of the activities or professional conduct is necessary, the Hospital CEO or CMO, together with the President of the Medical Staff or designee, may ask the Practitioner to voluntarily refrain from utilizing all or certain Clinical Privileges for an agreed period of time while further evaluation is performed and a decision is made whether further action is indicated (such as initiation of an Investigation for purposes of possible Corrective Action). This action is taken in the course of the Medical Peer Review process.
- 7.4.2 Not Corrective Action. A voluntary agreement pursuant to this section is not a surrender or suspension of Clinical Privileges, is not considered Corrective Action, and may be

terminated by the Practitioner at any time on the giving of at least three days prior written notice to the Hospital President or President of the Medical Staff or their designees. Nothing in this section prohibits a Practitioner from renewing a voluntary agreement one or more times with the agreement of the Hospital President and/or President of the Medical Staff.

8.0 INVESTIGATIONS

8.1 Request for Investigation

- 8.1.1 Any person who reasonably believes a basis for an investigation exists because of concerns regarding quality of patient care, or the conduct of a Member or Practitioner ("Subject"), may request an investigation. The request shall be directed to the Chief Executive Officer or the President of the Medical Staff.
- 8.1.2 Nothing hereunder shall be interpreted as providing an entitlement or right on the behalf of any Subject to the procedures set-forth under this Section 8.0. The procedures set out in this Section 8.0 are for the benefit of the Hospital and Medical Staff in general and to be used at their discretion to investigate a complaint as described in Section 8.1.1.

8.2 Ad Hoc Committee

- 8.2.1 The President of the Medical Staff, in consultation with the Chief Executive Officer, shall establish an Ad Hoc Committee to investigate any matter, which they determine requires an investigation.
- 8.2.2 Procedures for Ad Hoc Committee Investigation
 - 8.2.2.1 When an investigation is warranted pursuant to Section 8.0 of the Bylaws, the Chief Executive Officer and the President of the Medical Staff shall select the chair and other Members of the Ad Hoc Committee no later than ten (10) days following receipt of a request for an investigation. The Committee shall include three (3) Medical Staff Members in the Active category. At least one (1) of the three (3) Medical Staff Members selected for the Ad Hoc Committee shall be a Member of the Department to which the Subject belongs. The Directors of Case Management, Risk Management and/or Quality or his designee(s) shall be available to the Committee for consultation. The Ad Hoc Committee shall commence its investigation no later than seven (7) days after being appointed.
 - 8.2.2.2 As part of the investigation, the Ad Hoc Committee shall meet with the Subject. The chair of the Ad Hoc Committee shall request in writing that the Subject meet with the Ad Hoc Committee. The Subject shall confirm in writing his intent to meet with the Committee at the time specified in the notice no later than five (5) working days after receipt of the request from the chair of the Committee. If the Subject does not respond in writing within such five- (5) day period, he shall be deemed to have waived his opportunity to meet with the Ad Hoc Committee.
 - 8.2.2.3 The meeting of the Ad Hoc Committee and the Subject shall be informal. The purpose of the meeting is to enable the Ad Hoc Committee to gather information and give the Subject an opportunity to provide information to the Ad Hoc Committee. Neither the Subject nor the Ad Hoc Committee shall be entitled to representation by an attorney or any other person at the meeting. The Ad Hoc Committee may have a record of the meeting made by the Director of Medical Staff Services or his designee. The Subject shall not be entitled to a copy of the record, if a copy is made.

8.2.2.4 No later than thirty (30) days following its Appointment, the Ad Hoc Committee shall conclude its investigation and forward a written report regarding its investigation, including all documentation, to the Credentials Committee.

8.3 Credentials Committee

8.3.1 At its next meeting following receipt of a written report from an Ad Hoc Committee as provided for in Section 8.2.2, the Credentials Committee shall review and consider the Ad Hoc Committee's Report and all other supporting documents. During its deliberations at that meeting or subsequent meeting, the Credentials Committee may consider outside consultation.

8.3.2 No later than fourteen (14) days following the completion of its deliberation, the Credentials Committee shall forward its report and recommendation(s) to the Medical Executive Committee. If the Credentials Committee recommends that a Professional Review Action be taken and the Medical Executive Committee approves the recommendation, the President of the Medical Staff shall promptly provide Written Notice thereof to the Subject in accordance with Section 9.0 and Section 10.0 of these Bylaws.

9.0 PROFESSIONAL REVIEW ACTIONS

9.1 Medical Executive Committee's Initiation of Professional Review Actions

- 9.1.1 Professional Review Actions may be initiated by the Medical Executive Committee as a result of matters presented for review and consideration from the Credentials Committee, including recommendations that a Professional Review Action be instituted, or as a result of matters brought to the Medical Executive Committee directly.
- 9.1.2 At its next meeting following receipt of information pertaining to a matter involving a potential Professional Review Action including receipt of a recommendation from the Credentials Committee, the Medical Executive Committee shall consider such proposed Professional Review Action including any recommendations of the Credentials Committee and any supporting documents. The Medical Executive Committee shall forward its findings and recommendation(s) to the Board of Directors within a reasonable period of time after considering the potential Professional Review Action.
- 9.1.3 If the Medical Executive Committee recommends that a Professional Review Action be taken in connection with a matter and involves grounds which would entitle a Member or Practitioner ("Subject") to a hearing, the Subject shall be entitled to the procedures described in Section 10.0. The President of the Medical Staff shall provide Written Notice to the Subject of the proposed Professional Review Action to be taken. The notice shall describe the procedures available to the Subject pursuant to Section 10.0. When a hearing is held after the Medical Executive Committee has recommended that a Professional Review Action be taken, the hearing panel shall forward its findings and recommendations to the Board of Directors. The Hearing Panel shall provide notice of its recommendation to the Medical Executive Committee.
- 9.1.4 The Board of Directors shall, at its next meeting after receipt of the findings and recommendations regarding a proposed Professional Review Action, review and consider the proposed Professional Review Action. If a hearing had been held in connection with the recommendation(s), the Board of Directors shall consider the findings and recommendation(s) of the Hearing Panel. Any decision of the Board of Directors regarding a proposed Professional Review Action shall be final.
- 9.1.5 The Board of Directors shall notify the President of the Medical Staff of its final decision promptly following the meeting at which the decision was made. The President of the Medical Staff shall notify the Subject no later than fourteen (14) days after the meeting. If the action taken by the Board of Directors adversely affects the Membership and/or Privileges of the Practitioner, the notice shall describe the action and the basis for the action.

9.2 Board of Directors' Initiation of Professional Review Actions

- 9.2.1 Professional Review Actions may be initiated by the Board of Directors as a result of matters presented for review and consideration from the Medical Executive Committee, including recommendations that a Professional Review Action be instituted, or as a result of matters brought to the Board of Directors directly.

9.2.2 If the Board of Directors recommends that a Professional Review Action be taken and the Medical Executive Committee had not previously recommended that a Professional Review Action be taken and the Professional Review Action may involve grounds which would entitle a Member or Practitioner to a hearing, the Subject shall be entitled to the procedures provided in Section 10.0. The Board of Directors shall promptly notify the President of the Medical Staff of its recommendation, and the President of the Medical Staff shall notify the Subject of the Board's recommendation and of the procedures available to the Subject pursuant to Section 10.0. The President of the Medical Staff shall also inform the Medical Executive Committee of the recommendation of the Board of Directors. If a hearing is held, the Hearing Panel shall provide its findings and recommendations to the Board of Directors. The determination of the Board of Directors in the matter shall be final either at the time of its initial recommendation if no hearing occurs or at the time the Board reconsiders the matter following receipt of the Hearing Panel's findings and recommendations.

9.3 Entitlement to Procedural Rights of Review

9.3.1 General. A Practitioner is entitled to the procedural rights of review set out below whenever:

9.3.1.1 The Medical Executive Committee takes an Adverse Recommendation or Action;

9.3.1.2 An Adverse Recommendation or Action is taken by the Board of Directors following a recommendation or action by the Medical Executive Committee that was not an Adverse Recommendation or Action; or

9.3.1.3 An Adverse Recommendation or Action is taken by the Board of Directors after failure of the Medical Executive Committee to act on an application for appointment or reappointment or a request for Corrective Action.

No other recommendations or actions shall entitle the Practitioner to a hearing.

9.3.2 Adverse Recommendation or Action Defined (Grounds for Procedural Rights of Review). Subject to the provisions in Section 9.3.3 or as otherwise provided in these Bylaws, only the following actions or recommendations when taken provided in Section 9.3.1 constitute an Adverse Recommendation or Action entitling a Practitioner to procedural rights of review under these Bylaws:

9.3.2.1 Denial of appointment to the Medical Staff;

9.3.2.2 Denial of reappointment to the Medical Staff;

9.3.2.3 Termination or revocation of appointment to the Medical Staff;

9.3.2.4 Denial of requested Clinical Privileges;

9.3.2.5 Termination or revocation of Clinical Privileges;

9.3.2.6 Suspension of Clinical Privileges, other than a temporary action pursuant to Article 7.3;

- 9.3.2.7 An observation or proctor requirement if the observer or proctor's approval is required for the Practitioner to exercise Clinical Privileges, or a proctor or supervisor requirement if the proctor or supervisor is required to be present or approve for the practitioner to exercise Clinical Privileges for more than 30 days based on competence or professional conduct;
 - 9.3.2.8 An education, training, evaluation, or counseling requirement that must be satisfied prior to exercising Clinical Privileges;
 - 9.3.2.9 A mandatory concurring consultation or supervision requirement (i.e., the consultant or supervisor must concur or approve the Practitioner's course of treatment before the Practitioner may exercise Clinical Privileges); or
 - 9.3.2.10 Any other restriction or limitation of Clinical Privileges based on competence or professional conduct if such action, when final, would be reportable to the National Practitioner Data Bank.
- 9.3.3 Not Grounds for Procedural Rights of Review. None of the following recommendations or actions, nor any others so referenced in the Bylaws, shall constitute an Adverse Recommendation or Action or entitle the Practitioner to the procedural rights of review in these Bylaws or otherwise. The Practitioner is entitled to submit a written explanation or rebuttal regarding the recommendation or action which shall be placed in the Practitioner's file.
- 9.3.3.1 Issuance of a letter of reprimand or admonition, placement on probation, or any other Corrective Action that is not accompanied by any limitation or restriction on the Practitioner's Clinical Privileges;
 - 9.3.3.2 Imposition of any conditions or other requirements, including without limitation proctoring or mandatory consultation, in the course of FPPE on an initial grant of Clinical Privileges;
 - 9.3.3.3 Any limitation, requirement, or restriction of Clinical Privileges imposed equally on all Practitioners with the same or similar Clinical Privileges;
 - 9.3.3.4 Imposition of an observation, proctoring, supervision, or consultation requirement (e.g., observation of the Practitioner's performance by a peer in order to provide information to a Medical Staff committee), but that does not require the observer, proctor, supervisor, or consultant's presence, approval or concurrence prior to the Practitioner's exercise of Clinical Privileges or that does not apply to every exercise of Clinical Privileges;
 - 9.3.3.5 Any requirement to complete an educational assessment, or to verify required health status through requested assessment or testing in accordance with the Bylaws or Policy that may be satisfied while the Practitioner continues to exercise Clinical Privileges;
 - 9.3.3.6 Imposition of a requirement for additional education or training or for treatment or counseling that may be satisfied while the Practitioner continues to exercise Clinical Privileges;

- 9.3.3.7 Imposition of any action pursuant to Section ___ of these Bylaws or any recommendation or action that is voluntarily accepted by the Practitioner, including without limitation, entry into a voluntary performance improvement agreement or a voluntary agreement pursuant to Section 7.4;
- 9.3.3.8 Retrospective chart review, conducting a review or Investigation into any matter, or a requirement to appear for a special meeting under the provisions of these Bylaws;
- 9.3.3.9 Any automatic action, including without limitation, any action under Section 7.3, or automatic relinquishment of Clinical Privileges, automatic resignation from the Medical Staff, or automatic withdrawal of an application from processing otherwise provided for in these Bylaws;
- 9.3.3.10 Imposition of a temporary action under Section 7.2 or summary Corrective Action except as provided in Section 7.2;
- 9.3.3.11 Denial of a request for leave of absence or for an extension of a leave of absence;
- 9.3.3.12 A voluntary surrender or relinquishment of Clinical Privileges by the Practitioner, including voluntary acceptance of a limitation on Clinical Privileges, while under an Investigation or to avoid such an Investigation or a professional review action;
- 9.3.3.13 Failure to expedite an application, or failure to process an application for Medical Staff appointment, reappointment, and/or Clinical Privileges: (i) due to a determination that the application is not a Complete Application or is untimely, (ii) due to a determination that the Practitioner is not eligible due to a failure to meet minimum or threshold criteria or requirements, a lack of need or resources, closure of a specialty, or because of an exclusive professional services arrangement, or (iii) as otherwise authorized by the Bylaws;
- 9.3.3.14 Denial of a requested change in Staff category, or lack of eligibility for or transfer to a Staff category due to Patient Contacts or reassignment of Staff category at the time of reappointment as provided in Section 5.9;
- 9.3.3.15 Termination or automatic relinquishment of or inability to exercise Clinical Privileges due to an exclusive professional services arrangement of the Hospital;
- 9.3.3.16 Failure to grant, termination or limitation of temporary Clinical Privileges;
- 9.3.3.17 Removal or limitation of emergency services call coverage obligations;
- 9.3.3.18 Expiration of membership and privileges as a result of failure to submit an application for reappointment within the allowable time period under these Bylaws; and
- 9.3.3.19 Grant of conditional appointment or appointment or reappointment for a duration of less than 24 months.

10.0 HEARINGS

10.1 Fair Hearing Procedure in General

In no event shall a Member or Practitioner ("Subject") be entitled to more than one hearing or review on a matter. Once the procedures set forth in Section 10.0 have been provided (or waived), and the Board's decision is final, there shall be no further right of the Subject to any review, reconsideration or challenge of the decision.

10.2 Notice of Proposed Action and Right to Hearing

A Subject against whom a Professional Review Action is recommended or proposed shall be given Written Notice, by the Chief Executive Officer within a reasonable period of time. Such notice shall:

- 10.2.1 Advise the Subject that a Professional Review Action has been recommended, including a statement of the reasons for the proposed action and a listing of any patient records in issue;
- 10.2.2 Advise the Practitioner of his right to a hearing upon timely and proper request pursuant to Section 10.3;
- 10.2.3 State that failure to request a hearing within the time period and manner required in Section 10.3 shall constitute a waiver of any rights to a hearing, or any other review of the matter;
- 10.2.4 State that upon receipt of the Subject's request for a hearing in the manner specified in Section 10.3, the Chief Executive Officer will notify the Subject of the date, time and place of the hearing as provided in Section 10.5;
- 10.2.5 Include a copy of the Medical Staff Bylaws, referencing the rights set forth in this Section, and a summary of those rights.

10.3 Request for Hearing

The Subject shall have thirty (30) days after receiving a notice under Section 10.2 to file a written request for hearing. The request must be delivered to the Chief Executive Officer by Written Notice.

10.4 Waiver of Hearing

A Subject who fails to request a hearing within the time limit or in the manner specified in Section 10.3 waives his right to any hearing or further review to which he might otherwise have been entitled.

10.5 Notice of Hearing

Within forty-five (45) days after receipt of a request for a hearing in accord with Section 10.3, the Chief Executive Officer shall schedule and arrange for such a hearing and shall notify the Subject by Written Notice of the hearing. The hearing notice shall contain the following:

- 10.5.1 The date and time for the hearing, which shall not be less than thirty (30) days after the date of this notice of hearing which was sent to the Subject;
- 10.5.2 The place of the hearing;
- 10.5.3 A list of witnesses expected to testify at the hearing to support the Professional Review Action;
- 10.5.4 Notice to the Subject that, at least fifteen (15) days before the hearing, the Subject is required to forward to the Chief Executive Officer by Written Notice a list of witnesses the Practitioner expects to present to testify against the recommended Professional Review Action; and
- 10.5.5 The names and specialties of the individuals appointed as the Hearing Panel.

10.6 Supplemental Notice

If, after the Section 10.5 notice, there are further acts or omissions that support the need for the Professional Review Action, they may be included in a supplemental notice to the Subject provided there is reasonable notice of such information given in advance of the hearing. The hearing may be rescheduled at the discretion of the Hearing Panel or the Chief Executive Officer if necessary to afford a reasonable time to respond to the further acts or omissions that support the need for the Professional Review Action.

10.7 Witness Designation

- 10.7.1 The affected Subject shall, at least fifteen (15) days prior to the hearing date, advise the Chief Executive Officer, by Written Notice, of the names and addresses of those witnesses that the Subject expects to testify at the hearing.
- 10.7.2 Each witness list may be amended by Written Notice, to the other party as soon as possible when a change in witnesses is needed. The Presiding Officer appointed pursuant to Section 10.10 or the person acting as such shall have sole discretion to allow any newly identified witnesses in an amended witness list to testify.
- 10.7.3 Failure to identify a witness as required under Section 10.5 or 10.7 shall be grounds to refuse testimony from such witness, at the sole discretion of the Hearing Panel.

10.8 Documents and Other Discovery

Except as provided in this Section, there shall be no right of discovery prior to or during the hearing or any subsequent review. The Subject shall be provided with access during reasonable working hours to any patient records or other Hospital documents (except as qualified below) cited in the notices required under Sections 10.2, 10.5 or 10.6, or shall be permitted to copy such records and documents at the Subject's expense. The Subject shall not, however, be entitled to access, copy or discover in any manner any documents of any Hospital committee nor information concerning any proceedings of any Hospital committee.

The Medical Executive Committee will provide a copy of all documents/exhibits that will be presented in the hearing to the Subject at least fourteen (14) days prior to the hearing. The Subject must also present all documents/exhibits at least fourteen (14) days prior to the hearing.

10.9 Composition of the Hearing Panel or Hearing Officer

Promptly after a hearing has been properly requested, the Chief Executive Officer, shall appoint a Hearing Panel to act as the peer review committee in the hearing with one Member designated as Chair. If not enough Medical Staff Members meet the qualifications to serve on the Hearing Panel as listed below, Physicians who are not Members of the Medical Staff may serve. The Hearing Panel shall consist of at least three (3) Members who shall not be in direct economic competition with the affected Subject. Hearing Panel members may not have participated in the professional review action proceeding or any investigation. If a single member panel is selected, the person selected will be referred to as the Hearing Officer, and will not be a member of the Medical Staff and in such event all references in these Bylaws to "Hearing Panel" shall be deemed to refer instead to the Hearing Officer, unless the context would clearly otherwise require. The Subject shall be provided with Written Notice of the names and specialties of the Hearing Panel or the Hearing Officer and may file written objections with the Presiding Officer if they have an objection to the members of the Hearing Panel or the Hearing Officer. Written objections must be received by the Presiding Officer within 10 days of notice to the Subject of the Hearing Panel or Hearing Officer and the Presiding Officer shall rule on any objections. The Subject also may submit written questions to the Hearing Panel or Hearing Officer through the Presiding Officer if information is needed to file the objections.

10.10 Presiding Officer

10.10.1 The Chief Executive Officer, in his discretion, appoint a Presiding Officer (independent attorney) to conduct the hearing and rule on procedural matters. The Presiding Officer may be a member of the State Bar and should be familiar with the law applicable to hospital administrative proceedings. The Presiding Officer shall conduct the hearing such that the proceedings will be, to the extent reasonably possible, fair, efficient, and protective of the rights of all parties and witnesses. The Presiding Officer may act as advisor to the Hearing Panel but may not vote. If no Presiding Officer is appointed, the Chair of the Hearing Panel shall preside. The Presiding Officer may not have represented or advised the Medical Staff or the Hospital on the Professional Review Action. The Presiding Officer is responsible to conduct the proceedings consistent with the Medical Staff Bylaws.

10.10.2 The Subject shall be provided with Written Notice of the name of the Presiding Officer and the opportunity to object as under Section 10.9, with the Chief Executive Officer ruling on any objections.

10.11 Medical Staff or Board Representative

10.11.1 Promptly after a hearing has been properly requested, the President of the Medical Staff shall appoint a Medical Staff Member to act as the Medical Staff Representative to present the case on behalf of, and otherwise represent, the body whose decision prompted the hearing. If the hearing is the result of a Professional Review Action initiated by the Board (see Section 9.2), the Chair of the Board shall appoint an individual to act as the Board's representative for the hearing. For purposes of the remainder of this Article, "Representative" shall refer to the Medical Staff or Board representative appointed for the hearing.

- 10.11.2 The Hospital, through the Chief Executive Officer, will provide legal counsel to assist the Representative in preparing for and presenting at the hearing. The Subject shall be provided with Written Notice of the name of the Representative and legal counsel at least 30 days prior to the date of the hearing.

10.12 Hearing Procedure

- 10.12.1 Summary of Rights. The following is a summary of the rights of the Subject and the Representative as further detailed below:

10.12.1.1 Be present at the hearing;

10.12.1.2 Be represented by an attorney or another person of the party's choice;

10.12.1.3 Have the Hospital make a record of the hearing as provided in Section 10.12.3 below;

10.12.1.4 Call, examine and cross-examine witnesses on any matter relevant to the issues;

10.12.1.5 Present evidence determined to be relevant by the Presiding Officer, regardless of its admissibility in a court of law;

10.12.1.6 Submit a written statement at the close of the hearing as set out in Section 10.12.8 below;

10.12.1.7 Upon completion of the hearing, receive the written report of the Hearing Committee, including a statement of the basis of the recommendation; and

10.12.1.8 To receive the final written decision of the Board of Directors, including a statement of the basis for the decision.

10.12.2 Failure to Appear

The personal presence of the Subject is required throughout the hearing. Unless good cause is found, the failure of the affected Subject to appear at the hearing or to be personally present as required herein shall be deemed to constitute the Subject's voluntary acceptance of the recommendation or action involved and waiver of all rights to hearing. Good cause shall be determined by the Presiding Officer or, in the absence of a Presiding Officer, the CEO in consultation with the Chair of the Hearing Panel.

10.12.3 Subject's Representation and Role of Attorneys

10.12.3.1 The Subject shall be entitled to be accompanied by and represented at the hearing by an attorney or other person of his choice. By Written Notice, at least 20 days prior to the hearing, the Subject must provide the Chief Executive Officer or Presiding Officer with the name of his representative, the qualifications to act in such representative capacity and whether he is an attorney. Failure to provide such notice shall constitute grounds to refuse such representative's participation in the hearing.

10.12.3.2 If either party is represented by an attorney (or if the Subject is represented by another person of his or her choice), that individual may present witnesses and documentary evidence, cross-examine witnesses, address the Hearing Panel, submit any written statements, and exercise the rights of the Subject or Medical Executive Committee or Board, respectively, in the hearing in the same manner as the party.

10.12.4 Transcription of Proceedings

A court reporter selected by the Hospital shall make a record of the hearing. The cost of attendance of the reporter shall be borne by the Hospital, but the cost of obtaining a copy of the transcript shall be borne by the requesting party.

10.12.5 Burden of Proof

In the hearing, the Representative shall first present any evidence in support of the recommendation. The Hearing Panel and Subject may question the Representative and any witnesses. The Subject shall then present any evidence against the recommendation and shall have the burden of proof to persuade the Hearing Panel that there is not sufficient evidence to support an adverse recommendation or that an adverse recommendation would be arbitrary, capricious or discriminatory. The Hearing Panel and Representative may question the Subject and any witnesses.

10.12.6 Authority of Presiding Officer

The Presiding Officer shall have the authority to hold pre-hearing conferences and make rulings on procedural matters pre-hearing. The Presiding Officer shall provide participants in the hearing with a reasonable opportunity to present relevant oral and documentary evidence in an efficient and expeditious manner, to call, examine, or cross-examine witnesses presented, and shall maintain proper decorum. The Presiding Officer shall be entitled to have the authority and discretion to make all rulings on questions that arise during the hearing or in connection with preparation of the hearing report. The Presiding Officer may be present during deliberations and assist with preparation of the hearing report, but has no vote.

10.12.7 Evidence

Judicial rules of evidence and procedure relating to the conduct of the hearing, examination of witnesses and presentation of evidence shall not apply to a hearing conducted under these Bylaws. Any relevant evidence, including hearsay, shall be admitted if it is the sort of evidence responsible persons are accustomed to relying on in the conduct of serious affairs, regardless of the admissibility of such evidence in a court of law. The Presiding Officer shall order that oral evidence be taken on oath or affirmation administered by any person designated by him and as authorized by state law.

10.12.8 Decorum

No person shall disrupt any hearing. Any person in attendance who disrupts a hearing after being warned by the Presiding Officer to cease such disruption on penalty of indefinite exclusion, shall, at the direction of the Presiding Officer, leave the hearing. If the disruptive

person is the Subject, the hearing will then be terminated. If the disruptive person is a witness, said witness will then be excluded. Unless directed otherwise for good cause as determined at the sole discretion of the Presiding Officer, the hearing shall proceed in the absence of the excluded witness.

10.12.9 Written Statement

Both the Subject and the Representative shall have the right to submit to the Hearing Panel for consideration a written statement on any matter(s) pertinent to the Professional Review Action within five (5) working days of the hearing being closed.

10.13 Hearing Panel Decision

- 10.13.1 The Members of the Hearing Panel must be present throughout the hearing and deliberations. If a Member is absent from any part of the proceedings, he shall not be permitted to participate in the deliberations or the recommendation unless he certifies in writing that he has read the transcript of all proceedings that occurred in his absence prior to the deliberations. At least two-thirds of the Members of a panel must be present to continue the hearing.
- 10.13.2 The Hearing Panel shall, at a convenient time, and after five (5) working days of the hearing being closed, conduct deliberations outside the presence of the parties and court reporter. The Hearing Panel shall recommend rejection, affirmation, or modification of the recommended Professional Review Action. The affirmative vote of a majority of the Members eligible to vote shall constitute the Hearing Panel's decision. Upon conclusion of deliberations, the hearing shall be declared adjourned.
- 10.13.3 Within fifteen (15) days after adjournment of the hearing, the Hearing Panel shall issue its written recommendation, including a statement of the basis for the recommendation, and shall forward the recommendation together with the admitted exhibits of both parties and all other documentation to the CEO.
- 10.13.4 The CEO shall notify the Subject by Written Notice of the Hearing Panel's recommendation and shall provide the Subject with a copy of the Hearing Panel's written recommendation, including a general statement of the basis for the recommendation. A copy of the recommendation shall also be forwarded by the CEO to the Board, the Representative and the President of the Medical Staff for presentation to the Medical Executive Committee.

10.14 Final Decision

- 10.14.1 The Board of Directors shall, at its next meeting after receipt of the findings and recommendations regarding a Professional Review Action, review and consider the proposed Professional Review Action and the findings and recommendations of the Hearing Panel. No recommendation or finding is binding on the Board of Directors. Any decision of the Board of Directors regarding a proposed Professional Review Action shall be final.
- 10.14.2 The Board of Directors shall notify the CEO and the President of the Medical Staff of its final decision promptly following the meeting at which the decision was made. The CEO shall provide the Subject with Written Notice of the final decision no later than fourteen

(14) days after the meeting. If the action taken by the Board of Directors adversely affects the Membership or Privileges of the Subject, the notice shall describe the action and contain a general statement of the basis for the action.

10.15 Mediation Option

- 10.15.1 If a Subject is entitled to a hearing under this Section 10.0 or the Credentials Committee has failed to take action on a complete application or reapplication within 90 days of its receipt, and the Subject believes that mediation is desirable, the Subject may request mediation pursuant to Texas Health and Safety Code §241.101(d) and as provided in Texas Civil Practice and Remedies Code Chapter 154.4.4.1.
- 10.15.2 The mediation must be requested within thirty (30) days following receipt of the notice pursuant to Section 10.2 in the case of a Professional Review Action or, in the case of failure to act on a complete application, within ten (10) days of the application being deemed complete. A Subject is entitled to only one mediation in connection with a Professional Review Action or an alleged failure to act by the Credentials Committee.
- 10.15.3 The request for mediation must be made in writing to the Chief Executive Officer and, in the case where a hearing has been requested as provided in Section 10.3, will temporarily suspend the hearing timelines until completion of the mediation. The mediation must be commenced within thirty (30) days from the date of receipt of the request for mediation unless otherwise agreed in writing by the parties. Once begun, the mediation must be completed within thirty (30) days.
- 10.15.4 The mediation shall be conducted by a person meeting the qualifications required by Texas Civil Practice and Remedies Code § 154.052 and selected by the Chief Executive Officer with the approval of the Subject which shall not be unreasonably withheld. The mediator's fee shall be shared equally by the Hospital and the Subject, and shall be limited to one-half day of mediation unless otherwise agreed by the parties.
- 10.15.5 A representative of the Medical Executive Committee and of the Board shall attend the mediation on behalf of the Hospital and, unless otherwise provided by the Medical Executive Committee and the Board, shall have the authority to enter into a binding settlement agreement at the mediation. The parties also may be represented by counsel at the mediation.

11.0 MISCELLANEOUS

11.1 Voting or Approval Process

In the course of any proposal affecting the Medical Staff Bylaws, Rules and Regulations or policy and procedure which may call for a vote or approval, the process for obtaining such vote or approval may be by written ballot collected at a meeting or by fax, email or any other electronic means.

11.2 Rules and Regulations

The Medical Staff and each Practitioner applying for, attempting to exercise or exercising Clinical Privileges at the Hospital shall abide by the Rules and Regulations, and shall be subject to the Rules and Regulations as are necessary for the proper conduct of its or his work and which implement more specifically the general principles in these Bylaws.

- 11.2.1 The Medical Staff shall amend the Rules and Regulations by delegating the authority to take such action to the Medical Executive Committee (MEC) subject to 11.2.5 below.
- 11.2.2 Amendment of the Rules and Regulations requires the approval of the Medical Executive Committee and the Board of Directors.
- 11.2.3 A proposed amendment to the Rules and Regulations, or policies may be made by the MEC.
- 11.2.4 A proposed amendment to the Rules and Regulations, or policies may also be made by a petition to the MEC signed by twenty-five percent (25%) of the active Members of the Medical Staff. Such petition will be sent directly to the MEC no less than fourteen (14) days before it is to be considered.
- 11.2.5 Once an amendment to the Rules and Regulations is proposed by the MEC, it will communicate the proposed amendment to the Medical Staff by written or electronic means. The recommendation will be forwarded to the Board of Directors for final action. Should Members of the Medical Staff disagree with the approved Rules and Regulations, they may then follow the conflict resolution process in Article 11.8.
- 11.2.6 Amendments to Rules and Regulations shall be effective when approved by the Board of Directors.
- 11.2.7 If any amendment to the Rules and Regulations is required to comply with any law or regulation or any standard or requirement of any accreditation body, and if the MEC fails to enact said amendment, the Board of Directors may adopt a provisional amendment(s) on its own initiative. After adoption, these provisional amendments to the Rules and Regulations will be communicated to the MEC for their review.
 - 11.2.7.1 If the MEC approves of the amendment or recommends an alternate amendment, it will follow the process outlined above. (11.2.5 – 11.2.8)
 - 11.2.7.2 If the MEC approves the amendment, yet twenty-five percent (25%) of the active Medical Staff does not approve of the provisional amendment, this will be resolved using the conflict resolution process noted in Section 11.8.
 - 11.2.7.3 If a substitute amendment is then proposed by twenty-five percent (25%) of the

active Medical Staff, it will follow the approval process set forth in Section 11.8.

11.2.7.4 The Board of Directors shall make the final decision on enacting such provisional amendment.

11.2.8 If the Medical Staff disagrees on the amendment of the Rules and Regulations it may use the mechanisms noted in the conflict resolution process, set forth in Section 11.8 of these Bylaws to resolve the dispute. This process may take place before or after the Board of Directors votes on the amendment to the Rules and Regulations.

11.3 Quorum

11.3.1 Meetings of Medical Staff, Department, or Committee

A quorum is constituted by those Members present at any regular or specially called meeting of the General Medical Staff, Department, committee, or subcommittee, unless otherwise provided in these Bylaws.

11.3.2 Meetings of Medical Executive Committee or Credentials Committee

A quorum is constituted by fifty percent (50%) of the Membership plus one Member at any regular or specially called meeting of the Medical Executive Committee or the Credentials Committee.

11.3.3 Quorum Not Present During Entire Meeting

If a quorum is present at any time during a meeting, but not during the entire meeting, the Members present may still continue to transact the business to be conducted at the meeting and it will be considered that such business will have been conducted with a quorum present.

11.4 Bylaws

11.4.1 Amendments to the Bylaws

An amendment to these Bylaws may be proposed by the Medical Executive Committee or by petition signed by twenty-five percent (25%) of the Active Staff. To be adopted, an amendment to the Bylaws must be approved by a majority vote of the Medical Staff Members eligible to vote at a meeting of the Medical Staff where a quorum is present or by a majority of those Members voting by ballot. The proposed amendment(s) to the Bylaws shall be transmitted by written or electronic notice, to the Active Members of the Medical Staff. The proposed amendment(s) shall be accompanied by a ballot to record the approval or disapproval by the active Medical Staff Member. The ballot vote must be received by Medical Staff Services by written or electronic notice, within thirty days of receipt of the proposed amendment(s). Amendments to the Bylaws shall become effective when approved by the Board of Directors.

11.4.2 The Medical Staff will ensure that its Bylaws, Rules and Regulations and policies, are compatible with each other, with the policies and Bylaws of the hospital, and are compliant with law and regulation.

- 11.4.3 The Board of Directors upholds the Medical Staff Bylaws, Rules and Regulations, and policies that have been approved by the Board of Directors.
- 11.4.4 The Medical Executive Committee may adopt amendments to the Bylaws that are, in the Committee's judgment, technical or legal modifications or clarifications, or which require reorganization or renumbering, or that are needed due to punctuation, spelling, or other errors of grammar or expression. Such amendments shall be effective immediately and shall be permanent if not disapproved by the Board within 60 days of adoption by the Medical Executive Committee. Immediately upon adoption, such amendments shall be sent to the Chief Executive Officer or designee and made available to the Members of the Medical Staff.

11.5 Conditions of Practice, Confidentiality, and Immunity from Liability

11.5.1 Authorization and Conditions Arising From Application Process

By submitting an Application for Appointment, Reappointment, or Clinical Privileges an Applicant:

- 11.5.1.1 Authorizes representatives of the Hospital and Medical Staff to solicit, provide and act upon information bearing on the Applicant's competence and conduct;
- 11.5.1.2 Authorizes third parties to provide information to the Hospital and Medical Staff about the Applicant's competence and conduct;
- 11.5.1.3 Agrees to be bound by the provisions of this Section 11.4 and to waive all legal claims against any representative or third party who acts in accordance with the provisions of this Section 11.4; and
- 11.5.1.4 Acknowledges that the provisions of this Section 11.4 are express conditions to the Applicant's Application and acceptance of Medical Staff Appointment, the continuation of such Appointment, and the exercise of Clinical Privileges and any action regarding those privileges.

11.5.2 Confidentiality

- 11.5.2.1 Information with respect to any Member or Practitioner that is submitted, collected or prepared by any representative of the Hospital or Medical Staff or by any third party for purposes of Professional Review Activity shall, to the fullest extent permitted by law, be confidential.
- 11.5.2.2 Unless otherwise provided by law, disclosure of any information generated by or at the direction of a committee (whether Medical Staff committee, Department or subcommittee) or Department, or provided to the committee or Department, to any person other than within the Medical Staff or Hospital for authorized purposes shall require execution of a written waiver by the committee's or department's chair and approval of the CEO.
- 11.5.2.3 All committee and Department documents shall be maintained by the Hospital on behalf of the committee or Department and the Hospital in accord with Hospital policy. Access to committee or Department documents shall be in accord with

Hospital policy and applicable legal requirements to maintain any available privileges of confidentiality.

11.5.2.4 In accepting Appointment to the Medical Staff and/or Clinical Privileges, each Member and/or Practitioner agrees to respect and maintain the confidentiality of all discussions, deliberations, proceedings, and activities of the Medical Staff and all committees and Departments engaging in Professional Review Activities and other matters, except as directed by the Medical Executive Committee or required by law. Any questions regarding whether information is confidential shall be resolved by the President of the Medical Staff and the CEO. Any violation or threatened violation of this provision shall be grounds for corrective action.

11.5.3 Privilege and Immunity from Liability

Any act, communication, report, recommendation, or disclosure regarding an Applicant, Practitioner or Medical Staff Member performed or made at the request of an authorized representative of the Hospital or any other health care entity for the purpose of achieving and maintaining quality patient care in the Hospital or any other health care entity is privileged and protected from disclosure to the fullest extent permitted by law.

Each Member of a committee of the Hospital or Medical Staff shall not be liable in damages, and shall be immune from liability, for any actions taken or recommendations made, within the scope of the functions of such committee. Each person furnishing information, data, reports or records to the Hospital or any committee of the Hospital or Medical Staff shall not be liable in damages therefore and shall be immune from liability for any such action.

Each Practitioner and Member agrees to release, indemnify and hold harmless the Hospital and all Medical Staff Members and other persons providing information to the Hospital or Medical Staff (the Indemnitees) regarding the Practitioner or Member from and against any and all claims, actions, causes of actions, demands, suits, liabilities, damages, losses, costs or expenses (including attorneys' fees, court costs and costs of settlement) in connection with any injury, or damage or loss resulting from acts or omissions of the Indemnitees in connection with the Member's or Practitioner's Medical Staff Membership or Clinical Privileges.

11.5.4 Scope

The confidentiality and immunity provided by this Section 11.4 apply to all information, actions and recommendations in connection with this or any other health care entity's or organization's activities concerning, but not limited to:

11.5.4.1 Application for Appointment, Reappointment, or Clinical Privileges;

11.5.4.2 Professional review activity;

11.5.4.3 Corrective or automatic action and administrative or temporary suspension;

11.5.4.4 Hearings and Board reviews;

- 11.5.4.5 Quality management, utilization review and risk management, including profiles and profile analysis program activities;
- 11.5.4.6 Any recommendation or action authorized by these Bylaws or the Rules and Regulations; and
- 11.5.4.7 Other Hospital and Medical Staff activities related to monitoring and maintaining quality and efficient patient care and appropriate professional conduct.

11.5.5 Cumulative Effect

Provisions in these Bylaws and relating to the matters set forth in this Section 11.4 are in addition to, not in limitation of, any other protections provided by law.

11.5.6 Releases

Each Member or Practitioner shall execute general or specific releases and authorizations in accordance with the provisions of this Section 11.4. Execution of the releases and authorizations is not a prerequisite to the effectiveness of any section of these Bylaws or the Rules and Regulations.

11.6 Construction of Terms and Headings

The captions and headings in these Bylaws and the Rules and Regulations are provided for convenience only and are not intended to limit or define the scope of or affect any of the substantive provisions contained therein.

11.7 Order and Procedure

Except where it may conflict with the procedure stated within these Bylaws, all meetings of the Medical Staff and its Departments and committees shall be governed in its procedures by Roberts Rules of Order Newly Revised, latest edition. The Chair of each Department, committee or meeting shall insure that such parliamentary procedure is properly followed.

11.8 Conflict Resolution Process

11.8.1 Any conflict between the Medical Staff and the MEC, related to the adoption or amendment of Rules and Regulations and policies adopted by the MEC, will be resolved using the process below. The Medical Staff may challenge any Rule and Regulation or policy established by the MEC as follows:

11.8.1.1 Any Medical Staff Member may submit to the President of the Medical Staff, a petition signed by twenty-five percent (25%) of the active Members of the Medical Staff, requesting review and possible change of a Rule, and Regulation, or policy adopted by the MEC.

11.8.1.2 The petition must include the basis for the challenge, including any recommended changes to the Rule and Regulation or policy.

- 11.8.1.3 At the meeting of the MEC that follows such notification, the MEC shall discuss the challenge and determine if any changes will be made to the Rule and Regulation or policy.
 - 11.8.1.4 In response to a written challenge to a Rule and Regulation or policy, the MEC may, but is not required to, appoint a task force to review the challenge and recommend potential changes.
 - 11.8.1.5 If a task force is appointed, following its recommendation, the MEC will take final action on the Rule and Regulation or policy. If the MEC adopts changes, it will communicate such changes to the Medical Staff.
 - 11.8.1.6 Once the MEC has taken final action in response to the challenge, with or without recommendations from a task force, any Medical Staff Member may submit a petition signed by twenty-five percent (25%) of the active Members of the Medical Staff requesting review and possible change of a Rule and Regulation or policy to the Board.
 - 11.8.1.7 The MEC may choose to put the matter to the Medical Staff for a referendum.
- 11.8.2 If the Medical Staff, via petition signed by twenty-five percent (25%) of the active Members directly recommends an amendment to the Bylaws, Rules and Regulations or policy to the Board that is different from that recommended by the MEC, the following conflict resolution process will be used.
- 11.8.2.1 The MEC shall have the option of appointing a task force to review the differing recommendations of the MEC and the Medical Staff, and develop recommended language to the Bylaws, Rules and Regulations, or policies that is agreeable to both the Medical Staff and the MEC.
 - 11.8.2.2 Whether or not the MEC adopts modified language, the Medical Staff shall still have the opportunity to recommend directly to the Board alternative language. If the Board receives differing recommendations for Bylaws, Rules and Regulations, or policies from the MEC and the Medical Staff, the Board shall also have the option of appointing a task force of the Board to study the basis of the differing recommendations and to recommend appropriate Board action.
 - 11.8.2.3 At any point in the process of addressing a disagreement between the Medical Staff and MEC regarding the Bylaws, Rules and Regulations, or policies, the Medical Staff, MEC, or the Board shall each have the right to recommend use of an outside resource to assist in addressing the disagreement. The final decision regarding whether or not to utilize an outside resource, and the process that will be followed in so doing, is the responsibility of the Board.

11.8.2.4 **Whether or not the Board appoints such a task force, the Board shall have final authority to resolve the differences between the Medical Staff and the MEC which will then be subject to the Bylaw amendment process specified in 11.4 of the Medical Staff Bylaws.**

TEXAS HEALTH HUGULEY HOSPITAL

MEDICAL STAFF BYLAWS

ADOPTED by the Medical Staff on April 13, 2021

APPROVED by the Board of Directors on April 16, 2021



MEDICAL STAFF RULES AND REGULATIONS

OF

TEXAS HEALTH HUGULEY HOSPITAL

Approved October 15, 2021

RULES AND REGULATIONS

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1.0 INTRODUCTION

1.1 Purpose

These are the Rules and Regulations (the "Rules and Regulations") of the Medical Staff (the "Medical Staff") of Texas Health Huguley Hospital (the "Hospital"). The Medical Staff has adopted these Rules and Regulations to implement the Medical Staff Bylaws of the Hospital (the "Medical Staff Bylaws" or "Bylaws").

1.2 Relationship to Medical Staff Bylaws

These Rules and Regulations shall not alter, modify, or take precedent over the Medical Staff Bylaws and to the extent that there is any conflict between this policy and the Medical Staff Bylaws, then the Medical Staff Bylaws shall control. They shall not be construed to limit or impose conditions or obligations with respect to the peer review processes and fair hearing processes stated in the Medical Staff Bylaws.

1.3 Definitions

1.3.1 The definitions in the Medical Staff Bylaws are hereby incorporated by reference into these Rules and Regulations.

Admitting Physician shall mean the Physician Practitioner who accepts the patient into the Hospital. There may be only one Admitting Physician for each inpatient encounter.

1.3.2 Attending Physician shall mean the Physician Practitioner who currently has primary responsibility for the care of a hospital patient. There may be more than one Attending Physician for each hospital encounter, but there may be only one Attending Physician at any given time during the hospital encounter. The Attending Physician may or may not be the Admitting Physician, depending on whether the Admitting Physician transfers care of the patient to another Physician Practitioner during the hospitalization.

1.3.3 Consultant shall mean any Practitioner who consults, after being asked, on a patient during a hospital encounter.

1.3.4 Discharging Physician shall mean the Physician who enters the discharge order. The Discharging Physician shall have sole responsibility for all duties associated with discharging a patient at the end of a hospital encounter.

1.3.5 Emergency Medical Condition shall mean:

1.3.5.1 a medical condition manifested by acute symptoms of sufficient severity, including severe pain, such that the absence of immediate medical attention could reasonably be expected to result in (1) placing the health of the individual or, with respect to a pregnant woman, the health of the woman or her unborn child, in serious jeopardy; (2) serious impairment of bodily functions; (3) serious dysfunction of any bodily organ or part; or

1.3.5.2 with respect to a pregnant woman having contractions (1) that there is inadequate time to effect a safe transfer to another hospital before delivery; or (2) that transfer may pose a threat to the health or safety of the woman or her unborn child.

1.3.6 Stabilize shall mean:

1.3.6.1 to provide such medical treatment of the Emergency Medical Condition as may be necessary to assure, within reasonable medical probability, that no material deterioration of the condition is likely to result from or occur during the transfer of the individual; or

1.3.6.2 in the case of a pregnant woman having contractions, to deliver the child, including the placenta.

1.4 Compliance

Each Medical Staff Member and each other Practitioner providing patient care services in the Hospital shall comply with these Rules and Regulations. A Member failing to comply with these Rules and Regulations shall be subject to Corrective Action.

2.0 DEPARTMENTS

2.1 Departments

2.1.1 The Medical Staff shall be organized into the following Departments:

- 2.1.1.1 Anesthesiology
- 2.1.1.2 Emergency Medicine
- 2.1.1.3 Family Medicine
- 2.1.1.4 Medicine
- 2.1.1.5 Obstetrics and Gynecology
- 2.1.1.6 Pathology
- 2.1.1.7 Pediatrics
- 2.1.1.8 Psychiatry
- 2.1.1.9 Radiology
- 2.1.1.10 Surgery

2.2 Additional Specialties

Additional specialties may be added to a Department. A Department's request to add a specialty must be submitted to the Medical Executive Committee. If approved by the Medical Executive Committee, the President of the Medical Staff shall submit the request to the Board of Directors. If approved by the Board of Directors, the specialty shall be added to the Department.

2.3 Additional Departments

Additional Medical Staff Departments may be created as follows:

- 2.3.1 The President of the Medical Staff, upon receipt of a written request to form a new Department, shall forward the request to the Medical Executive Committee. There must be no less than five (5) Medical Staff Members in the Active category who would be eligible to belong to the proposed Department before the request can be considered. The request must be signed by no less than two-thirds of those Members who would be eligible to belong to the new Department.
- 2.3.2 The request must be by the Medical Executive Committee and forwarded to the Board of Directors. Upon approval by the Board of Directors, the Department will be organized. The chair-of the Department shall, upon his confirmation and approval as chair, become a voting member of the Medical Executive Committee.

2.4 Purpose and Functions of the Departments

The Departments are organized to provide continuity of administration of the Medical Staff and shall be responsible for the following functions:

- 2.4.1 monitoring, assessing, and improving the quality of patient care provided by all members of the Department;
- 2.4.2 reviewing, developing, and implementing policies and procedures that guide and support the provision of services in the Department;
- 2.4.3 submitting reports to the Credentials Committee and other committees as appropriate;
- 2.4.4 coordinating proctoring, evaluating its Members, and providing appropriate continuing education for Department members; and
- 2.4.5 assessing and recommending to the relevant hospital authority off-site sources for needed patient care services not provided by the department or the organization.

2.5 Department Meetings

Department meetings will be held at least as often as needed to conduct the business of the Department, but not less than one time per year. The business of each Department shall include, but not be limited to:

- 2.5.1 establishing or amending Department policies;
- 2.5.2 making recommendations regarding patient care and other matters affecting the Department;
- 2.5.3 reviewing quality data and recommending action as necessary; and
- 2.5.4 receiving and implementing Medical Executive Committee and/or Board of Directors directives.

2.6 Membership Requirements

- 2.6.1 Only Members who belong to a specialty in the Department and who are otherwise qualified may be appointed to a Department.
- 2.6.2 A Medical Staff Member is eligible to become a member in only one Department but may have Clinical Privileges in more than one Department. Additionally, with the consent of the Chair, he may attend meetings of any Department for the purpose of discussion without vote.

2.7 Election of Department Chair

- 2.7.1 No later than October 31 of each Even Year, each Department shall hold a Department meeting and confirm the nomination of a Department Chair. The election results shall be forwarded to the Medical Executive Committee for recommendation. After Medical Executive Committee reviews, the recommendation will be forwarded to the Board of Directors.

2.7.2 A Chair-elect shall not assume office until the Board of Directors approves his election. If the Medical Executive Committee or the Board of Directors does not approve the election of the Department Chair, another nominee shall be nominated and confirmed. The Department Chair holding office at the time of such disapproval shall continue to hold office until his successor is nominated, confirmed and approved by the Board of Directors.

2.8 Term

2.8.1 Each Department Chair shall be elected for a two-year term commencing January 1, Odd Year through December 31, even year. Any Department Chair may succeed himself.

2.9 Vacancies in Elected Office

2.9.1 If a vacancy occurs in the office of the Department Chair, the office shall be filled by special election of the members of the Department. The member shall serve the unexpired term of office.

2.10 Duties of Department Chair

The chair of each Department shall be a member of the Department in the Active Category and have certification by an appropriate specialty board or affirmatively established comparable competence through the credentialing process and have the following duties:

2.10.1 Serve as a member of the Medical Executive Committee.

2.10.2 Call and preside at all Department meetings and prepare the agenda for such meetings.

2.10.3 Implement the policies of the Board of Directors and report to the Medical Executive Committee regarding patient care matters and all other matters affecting the Department.

2.10.4 Enforce the Medical Staff Bylaws and the Rules and Regulations and Department policies and procedures.

2.10.5 Select a Member of the Department to fill the position of Vice-Chair.

2.10.6 Review appointment and reappointment credentials and quality file(s) including, as applicable, ongoing, and focused professional practice evaluations.

2.10.7 Perform such other duties as provided in the Bylaws, these Rules, or as may be delegated by the Medical Executive Committee and/or the Board of Directors.

2.10.8 Submit recommendations to the Credentials Committee concerning Applications for Appointment, Applications for Reappointment, and Requests for Clinical Privileges; recommend criteria for Clinical Privileges in the Department.

2.10.9 Be responsible for the clinically related activities of the Department and conduct ongoing quality management and utilization activities of the care and services provided in the Department; shall maintain a performance improvement plan for the Department.

- 2.10.10 Be responsible for the continuing surveillance of the professional performance of individuals who have delineated Clinical Privileges in the Department; the determination of the qualifications and competence of Department personnel who are not licensed independent practitioners and who provide patient care services.
- 2.10.11 Be responsible for administratively related activities of the Department, unless otherwise provided for by the Hospital. This includes integration of the Department into the primary functions of the organization; the coordination and integration of interdepartmental and intradepartmental services; the development and implementation of policies and procedures that guide and support the provision of services; the recommendations for a sufficient number of qualified and competent persons to provide care; continuing education within the Department; and recommendations for space and other resources needed by the Department.
- 2.10.12 Assess and recommend to the relevant hospital authority offsite sources for needed patient care services not provided by the department or the organization.
- 2.10.13 Be responsible for the continuous assessment and improvement of the quality of care and services provided, and the maintenance of quality control programs, as appropriate.

2.11 Surveys

2.11.1 Accreditation Requirements & Surveys

Each Department Chair shall be responsible for assisting the Hospital and Medical Staff in meeting the requirements of all accrediting organizations as required by the hospital. Members of each Department shall assist and cooperate with Hospital administration in preparation for, and during, any on-site accreditation survey(s).

3.0 EMERGENCY SERVICES

3.1 Admission and Assignment of Patients

- 3.1.1 Members who only have Clinical Privileges to provide medical services in the Department of Emergency Medicine may admit patients to the Hospital but may not provide ongoing care.
- 3.1.2 When appropriate, as determined by the Emergency Medicine Physician on duty, the patient's physician shall be called when the patient presents to the Emergency Department for treatment. If a patient does not have a physician who has Clinical Privileges at the Hospital, the Practitioner on the Emergency Department Call Schedule in the appropriate specialty shall be contacted.
- 3.1.3 If the patient's condition upon admission requires continuing physician attendance in the Emergency Department, the Emergency Department Physician shall continue the care and treatment of the patient until the Attending Physician arrives in the Hospital to care for the patient.

3.2 Physician Coverage

- 3.2.1 Practitioners shall participate as assigned in the Department of Emergency Medicine on-call roster. A physician shall be available to render emergency patient care in his specialty when his name appears on the Department of Emergency Medicine on-call roster.
- 3.2.2 Maximum time any one physician can be expected to be on call any given month is 16 days.
- 3.2.3 In accordance with federal law, any physician who is on call must provide timely follow-up as necessary and may not refuse to accept patients or delay follow-up based on payment issues.
- 3.2.4 Practitioners on-call shall meet the response requirements outlined in Section 14.

3.3 Medical Records

An appropriate medical record shall be maintained for each patient receiving care in the Department of Emergency Medicine and the medical record shall include the usual requirements as well as:

- 3.3.1 Medical history and physical examination report including first aid or emergency care provided to the patient prior to arrival at the Hospital;
- 3.3.2 Final disposition;
- 3.3.3 Condition at discharge; and
- 3.3.4 Instructions for follow-up care.

3.4 Patient Transfers

If a patient is to be transferred to another facility, the patient's transfer shall be conducted in accordance with Hospital's policies and procedures. All state and federal laws governing patient transfer will be followed. The medical record will reflect the reason for transfer and the stability of the patient.

3.5 Resolution of Differences

- 3.5.1 If the Department of Emergency Medicine Physician and the Practitioner on call differ about the treatment or disposition of any patient in the Department of Emergency Medicine, the Practitioner shall assume responsibility for the patient's care in the Department of Emergency Medicine. The President of the Medical Staff, in consultation with the Chief Executive Officer, shall resolve any differences between Practitioners regarding the treatment or disposition of patients.
- 3.5.2 If the interpretation of an x-ray, EKG, or other study is different from that of the Department of Emergency Medicine Physician, the interpreting physician shall promptly notify the Department of Emergency Medicine physician and provide copies of his interpretation.

4.0 SURGERY AND SURGICAL CARE

4.1 Reports

The reports specified in Rule 18.5 and 18.7 shall be included in a patient's medical record prior to the induction of anesthesia. If these documents are not included in the medical record, the surgeon shall be notified.

4.2 Informed Consent

It is the responsibility of the physician to obtain informed consent. The physician is responsible for documenting in the medical record that he has discussed the risks and benefits, alternatives (including not performing the procedure), and potential complication with the patient/family prior to pre-medicating a patient before an operative procedure.

4.3 Emergency Consent

If during an emergency, consent cannot be obtained from the patient or his legal representative, the physician or his designee shall record the reason for not being able to obtain written consent.

4.4 Abortions

Elective termination of pregnancy shall not be performed at Texas Health Huguley Hospital.

4.5 Dentists

4.5.1 Dental patients shall receive care from an Attending Physician and a Consulting Dentist as outlined below.

4.5.2 The Dentist shall complete:

4.5.2.1 Complete a dental history;

4.5.2.2 Provide a description of the examination of the oral cavity and a preoperative diagnosis;

4.5.2.3 Complete an operative report for any procedures performed describing the findings and technique used. When the patient has had teeth extracted, the dentist shall record in the operative report the type and number of teeth and fragments removed. All tissue and fragments shall be sent to the Department of Pathology for examination;

4.5.2.4 Complete progress notes regarding the patient's oral condition; and

4.5.2.5 Complete orders for the patient as applies to dental care.

4.5.3 The Physician shall:

4.5.3.1 Complete a medical history and physical examination report; and

4.5.3.2 Be responsible for the patient's medical care and treatment while in the Hospital.

4.6 Podiatrists

4.6.1 Podiatric patients shall receive care from an Attending Physician and a Consulting Podiatrist as outlined below:

4.6.2 The Podiatrist shall:

4.6.2.1 Complete a podiatric history;

4.6.2.2 Provide a description of the examination of the patient's feet and a pre-operative diagnosis;

4.6.2.3 Complete an operative report for any procedures performed describing the findings and techniques used. If tissue is removed, it shall be sent to the Department of Pathology for examination;

4.6.2.4 Complete progress notes regarding the patient's podiatric condition; and

4.6.2.5 Complete orders for the patient only as applies to podiatric care.

4.6.3 The Physician shall:

4.6.3.1 Complete a medical history and physical examination; and

4.6.3.2 Be responsible for the patient's medical care and treatment while in the Hospital.

5.0 PSYCHIATRIC CARE

5.1 Clinical Direction

Overall clinical direction of psychiatric services shall be provided by a designated qualified psychiatrist.

5.2 Restraint and Seclusion

An order to place a patient in restraints or seclusion will be in accordance with hospital policy.

5.3 Multidisciplinary Treatment

When multidisciplinary treatment plans are used for care of psychiatric/substance abuse patients, there shall be written policies and procedures relating to their use, including appropriate physician involvement.

6.0 COMMITTEES

6.1 Meeting Requirements

All Medical Staff Committees shall meet as frequently as necessary to complete their duties but no less than once per year. All Medical Staff Committees shall also meet on the call of their Chair as necessary to perform their functions and as otherwise specified in these Bylaws.

6.2 General Responsibilities

Each Medical Staff Committee shall:

- 6.2.1 Perform those duties specifically described in these Bylaws and such other duties as may be delegated by the Medical Executive Committee;
- 6.2.2 Maintain a permanent record of its proceedings; and
- 6.2.3 Report to the Medical Executive Committee. The Medical Executive Committee shall report to the Board of Directors.

6.3 Committee Members

Unless otherwise specified in the Bylaws or Rules and Regulations, each committee shall be comprised of a majority of Members in the Active category. Other Practitioners, including Non-Voting Members and Non-Members may be appointed to committees, or invited to attend Committee meetings, with voice but without vote, in accordance with the Bylaws and Rules and Regulations. Unless otherwise provided in the Bylaws or Rules and Regulations, the Chief Executive Officer, or his designee, and the Chief Medical Officer shall serve as Ex-Officio members of each committee with voice but without vote.

- 6.3.1 Appointment of Department Committee Members: During the last quarter of each even year, the Department Chair Elect shall appoint the members of each Department Committee and designate the committee chair.
- 6.3.2 Appointment of Multi-Disciplinary Committees: At any time, the President of the Medical Staff may create, charge and appoint members to a multi-disciplinary committee and designate the committee chair. The President of the Medical Staff may also dissolve any such Multi-Disciplinary Committee.
- 6.3.3 Term: is dissolved. Each committee member shall serve a maximum of two years, starting January 1, odd years, and ending December 31, even years. A committee member may be appointed to successive terms.
- 6.3.4 Quorum: A quorum is constituted by those committee members present at any regular or specially called meeting of the general medical staff, department, committee, or subcommittee, unless otherwise provided in these Bylaws.
- 6.3.5 Removal: The Medical Executive Committee, by majority vote may remove any member of any committee for any reason whether or not good cause exists. The President of the Medical Staff may remove a committee member on behalf of the Medical Executive

Committee at any time; however, this action must be approved by a majority vote of the Medical Executive Committee at its next regularly scheduled meeting.

6.3.6 **Vacancy:** If a vacancy occurs on a committee, the President of the Medical Staff may appoint a replacement.

6.4 Attendance of Committee Chair

If a committee chair cannot attend a scheduled meeting of the committee, he shall, unless prevented by an emergency, provide verbal notice as soon as practicable to at least one (1) other committee member who will be in attendance. The oral notice shall designate the committee member who shall act as chair in the chair's absence.

6.5 Subcommittees

Any Medical Staff or Department committee may create one (1) or more subcommittees for the purpose of performing tasks within the scope of the duties of the committee. The Chair of the committee shall appoint the subcommittee members.

6.6 Department Committees

Each Department shall have, at a minimum, a Department Committee consisting of all members. Each Department may have other committees as provided for in the Bylaws and Rules and Regulations.

6.6.1 Department Officer Nominating Process

6.6.1.1 Each department shall nominate a Chair and Vice Chair for the subsequent term by majority vote of the quorum present at a scheduled department meeting prior to October 31 of each even year.

6.6.1.2 In the event of a vacancy in any office of the Department, the Department shall nominate replacement officer(s) by majority vote of the quorum present at a scheduled meeting.

6.6.1.3 The Vice Chair, if one is serving, shall be acting Chair until the Board of Directors approves a new Chair.

6.7 Other Performance Improvement Functions of the Medical Staff

The Medical Staff shall provide a leadership role and participate in assessing and monitoring the quality and safety of care that occurs at the various levels within the organization as part of the Organizational Performance Improvement Plan (OPIP).

6.8 Medical Staff Nominating Committee

6.8.1 Members

The Members of the Medical Staff Nominating Committee shall be the Immediate Past President of the Medical Staff, who shall serve as Chair, and two (2) Members in the Active category which shall be appointed by the President of the Medical Staff.

6.8.2 Duties and Meetings

6.8.2.1 The Medical Staff Nominating Committee shall meet no less than 120 days before the expiration of the present term of office to select a qualified nominee for each office.

6.8.2.2 In the event of a vacancy in any Medical Staff office, the Medical Staff Nominating Committee shall meet as soon as practicable to select a nominee for the vacant position.

6.9 Bylaws Committee

6.9.1 Members

The voting members of the Bylaws Committee shall be five (5) Medical Staff Members appointed by the President of the Medical Staff. At least four (4) of these Members shall be in the Active category.

6.9.2 Meeting Requirements and Duties

6.9.2.1 The Bylaws Committee shall meet no less frequently than once each year and shall review the Medical Staff Bylaws and Rules and Regulations and make recommendations regarding any revisions to the Bylaws and Rules and Regulations necessary to reflect current practices; and

6.9.2.2 Receiving and reviewing recommendations from other committees or from members of the Medical Staff regarding any proposed changes to the Medical Staff Bylaws and Rules and Regulations.

6.10 Physician Health Committee

The Physician Health Committee exists to ensure a proper process to identify and manage matters of individual physician health that is separate from the medical staff disciplinary function. (See medical staff policy for committee guidelines.)

6.11 Centralized Performance Improvement (CPI) Committee

6.11.1 The Chair of the Centralized Performance Improvement Committee (CPI) shall be appointed by the President of the Medical Staff.

6.11.2 The CPI committee shall consist of Members in the Active category appointed by the Chair.

6.11.3 All members including the Chair may vote.

6.11.4 The Centralized Performance Improvement Committee shall meet as needed.

6.11.5 The duties of the Committee shall include, but not be limited to:

6.11.5.1 Assisting in implementation of the Organizational Performance Improvement Plan by participation in Performance Improvement priorities;

- 6.11.5.2 Providing leadership in measurement, assessment, and design of processes to improve and enhance patient care. Those processes include utilizing corporate, state, federal and other regulatory initiatives;
 - 6.11.5.3 Reporting to the Medical Executive Committee on matters which may affect patient care and processes;
 - 6.11.5.4 Review of electronic incident reports regarding Medical Staff members; and
 - 6.11.5.5 Review of ongoing professional practice evaluation trends.
- 6.11.6 Cases forwarded to CPI for review will be initially triaged by the Centralized Performance Improvement Committee Leadership Council (CPI-LC). This committee may obtain further information as needed to make a determination. Members include the Chair of CPI, Chief Medical Officer, Chief Nursing Officer, President of the Medical Staff and other medical staff as deemed necessary. Any cases that require further review will be forwarded to the Centralized Performance Improvement Committee.

6.12 Pharmacy and Therapeutics Committee

The Pharmacy and Therapeutics Committee exists to ensure a proper process for the use of medications in the hospital. (See hospital administrative policy for committee guidelines.)

7.0 MEDICAL STAFF OFFICERS

7.1 Qualifications

Each officer of the Medical Staff shall be a Member in Good Standing in the Active category at the time of nomination, confirmation, succession, and during term of office. Failure to maintain such standing shall provide grounds for removal.

7.2 Nomination of Officers

7.2.1 Each even year, the Nominating Committee shall select one (1) qualified nominee each for the positions of President, Vice President and Assistant Vice President of the Medical Staff.

7.2.2 The Nominating Committee shall meet and submit its recommendation to the Medical Executive Committee no less than 120 days before the expiration of the present term of office. If the Medical Executive Committee does not approve a nominee for confirmation, the Nominating Committee shall meet promptly to select another nominee. After selecting another nominee, the Nominating Committee shall submit its recommendation to the Medical Executive Committee for approval. If the Medical Executive Committee does not approve that nominee, the President of the Medical Staff, in consultation with the Medical Executive Committee or designated Medical Executive Committee Members, shall select another nominee.

7.2.3 The Medical Executive Committee shall present the nominees selected to the Members of the Medical Staff eligible to vote no less than 105 days before the expiration of the present term of office.

7.2.4 A Member, who is in good standing in the Active category, may also be presented to the Medical Executive Committee for nomination by a petition signed by at least ten (10) Members in the Active category. The petition must also include a signed statement by the nominee attesting to the candidates' willingness to hold office. This petition must be submitted to the Medical Executive Committee no less than 90 days before the expiration of the present term of office

7.3 Confirmation of the election

7.3.1 A nominee must receive a majority of the votes by ballot in order to be confirmed. In the case of multiple candidates for a position the candidate who received the most votes will be confirmed.

7.3.2 The Nominating Committee shall submit a slate of candidates for approval. If only one candidate is submitted for a position and the candidate is not confirmed by majority with positive votes or if votes for two leading candidates result in a tie, then a special meeting of the Medical Staff eligible to vote shall be called to meet at a date no less than fifteen days before the expiration of the present term of office. The eligible Members present at the meeting shall immediately vote by secret ballot to confirm the nominee in the manner prescribed in Rule 7.3.1. The members of the Nominating Committee shall count all votes cast in confirmation of each nominee and immediately forward the results of the election to the MEC. If a nominee selected by the Nominating Committee fails to be confirmed by a majority of the Members eligible to vote who are present at the meeting, the Nominating

Committee shall again retire and the process in this Rule 7.3.2 shall repeat itself until a nominee is confirmed and approved.

7.3.3 The MEC shall forward the results to the Board of Directors for approval. The Board of Directors shall meet to approve the nomination of Medical Staff Officers no later than the last business day of each year.

7.3.4 An officer-elect shall not assume office until the Board of Directors approves his election. If the Board of Directors does not approve the election of any officer, another nominee shall be nominated and confirmed in the manner specified in this Rule 7.3.2. The officer holding office at the time of such disapproval shall continue to hold office until his successor is nominated, confirmed and approved by the Board of Directors.

7.4 Term and Succession in Office

7.4.1 Each Medical Staff officer shall serve a term of two years, elected at the end of each even year, or until his successor is confirmed by the Medical Staff and is approved by the Board of Directors.

7.4.2 If a Medical Staff Officer is elected as a result of a vacancy; their term would be served to the end of the two-year term.

7.4.3 The term shall run from Jan 1, Odd Year through Dec 31, Even Year.

7.5 Vacancy

7.5.1 If a vacancy occurs in the office of President, Vice President or Assistant Vice President of the Medical Staff, the Nominating Committee shall meet as soon as practicable to select a nominee for the vacant position. The Medical Executive Committee shall call a special meeting of the Medical Staff in accordance with 7.3.2.

7.5.2 In the event of a vacancy in the office of President, the office shall be occupied by the Vice President until a nominee has been confirmed by the Medical Staff and approved by the Board of Directors. The office of Vice President shall be occupied by the Assistant Vice President until a nominee has been confirmed by the Medical Staff and approved by the Board of Directors. The office of Assistant Vice President shall be occupied by a Medical Staff Member appointed by the Medical Executive Committee. Such persons shall hold the offices specified until a successor President has been selected. The Vice President and Assistant Vice President shall resume their positions.

7.5.3 If the Vice President of the Medical Staff is nominated and confirmed to fill a vacancy in the office of President of the Medical Staff, a successor Vice President of the Medical Staff shall be nominated and confirmed. If the Assistant Vice President of the Medical Staff is nominated and confirmed to fill a vacancy in the office of the President of the Medical Staff or Vice President of the Medical Staff, a successor Assistant Vice President of the Medical Staff shall be nominated and confirmed.

7.5.4 In the event of a vacancy in the office of Immediate Past President of the Medical Staff, the President of the Medical Staff shall appoint a Member in the Active category who is also a Past President of the Medical Staff to assume the duties of Immediate Past President until a President of the Medical Staff leaves office and assumes the office of Immediate

Past President of the Medical Staff. The President of the Medical Staff leaving office shall assume the office of Immediate Past President of the Medical Staff following appointment by the Medical Executive Committee and approval of the Board.

7.6 Removal

A Medical Staff officer may be removed from office by:

- 7.6.1 a two-thirds vote of the Medical Executive Committee at the meeting acting on its own initiative;
- 7.6.2 a petition signed by at least two-thirds of the Members of the Active category of the Medical Staff with full status; or
- 7.6.3 a majority vote of the Board of Directors present at the meeting acting on its own initiative.

7.7 Grounds for Removal

Grounds for removal of an elected officer include:

- 7.7.1 Revocation of professional license by the authorized State Board;
- 7.7.2 Suspension from the Medical Staff;
- 7.7.3 Failure to perform the required duties of office;
- 7.7.4 Failure to adhere to professional ethics;
- 7.7.5 Failure to comply with or support enforcement of the Hospital and Medical Staff Bylaws, Rules and Regulations and Hospital policies;
- 7.7.6 Failure to maintain the stated limits for professional liability insurance;
- 7.7.7 Failure to remain in the Active category; or
- 7.7.8 Inability or unwillingness to continue in office.

7.8 Duties of Officers

- 7.8.1 President of the Medical Staff - Duties include:
 - 7.8.1.1 Serve as the Chief Administrative Officer of the Medical Staff;
 - 7.8.1.2 Preside at all meetings of the entire Medical Staff;
 - 7.8.1.3 Supervise, coordinate, and facilitate the activities of the Medical Staff, including effective functioning of its committees;
 - 7.8.1.4 Serve as liaison between the Medical Staff, Hospital administration and the Board of Directors in all matters of mutual concern affecting the Hospital;

- 7.8.1.5 Enforce the Medical Staff Bylaws, the Rules and Regulations and the Hospital's policies and procedures;
 - 7.8.1.6 Serve as an Ex-Officio, non-voting member of all Medical Staff committees, including the Medical Executive Committee. The President of the Medical Staff shall, however, vote in the event of a tie;
 - 7.8.1.7 Serve as chair of the Medical Executive Committee;
 - 7.8.1.8 Serve as a member of the Board of Directors;
 - 7.8.1.9 Implement the policies of the Board of Directors;
 - 7.8.1.10 Report on all other matters affecting the Medical Staff to the Board of Directors;
 - 7.8.1.11 Serve as a spokesman for the Medical Staff;
 - 7.8.1.12 Intervene, when required, in patient care during a Department Chair's absence;
 - 7.8.1.13 Oversee the functioning of hearings, as described in the Bylaws or these Rules;
 - 7.8.1.14 Appoint members to all Medical Staff committees and Hospital committees requiring Medical Staff representation, as required in these Bylaws. In all such appointments, the President of the Medical Staff may consult with the Department Chair affected;
 - 7.8.1.15 Take those actions necessary, in conjunction with the Chief Executive Officer, to ensure the orderly functioning of the Medical Staff and the proper provision of patient care; and
 - 7.8.1.16 Perform such other duties as set forth in these Bylaws, these rules, or as may be delegated by the Medical Executive Committee and/or the Board of Directors.
- 7.8.2 Vice President of the Medical Staff - Duties include:
- 7.8.2.1 Assume all duties and have the authority of the President of the Medical Staff during his absence;
 - 7.8.2.2 Serve as a member of the Medical Executive Committee;
 - 7.8.2.3 Serve as a member of the Board of Directors;
 - 7.8.2.4 Serve as chair of the Credentials Committee; and
 - 7.8.2.5 Perform such other duties as set forth in the Bylaws, these Rules, or as may be delegated by the President of the Medical Staff, the Medical Executive Committee and/or the Board of Directors.
- 7.8.3 Assistant Vice President of the Medical Staff - Duties include:
- 7.8.3.1 Serve as a member of the Medical Executive Committee;

- 7.8.3.2 **Serve as a member of the Credentials Committee; and**
- 7.8.3.3 **Perform such other duties that are customary for the office and as are set forth in the Bylaws, these Rules, or as may be delegated by the President of the Medical Staff, the Medical Executive Committee and/or the Board of Directors.**
- 7.8.4 **Immediate Past President of the Medical Staff - Duties include:**
 - 7.8.4.1 **Serve as a member of the Medical Executive Committee;**
 - 7.8.4.2 **Serve as chair of the Nominating Committee;**
 - 7.8.4.3 **Serve as chair of the Professional Conduct Committee;**
 - 7.8.4.4 **Serve as member of Credentials Committee; and**
 - 7.8.4.5 **Perform such other duties as set forth in the Bylaws, these Rules, or as may be delegated by the Medical Executive Committee and/or the Board of Directors.**

8.0 QUALIFICATIONS FOR MEDICAL STAFF MEMBERSHIP AND CLINICAL PRIVILEGES

Section 5.0 of the Bylaws sets out requirements and qualifications for Medical Staff Membership and Clinical Privileges. This Rule will more specifically describe such requirements and qualifications in the areas listed below.

8.1 Education and Experience

- 8.1.1 Each Physician must provide evidence of having completed a residency training program in his specialty approved by the American Council of Graduate Medical Education or the American Osteopathic Association.
- 8.1.2 Physician who is qualified, may be appointed Membership and/or granted Clinical Privileges provided he obtain certification by one of the American Board of Medical Specialties (ABMS) or Bureau of Osteopathic Specialists (BOS) within five years of completing required training. If ABMS or BOS board certification is not obtained within five (5) years of completion of residency training, the Physician will voluntarily relinquish his Membership and/or Clinical Privileges, and he may not reapply until the ABMS or BOS board certification is obtained.
- 8.1.3 Physicians who hold Medical Staff Membership and/or specific departmental Clinical Privileges as of June 30, 2009 shall be exempt from the board certification requirements in 8.1.2 above. If a Physician requests additional Clinical Privileges, or if Clinical Privileges have lapsed, then the current credentialing criteria must be met.
- 8.1.4 If the Physician is on staff as of June 30, 2013 and has ABMS or BOS certification, that certification must be maintained to retain Membership and Clinical Privileges on the medical staff. If the physician allows the certification to expire, the Physician will have two (2) years to regain his board certification. If board certification is not obtained within that time period, the physician will voluntarily relinquish his Membership and/or Clinical Privileges, and he may not reapply until the ABMS or BOS board certification is obtained. The preceding requirement to maintain current board certification status on or after the date specified above shall not be subject to any grandfathering provision. This provision 8.1. shall not apply to Physicians who have been grandfathered according to 8.1.3 or who have allowed their board certification to expire before the date specified above.
- 8.1.5 Each department may establish criteria for Clinical Privileges that specify different ABMS or BOS board certification requirements as long as these requirements are not less stringent than those specified in this section.
- 8.1.6 Dentists must provide evidence of graduation from a school of dentistry accredited by the Commission on Dental Accreditation, a certificate evidencing completion of an Advanced Dental Education Program (ADEP) accredited by the Commission on Dental Accreditation, current certification by a board recognized by the American Dental Association (ADA), and a valid Texas license to practice dentistry issued by the Texas State Board of Dental Examiners.
- 8.1.7 Within five (5) years of completion of the ADEP specified in 8.1.5, a Dentist who is not certified by a board recognized by the ADA, but who is otherwise qualified, may be appointed Membership and/or granted Clinical Privileges provided that he obtain board certification within five (5) years of completion of the ADEP. If board certification is not obtained within five (5) years of completion of ADEP, the Dentist will voluntarily

relinquish his Membership and/or Clinical Privileges, and he may not reapply until the board certification is obtained.

- 8.1.8 If the Dentist allows the certification to expire, the Dentist will have two (2) years to regain his board certification. If board certification is not obtained within that time period, the Dentist will voluntarily relinquish his Membership and/or Clinical Privileges, and he may not reapply until the required board certification is obtained.
- 8.1.9 Podiatrists must provide evidence of graduation from a school of podiatric medicine accredited by the Council on Podiatric Medical Education (CPME), a certificate evidencing completion of a residency program approved by the CPME, current certification by a board recognized CPME, and a valid Texas license to practice podiatric medicine issued by the Texas State Board of Podiatric Medical Examiners.
- 8.1.10 Within five (5) years of completion of the residency program specified in 8.1.9, a Podiatrist who is not certified by a board recognized by the CPME, but who is otherwise qualified, may be appointed Membership and/or granted Clinical Privileges provided that he obtain board certification within five (5) years of completion of the residency program. If board certification is not obtained within five (5) years of completion of the residency program, the Podiatrist will voluntarily relinquish his Membership and/or Clinical Privileges, and he may not reapply until the board certification is obtained.
- 8.1.11 If the Podiatrist allows the certification to expire, the Podiatrist will have two (2) years to regain his board certification. If board certification is not obtained within that time period, the Podiatrist will voluntarily relinquish his Membership and/or Clinical Privileges, and he may not reapply until the required board certification is obtained.

8.2 Current Clinical Competence

- 8.2.1 Each Department shall establish current clinical competence requirements for Clinical Privileges.
- 8.2.2 In circumstances where the current clinical competence requirement is not met, the physician may be requested by the Medical Executive Committee to:
 - 8.2.2.1 Participate in a physician assessment program affiliated with the Coalition for Physician Enhancement and
 - 8.2.2.2 Show documentation of completion of any recommendations for retraining by the physician reentry program.

8.3 Foreign Medical School Graduates

Physicians who are foreign medical school graduates, other than graduates of Canadian medical schools, must have attained a passing score on the Educational Council for Foreign Medical Graduates (ECFMG) examination, obtain an ECFMG certificate, and pass any other examination which may be required by the Texas Medical Board.

8.4 English Language

A Practitioner must be able to demonstrate that he can read and understand the English language, communicate effectively in writing and verbally in the English language and prepare medical record entries in a complete, timely, accurate and (if hand-written) legible manner.

9.0 PROFESSIONAL LIABILITY INSURANCE

- 9.1 Every Member and/or Practitioner, at the time of Application and continuously thereafter, must maintain professional liability insurance and meet the following standards.**
- 9.1.1 Each Applicant, Medical Staff Member and Practitioner, other than a Member in the Retired or Honorary categories, must have and maintain and provide proof of his current professional liability insurance policy in such form and with such limits as determined from time to time by the Board of Directors. These amounts are \$100,000 per occurrence and \$300,000 in the aggregate. These amounts are subject to change in accordance with these Rules and Regulations and the Medical Staff Bylaws.**
 - 9.1.2 If coverage can only be obtained by means of a "claims made policy," the Practitioner shall acquire a policy or policies of insurance which would provide coverage for all times when a claim may arise, whether by purchasing Prior Acts Coverage**
 - 9.1.3 When requested, each Member and/or Practitioner shall provide a copy of his r current professional liability insurance policy, the policy face sheet, or other evidence specifying policy limits and coverage provided by the professional liability insurance carrier.**
 - 9.1.4 Any Member and/or Practitioner who does not maintain or provide proof of professional liability insurance as required by these Bylaws may not admit or treat patients in the Hospital and shall be subject to automatic suspension of Membership and/or Clinical Privileges.**

10.0 PROCESS FOR MEDICAL STAFF APPOINTMENT AND GRANTING OF CLINICAL PRIVILEGES

10.1 Complete Application

Appointment to the Medical Staff and granting of Clinical Privileges is governed by Section 6.0 of the Bylaws. In accord with sub-sections of Section 6.0 of the Bylaws, including sub-section 6.2, Applicants must provide a Complete Application. An Application will only be considered complete when the following items have been submitted and/or verified by the Medical Staff office:

- 10.1.1 A Complete Credentialing Application, including appropriate Request for Clinical Privileges form(s), with all questions answered and all supporting documents furnished;
- 10.1.2 A current Texas license to practice and a current DEA Certificate may be required. If the applicant does not have a DEA or has restrictions on his license or certificate, an explanation must be provided.
- 10.1.3 A copy of the Applicant's current professional liability insurance policy, or policy face sheet or other evidence, if the face sheet or other evidence specifies policy limits and coverage, and a claims history for the immediately preceding five (5) years or for the period of time the Applicant has been licensed to practice, whichever is less, provided by the Applicant's professional liability insurance carrier;
- 10.1.4 Certificates or letters confirming completion of an approved residency or training program as required by these Bylaws;
- 10.1.5 Certificate(s) or a letter(s) from appropriate specialty board(s) of board eligibility or board certification;
- 10.1.6 Three (3) professional references forwarded directly to the Medical Staff office from peers who have recently worked with the Applicant and directly observed his professional performance. Each letter must provide reliable and specific information regarding the Applicant's current clinical competence, ethical character, and ability to work with others;
- 10.1.7 Evaluations from all other health care facilities where the Applicant exercises clinical privileges, except that at least ten (10) random affiliations will be verified for telemedicine Applicants who have more than ten (10) affiliations;
- 10.1.8 Any other information or documents which may be requested regarding the Applicant's current clinical competence and professional qualifications;
- 10.1.9 Response/explanation of the following:
 - 10.1.9.1 Challenges to any license or registration;
 - 10.1.9.2 Voluntary or involuntary relinquishment of any license or registration;
 - 10.1.9.3 Voluntary or involuntary termination of medical staff membership;
 - 10.1.9.4 Voluntary or involuntary limitation, reduction, or loss of clinical privileges;
 - 10.1.9.5 Final judgments or settlements; and

- 10.1.9.6 Any requests for additional information made by the Credential's Committee.
- 10.1.10 Completion of an immunization status/immunity status form. Telemedicine physicians shall be exempt from this requirement.
- 10.1.11 Other forms as required.
- 10.1.12 Any other information required by law to be obtained.
- 10.1.13 Application fee as set by the Medical Executive Committee.
- 10.1.14 Consent to criminal background check report.
- 10.1.15 The results of an interview with the applicant.
- 10.1.16 Completion of a TB symptom screening which will include questions regarding Tuberculosis (TB) infection history and previous TB test results and obtain TB screening as follows:
 - 10.1.16.1 TST or IGRA
 - 10.1.16.1.1 TST or IGRA must have been completed within the last twelve (12) months;
 - 10.1.16.1.2 If TST is positive, then IGRA is required;
 - 10.1.16.1.3 If IGRA is positive, then a chest x-ray will be obtained;
 - 10.1.16.1.3.1 If the chest x-ray shows evidence of active TB infection, then the applicant will be referred to the Texas Department of State Health Services (DSHS) and must comply with DSHS directives for treatment and patient contact;
 - 10.1.16.1.3.2 If chest x-ray completed and is negative, then the Applicant will complete the TB symptom screening at each reappointment.
 - 10.1.16.2 If exposed to TB and had a previous negative TB test result, a symptom screen will be completed along with TB test;
 - 10.1.16.2.1 If TST is positive, then IGRA is required.
 - 10.1.16.2.2 If TB test is negative, repeat in 8-10 weeks.
 - 10.1.16.2.3 If exposed to TB and had a documented history of a positive IGRA result, they will complete a TB symptom screen. If symptoms develop, they will be evaluated for TB disease.

10.1.16.2.4 Telemedicine physicians are exempt from this requirement.

10.2 Verification of Information

The Medical Staff office shall collect all information necessary to verify an Applicant's professional qualifications and/or clinical competence. The completed Application with verified information shall be forwarded to the Department Chair.

10.3 Processing the Application

10.3.1 After verification, the Medical Staff Office will forward the Application to the chair of the Applicant's Department.

10.3.2 After the Department Chair reviews the Application, including any requests for Clinical Privileges, his recommendations will be forwarded to the Credentials Committee. A Department Chair may, at his discretion, interview any Applicant.

10.3.3 At its next meeting, the Credentials Committee shall review the Application and all other documentation provided and obtain such additional information as it deems necessary. At its discretion, the Committee may request an interview with the Applicant. Once its review is completed, the Credentials Committee shall submit its recommendation to the Medical Executive Committee.

10.3.4 At its next meeting, the Medical Executive Committee shall review the Application and all previous findings and recommendations. Once its review is completed, the Medical Executive Committee shall submit the Application and its recommendation to the Board of Directors. If the Medical Executive Committee recommends a Professional Review Action, the Applicant shall be entitled to the procedural protections described in Sections 9 and 10 of the Bylaws.

10.3.5 At its next meeting, the Board of Directors shall review and consider the Application and all previous findings and recommendations. Once its review is completed, the determination of the Board of Directors shall be final. The Chief Executive Officer shall promptly notify each Applicant in writing of the determination of the Board of Directors regarding his Application. If the Board of Directors recommends a Professional Review Action, the Applicant shall be entitled to the procedural protections described in Sections 9 and 10 of the Bylaws.

11.0 PROCTORING

11.1 Proctoring

The purpose of the proctoring program is to assess first-hand the competence of Medical Staff Members. Proctoring may be required in the following circumstances:

- 11.1.1 To assess competence under Focused Professional Practice Evaluation (FPPE);
- 11.1.2 To assess competence under Ongoing Professional Practice Evaluation (OPPE);
- 11.1.3 As part of the eligibility requirements for certain special privileges;
- 11.1.4 As part of a recommendation from the Centralized Performance Improvement Committee (CPI);
- 11.1.5 As part of a recommendation from the Medical Executive Committee;
- 11.1.6 As part of a requirement from the Board of Directors.

11.2 Proctors

- 11.2.1 A list of eligible staff Proctors will be provided by the Medical Staff Services Office to the practitioner being proctored.
- 11.2.2 Each Medical Staff Practitioner in the active or non-voting category is eligible to participate in the proctoring program by being available to serve as proctors.
- 11.2.3 A Proctor shall be a Medical Staff Practitioner who:
 - 11.2.4.1 Where possible, is not associated in practice with the Practitioner being proctored;
 - 11.2.4.2 Does not have a physician-patient relationship with the patient who is the subject of the proctored procedure;
 - 11.2.4.3 Does not anticipate, nor will receive, remuneration for his services as a Proctor; and
 - 11.2.4.4 Possess the clinical privileges to perform the procedure(s) being proctored.
- 11.2.5 The Proctor is present as an observer. Except as otherwise provided in Rule 11.2.10, the Proctor is not present to consult, advise or assist in the care of the patient.
- 11.2.6 Proctors serving within the scope of the proctoring program as described in this Rule 11 will be afforded protection from liability in accordance with the terms and conditions of the AdventHealth Risk Management Self- Insured Trust Agreement.
- 11.2.7 Responsibilities of Proctored Practitioner
 - 11.2.7.1 The Practitioner being proctored may provide documentation of proctored cases at another area hospital.

- 11.2.7.2 Each Practitioner shall be responsible for obtaining the required number of proctored procedures. A Practitioner requiring a Proctor shall be responsible for scheduling his procedure to accommodate the Proctor. Where no Proctor is available in a reasonable period of time, the Department Chair shall be contacted for assistance in obtaining a Proctor. However, no procedure shall be performed until a Proctor is available, unless the procedure is an emergency or unless approved by Departmental policy.
- 11.2.8 Emergencies
 - 11.2.8.1 In the event that a Proctor cannot be present for an emergency procedure on short notice, the initial appointee shall notify the Proctor of the emergency procedure, noting the patient's name and medical record number.
 - 11.2.8.2 The Proctor shall review the record of the emergency cases within five (5) working days of the procedure. He may also wish to speak to other individuals who were present during the procedure. He shall complete the Proctor's Report Form and submit it to Medical Staff Services.
- 11.2.9 Proctor's Report
 - 11.2.9.1 Following completion of the proctored case, the Proctor shall complete a Proctor's Report as soon as possible and submit the report to the Medical Staff Services Office. It is the responsibility of the Practitioner being proctored to determine that the form has been completed and returned.
 - 11.2.9.2 The Proctors will observe and critique each case according to the criteria on the evaluation form. Any additional information that the Proctor feels appropriate is to be added to the back of the form. The Proctor is not to assist, consult, write in or otherwise alter or add to, the patient's medical record. Should the Proctor feel that the care being rendered is substandard or inadequate he should immediately notify the Department Chair. The case will then be forwarded to the Centralized Performance Improvement Committee and Credentials Committee for review and action.
- 11.2.10 Emergency Action by the Proctor
 - 11.2.10.1 It is anticipated that a Proctor shall only observe. However, in the event there appears to be imminent compromise to patient safety, the Proctor may intervene. If time allows, a consultant may be obtained.
 - 11.2.10.2 If a Proctor intervenes in a proctored procedure, he shall promptly assume control of the procedure. If necessary for patient care, the Proctor may permit the Practitioner being proctored to assist in completing the procedure and/or stabilizing the patient.

12.0 PROCESS FOR REAPPOINTMENT TO THE MEDICAL STAFF

12.1 Application for Reappointment and/or Clinical Privileges

No later than one hundred eighty (180) days prior to the expiration of a Member's Medical Staff Appointment and/or expiration of a Practitioner's Clinical Privileges, the Medical Staff office shall provide each Member with an Application for Reappointment to the Medical Staff, and each Practitioner with an Application for Clinical Privileges. The appropriate Application, including the following documents, shall be returned to the Medical Staff Office no less than sixty (60) days prior to the expiration of his term. Failure to submit a complete, timely application will result in the expiration of Membership and/or Privileges, and the Member and/or Practitioner is not eligible to submit another application for a period of one (1) year following the date of withdrawal from processing.

- 12.1.1 A Complete Credentialing Application, updating all information provided on the previous Application;
- 12.1.2 A completed Request for Clinical Privileges form, if appropriate, including the basis for any change in Clinical Privileges requested;
- 12.1.3 Continuing medical education activities during the previous appointment period;
- 12.1.4 A copy of the face sheet of the Applicant's professional liability insurance policy specifying policy limits and coverage in the amounts required by the Board of Directors, including a claims history since the previous Application;
- 12.1.5 Evaluations from all other health care facilities where the Applicant exercises clinical privileges, except that at least ten (10) random affiliations will be verified for telemedicine Applicants who have more than ten (10) affiliations;
- 12.1.6 Completion of a TB symptom screening which will include questions regarding Tuberculosis (TB) infection history and previous TB test results.
 - 12.1.6.1 If exposed to TB and had a previous negative TB test result, a symptom screen will be completed along with TB test;
 - 12.1.6.1.1 If TST is positive, then IGRA is required
 - 12.1.6.1.2 If TB test is negative, repeat in 8-10 weeks
 - 12.1.6.1.3 If exposed to TB and had a documented history of a positive IGRA result, they will complete a TB symptom screen. If symptoms develop, they will be evaluated for TB disease.
 - 12.1.6.1.4 Telemedicine physicians are exempt from this requirement.
- 12.1.7 A completed immunization status/immunity status form (Telemedicine physicians shall be exempt from this requirement); and,
- 12.1.8 Other forms as required.

12.2 Processing the Application for Reappointment

The Medical Staff Office shall obtain the information and documents specified below regarding each Member and/or Practitioner before processing the Application. Each Member and/or Practitioner shall remain responsible for providing the Medical Staff Office with a complete Application and shall provide the information and documents requested. An application is not considered complete until the following items are received:

- 12.2.1 Verification of Applicant's current Texas license to practice, which may require that a copy be provided;
- 12.2.2 Evaluations from all other health care facilities where the Applicant exercises clinical privileges, except that at least ten (10) random affiliations will be verified for telemedicine Applicants who have more than ten (10) affiliations;
- 12.2.3 Evaluations or reports or reviews regarding the clinical performance, quality of care and conduct of Applicant;
- 12.2.4 A summary of clinical activity and medical staff service hours during the previous appointment period, including the parameters specified in section 5.9 of the Bylaws as necessary for Membership category assignment;
- 12.2.5 Current information regarding the Applicant available from the National Practitioner Data Bank and other relevant state board(s), organizations, or agencies;
- 12.2.6 The results of an interview with the Applicant (held at the discretion of the Credentials Committee or Medical Executive Committee);
- 12.2.7 Verification of DEA Certificate, which may require that a copy be provided;
- 12.2.8 Addresses of office and residence;
- 12.2.9 Current physical and mental condition;
- 12.2.10 All other information regarding the Applicant relevant to his Application;
- 12.2.11 Evidence of current professional liability insurance conforming with the requirements of the Bylaws and these Rules and Regulations;
- 12.2.12 Ongoing and focused professional practice evaluations (when applicable);
- 12.2.13 Response/explanation of the following:
 - 12.2.13.1 Challenges to any license or registration;
 - 12.2.13.2 Voluntary or involuntary relinquishment of any license or registration;
 - 12.2.13.3 Voluntary or involuntary termination of medical staff membership;
 - 12.2.13.4 Voluntary or involuntary limitation, reduction, or loss of clinical privileges;
 - 12.2.13.5 Final judgments or settlements; and

12.2.14 Any requests for additional information made by the Credentials Committee; and

12.2.15 Any other information required by law to be obtained.

12.3 Procedure for Reappointment

12.3.1 After verification, the Medical Staff Office will forward the Application to the chair of the Applicant's Department.

12.3.2 After the Department Chair reviews the Application, including any requests for Clinical Privileges, his recommendations will be forwarded to the Credentials Committee. A Department Chair may, at his discretion, interview any Applicant.

12.3.3 At its next meeting, the Credentials Committee shall review the Application and all other documentation provided and obtain such additional information as it deems necessary. At its discretion, the Committee may interview the Applicant. Once its review is completed, the Credentials Committee shall submit its recommendation to the Medical Executive Committee.

12.3.4 At its next meeting, the Medical Executive Committee shall review the Application and all previous findings and recommendations. Once its review is completed, the Medical Executive Committee shall submit the Application and its recommendation to the Board of Directors. If the Medical Executive Committee recommends a Professional Review Action, the Applicant shall be entitled to the procedural protections described in Sections 9 and 10 of the Bylaws.

12.3.5 At its next meeting, the Board of Directors shall review and consider each Application and all previous findings and recommendations. Once its review is completed, the determination of the Board of Directors shall be final. The Chief Executive Officer shall promptly notify each Applicant in writing of the determination of the Board of Directors regarding his Application. If the Board of Directors recommends a Professional Review Action, the Applicant shall be entitled to the procedural protections described in Sections 9 and 10 of the Bylaws.

13.0 LEAVE OF ABSENCE

13.1 Mandatory

Any Practitioner who will not be engaged in the Practitioner's customary or usual professional practice for longer than 45 consecutive days must take a Leave of Absence (LOA) in accordance with this Section. A Leave of Absence is not a surrender or relinquishment of Clinical Privileges.

13.2 Types of LOA

13.2.1 **Medical Leave of Absence.** A Practitioner may request and be granted a LOA for the purpose of evaluation and/or obtaining treatment for a health condition. If the Practitioner is unable to make his own request due to health reasons or unavailability, a member of the Practitioner's practice and/or spouse/first degree relative may make such a request on behalf of the Practitioner.

13.2.2 **Military Leave of Absence.** A Practitioner may request and be granted a LOA to fulfill military service obligations. In addition to a written request for the LOA, the Practitioner shall submit a copy of deployment/activation orders.

13.2.3 **Educational Leave of Absence.** A Practitioner may request and be granted a LOA to pursue additional education and training. Any additional Clinical Privileges that may be desired upon the successful conclusion of additional education and training must be requested in accordance with the Bylaws and/or Rules and Regulations.

13.2.4 **Personal Leave of Absence.** A Practitioner may request and be granted a LOA for personal reasons (e.g., to pursue a volunteer endeavor such as contributing work to "Doctors Without Borders/USA") or family reasons (e.g., maternity leave).

13.2.5 **Administrative Leave of Absence.** The President of the Medical Staff and Hospital President/CEO or designee(s), have the ability and authority to place a Practitioner on an Administrative LOA if a Practitioner is unable to notify Medical Staff Services of a request for LOA on his own due to emergent and unexpected circumstances. Placement on an Administrative LOA is not Corrective Action. The Practitioner will be notified of the Administrative LOA in writing by the President of the Medical Staff within five business days from the date of the LOA and such notification shall include the inclusive dates of the LOA. This LOA will terminate upon the next scheduled MEC meeting unless the Medical Executive Committee continues the Administrative LOA.

13.3 Process for Requesting LOA and Failure to Request

13.3.1 A Leave of Absence must be requested in advance specifying the type of leave requested and the requested duration. The request must be submitted to President of the Medical Staff by delivery to Medical Staff Services. Following recommendation by the Medical Executive Committee, the Board of Directors may grant a Practitioner a Leave of Absence under Article 13.0.

13.3.2 Failure to secure a Leave of Absence when required shall result in automatic relinquishment of Medical Staff Membership and/or Clinical Privileges on notice of the failure to the Medical Executive Committee, until the practitioner provides documentation of leave per 13.0, unless there is a finding by the Medical Executive Committee that emergent and unexpected circumstances as provided in Article 13.0

prevented submission of a request for the LOA. In such case, the Practitioner shall be placed on an Administrative LOA in accordance with that section.

13.4 Duration of LOA and Extension

A LOA may be requested for up to one year at a time and may be renewed one time only for up to an additional year. A Military LOA shall be for the period of deployment but not to exceed duration previously listed.

13.5 Status of Practitioner While on LOA

13.5.1 Unless sufficient extenuating circumstances (e.g., immediate military deployment/activation) preclude it, the Practitioner shall be responsible for completing all medical records for patients the Practitioner cared for before the LOA.

13.5.2 The Practitioner on LOA is responsible for arranging call coverage for the Practitioner's assigned Emergency Department Call unless sufficient extenuating circumstances preclude it (in which case the Department Chair shall resolve the issue). The Practitioner also is responsible for arranging coverage for any current inpatients, as well as coverage (or providing notification of alternatives) for care for the Practitioner's private practice in accordance with accepted standards of professional practice. The Practitioner will notify Medical Staff Services of the Practitioner's designated call and coverage substitutes.

13.5.3 During the LOA, the Practitioner shall not admit patients, exercise Clinical Privileges, or vote or hold Medical Staff office. Further, the Practitioner may not take Emergency Department call or serve as a proctor. The Medical Staff Department Chair or President of the Medical Staff will determine whether a Practitioner's LOA constitutes a vacancy on a committee and, if so, assign an alternate or fill the vacancy if required in these Bylaws.

13.6 LOA and Reappointment

13.6.1 A Member and/or Practitioner must submit an Application for Reappointment should his reappointment expire during his LOA. If the Member and/or Practitioner does not submit an Application prior to the end of his reappointment period, or does not submit a request for reinstatement of Membership and/or Privileges, then the Member and/or Practitioner will be considered to have voluntarily resigned.

13.7 Requesting Reinstatement

13.7.1 To request reinstatement, the Practitioner must file a written request not later than thirty days (30) prior to the requested date of reinstatement or the end of the LOA. The reinstatement request shall include any required information concerning the Practitioner's activities, professional or otherwise, during the LOA, and enable verification of continued compliance with the qualifications set out below.

13.7.2 The Practitioner must also:

13.7.2.1 Provide sufficient information that the Practitioner currently meets all of the qualifications for Medical Staff membership as set forth in Articles 5 of the Medical Staff Bylaws and Article 8 of the Medical Staff Rules and Regulations;

13.7.2.2 Demonstrate that the Practitioner meets the qualifications as set forth in Article 6 of the Medical Staff Bylaws for all Clinical Privileges for which the Practitioner is requesting reinstatement; and

13.7.2.3 Agree to provide all requested documentation and other information to allow the appropriate Medical Staff committees and Board of Directors to verify that the matter that necessitated the LOA has been resolved and that no other events have occurred during the LOA that could affect the Practitioner's ability to practice before the Practitioner is eligible for reinstatement.

13.8 Reinstatement Procedures

13.8.1 Expedited Approval Process

The President of the Medical Staff and/or, the Credentials Committee Chair, and either the Hospital President/CEO or designee together shall have the discretion to approve a reinstatement request on an expedited basis. However, any expedited approval process decision is subject to the Medical Executive Committee and Board of Director's determination at their next meetings.

13.8.2 The Credentials Committee, after consultation with the Practitioner's Department Chair, shall review the reinstatement request and any supporting documentation at its next meeting, and may conduct a personal interview with the Practitioner. After the reviews the reinstatement request and accompanying documentation, one of the following steps shall be taken:

13.8.2.1 The Credentials Committee shall issue a recommendation as to reinstatement and whether any conditions or limitations are recommended, with a statement of the reasons for any denial of reinstatement or conditions or limitations. Its recommendation shall be forwarded to the Medical Executive Committee.

13.8.2.2 In the case of any Medical LOA or other reinstatement request the Credentials Committee deems appropriate, the Credentials Committee shall refer to the request with its recommendation to the Physician Health Committee to be reviewed as provided in Medical Staff policy MS1007. The Physician Health Committee's recommendation regarding reinstatement and any recommendation of the Credentials Committee shall be forwarded to the Medical Executive Committee.

13.8.3 Medical Executive Committee

At its next meeting, the Medical Executive Committee shall review the reinstatement request and the recommendation of the Credentials Committee, as well as the recommendation of the Physician Health Committee if applicable. The Medical Executive Committee may conduct a personal interview with the Practitioner. The Medical Executive Committee shall issue a recommendation to the Board of Directors as to whether reinstatement should be granted and any conditions or limitations that should apply. If reinstatement is not recommended or any conditions or limitations are recommended, a statement of the reasons for such shall be included.

13.8.3.1 If the recommendation of the Medical Executive Committee is an Adverse

Recommendation or Action, the President of the Medical Staff shall provide the Practitioner with Special Notice of the recommendation as provided in Article 9 of the Medical Staff Bylaws and all further procedures shall be as set forth in that Article.

- 13.8.3.2 If the recommendation of the Medical Executive Committee is not an Adverse Recommendation of Action, it shall be forwarded with any supporting documentation to the Board of Directors for review.

13.8.4 Board of Directors

The Board of Directors shall review the recommendations from the involved committees and individuals listed above and issue its recommendation at its next meeting. If reinstatement is not approved, or there are conditions or limitations on reinstatement, a statement of the reasons for such shall be included in the recommendation.

- 13.8.4.1 If the recommendation of the Board of Directors is an Adverse Recommendation or Action, the Hospital President/CEO shall provide the Practitioner with Special Notice of the recommendation as provided in Article 9 of the Medical Staff Bylaws and all further procedures shall be as set forth in that Article.

- 13.8.4.2 If the recommendation of the Board of Directors is not an Adverse Recommendation or Action, it shall be the final decision of the Board of Directors. The Hospital President/CEO shall notify the Practitioner in writing within fourteen (14) days of the decision.

13.8.5 Failure to Request Reinstatement

If a Practitioner fails to request reinstatement as required above, or to provide all required documentation and information to process the request, the Practitioner's Medical Staff Membership and/or Clinical Privileges shall automatically expire on the last day of the LOA and the Practitioner must file an application for initial appointment.

13.8.6 Procedural Rights of Review

There are no procedural rights of review under these Rules and Regulations or otherwise for failure to grant a request for a LOA, failure to grant an extension of a LOA, or expiration of Medical Staff Membership and/or Clinical Privileges due to failure to timely request reinstatement or provide all required documentation and information to enable processing of the request.

14.0 ADMISSION, DISCHARGE AND PATIENT CARE

14.1 General

14.1.1 Who May Admit

14.1.1.1 Only Practitioners with admitting Privileges may admit patients to the hospital.

14.1.1.2 Dentists and Podiatrists - Dentists and podiatrists may consult on patients in accordance with the Bylaws and Rules and Regulations.

14.1.2 No Discrimination - No person in need of available Hospital services shall be denied access on the basis of sex, race, creed, color, national origin, or method of payment.

14.1.3 Types of Admissions

Each patient who is to be treated at the Hospital shall be admitted to the Hospital as one of the following types of admissions: (i) Emergency; (ii) Urgent; (iii) Elective; and (iv) Newborn.

14.1.3.1 Emergency Admission: A patient is an emergency admission if he has an Emergency Medical Condition. An Emergency Medical Condition is a medical condition manifesting itself by acute symptoms of sufficient severity, including severe pain, where the absence of immediate medical attention could result in placing the individual's health in serious jeopardy or serious impairment of bodily functions or serious dysfunction of any bodily part or organ or, in the case of a pregnant female with contractions, inadequate time exists to effect a safe transfer of the patient to another healthcare facility without endangering the health of the mother or unborn child.

14.1.3.2 Urgent Admission: A patient is an urgent admission if he does not have an Emergency Medical Condition, but his medical condition would worsen if he were not hospitalized promptly.

14.1.3.3 Elective Admission: All elective admissions not included in the categories of Urgent Admission or Short-Term Stay Admission.

14.1.3.4 Newborn: A patient born in the hospital at the beginning of his current inpatient hospitalization.

14.1.4 Restraint and Seclusion - An order to place a patient in restraints or seclusion will be in accord with hospital policy.

14.2 General Responsibilities

Each Practitioner shall comply with all requirements of the Medical Staff Bylaws, these Rules and Regulations and all rules and policies and procedures of the Hospital.

14.2.1 Performance Improvement

Each Practitioner shall cooperate with each committee of the Hospital and the Medical Staff and the members, employees and agents of each committee to accomplish the purposes of the committee.

14.2.2 Completion of Medical Records

Each Practitioner acknowledges and understands the importance of timely completing clear, accurate and (if hand-written) legible medical records and shall comply with all Hospital and Medical Staff requirements regarding medical records.

14.2.3 Care and Treatment of Patients

14.2.3.1 Each patient's Admitting Physician shall be and remain the patient's Attending Physician and shall remain responsible for the medical care of each patient he treats in the Hospital until the patient is discharged or until the responsibility for the medical care and treatment of the patient is transferred to another Physician Practitioner. Such responsibility shall include, but not be limited to, informed consent, the prompt and accurate completion of each patient's medical record, issuance of all orders, and the proper and prompt completion and transmittal of all reports concerning the patient.

14.2.3.2 A Podiatrist or a Dentist may consult on a patient in the Hospital. The Attending Physician shall be responsible for the care and treatment of the patient while the patient is in the Hospital. The Podiatrist or Dentist shall be responsible, respectively, for the Podiatric or Dental care and treatment of the patient.

14.2.4 Admitting Responsibilities

14.2.4.1 Prior to admission, a physician shall complete and record a preliminary diagnosis or otherwise determine the basis for the admission.

14.2.4.2 The Admitting Physician shall be responsible to see the patient to ensure that a history and physical examination of the patient is completed within twenty-four (24) hours after admission according to the Bylaws and Rules and Regulations.

14.2.5 Transferring Responsibilities – Any transference of care of a patient in the hospital from the patient's Attending Physician to another Practitioner (Accepting Physician) must be documented. The Attending Physician shall be responsible for notifying and obtaining consent from the Accepting Physician which must be documented as an order by the Accepting Physician accepting the transference of care. The Attending Physician shall complete an order authorizing the transfer; however, the Attending Physician remains responsible for the medical care and treatment of the patient until the Accepting Physician is notified, consents and accepts transference of care, after which time the Accepting Physician becomes the patient's Attending Physician. Acceptance of transfer is completed when the Accepting Physician provides care to the patient as indicated by orders or other documentation in the medical record.

14.3 Coverage and Call Responsibilities

14.3.1 Practitioner Backup Coverage and Response Time

14.3.1.1 Each Attending Practitioner and Consulting Practitioner shall be responsible for the continuous care of his inpatients and outpatients. In the event of unavailability, each Attending Practitioner and Consulting Practitioner shall have another appropriately qualified Practitioner in his specialty with equivalent clinical privileges at the Hospital available to provide medical care and treatment for these patients.

- 14.3.1.2 The name of the Practitioner providing backup coverage shall be designated on the initial application and each reapplication and may be changed on written notice to Medical Staff Services. In addition to the designated backup coverage, the Practitioner may utilize call coverage to provide backup coverage provided call coverage Practitioner has clinical privileges at the Hospital.
- 14.3.1.3 The failure of any Practitioner to obtain or provide agreed backup coverage or to notify of his unavailability in accordance with MS1003 shall subject the Practitioner to Corrective Action.
- 14.3.1.4 Practitioners who are unable to secure backup coverage may petition for an exemption to this rule as part of the initial application or reapplication process.
- 14.3.1.5 All exemptions to backup coverage will be considered by the Medical Executive Committee on a case-by-case basis, giving primary consideration to the best interest of the patients of the hospital. Any exemption granted expires at the end of the credentialing period for which it was granted. Failure to grant an exemption is not considered an Adverse Action and does not entitle the Practitioner to any procedural rights of review under the Medical Staff Bylaws or otherwise.
- 14.3.1.6 A Practitioner (or his backup coverage) with an inpatient or outpatient for whom he is responsible must return a phone call from any Practitioner or Hospital personnel within thirty (30) minutes from the time the call is made. The Practitioner (or his backup coverage) shall physically attend a critical or unstable inpatient or outpatient for whom he is responsible within two (2) hours of notification unless the patient's condition necessitates earlier attendance.
- 14.3.1.7 If appropriate coverage is not available, or a Practitioner fails to respond to a request to attend to a patient, the Department Chair (or, in his absence, the President of the Medical Staff) shall be notified and designate another qualified Practitioner to provide medical care and treatment. A Practitioner's failure to respond shall be referred to the Centralized Performance Improvement Committee for review.

14.3.2 Obligations of Discharging Practitioner/Consulting Practitioner.

The Discharging Practitioner and any Consulting Practitioner(s) (or their backup coverage) of a patient admitted to the Hospital must admit and/or consult on that patient if that patient returns to the Emergency Department within thirty (30) days of discharge for the same condition as the previous admission or a related condition. This obligation shall not delay provision of an appropriate medical screening examination of the individual and stabilization of any emergency medical condition in the Emergency Department.

14.3.3 Hospital Emergency Specialty Call and Response Time.

14.3.3.1 The Governing Board following consultation with the Medical Executive Committee and in accordance with legal requirements shall determine what specialties will provide call coverage for the Hospital.

14.3.3.2 A specialty required to provide call coverage under Section 14.3.3.1 will establish the schedule pursuant to written policy subject to approval of the Medical Executive Committee and Board of Directors. No Practitioner shall be

required to provide call coverage in his specialty more than eleven (11) days per month unless done so voluntarily.

14.3.3.3 The schedule for call coverage shall follow MS1003. The Physician Practitioner on call may not require that an Advanced Practice Professional (APP) be contacted first before contacting the Practitioner on call or that an APP first examine all patients. The Practitioner may use the services of an APP if indicated for a particular patient.

14.3.3.4 A Practitioner providing call coverage under this Section must respond as per 14.3.1.6. If the on-call Practitioner does not respond within the specified timeframe, the incident shall be referred to the Centralized Performance Improvement Committee for review.

14.3.4 Coverage of Practitioner's Private Practice.

14.3.4.1 Section 14.3 applies to inpatients and outpatients receiving or presenting for medical care at the Hospital. It does not apply to coverage or backup for a Practitioner's private practice, although the Medical Staff expects Practitioners to arrange for such as part of their professional obligations. A practitioner providing call coverage or backup for a Practitioner's private practice is not required to have clinical privileges at the Hospital.

14.3.4.2 If an individual who is a patient of a Practitioner presents to the Emergency Department and requests that the Practitioner be notified, reasonable attempts will be made to do so. An appropriate medical screening examination of the individual and stabilization of any emergency medical condition will not be delayed to allow for such notice.

15.0 CONSULTATIONS

15.1 Consultation Request

15.1.1 Any Practitioner may consult with any other Practitioner regarding a matter in his specialty. The Practitioner on call for the Emergency Department must also take inpatient call for consultations if requested and must complete consultations within twenty-four (24) hours. Consultations must be requested, except in extreme emergencies, under the following conditions:

15.1.1.1 When patient's management requires skills either beyond the Practitioner's scope or not recently utilized;

15.1.1.2 Where there is doubt as to the choice of therapeutic measures to be utilized;

15.1.1.3 In unusually complicated situations where specific skills of Practitioners may be needed; and

15.1.1.4 When the Practitioners' Clinical Privileges limit his ability to provide the medical care and treatment needed by the patient.

15.2 Attending Physician's Responsibilities

15.2.1 The Attending Physician shall be responsible for notifying and consulting with qualified Consultants as necessary. The Attending Physician shall complete an order in the medical record authorizing the Consultant to consult and participate in the care and treatment of the patient; verbal request for consultation is not a substitution for a written consultation order. It is the Attending Physician's responsibility to be aware of the Consultant's recommendations. The Attending Physician remains responsible for the medical care and treatment of the patient.

15.2.2 When there are indications that the best interests of a patient will be served, the Chair of the Department of the Attending Physician or the President of the Medical Staff may direct that a consultation be held and, if necessary, arrange for the consultation himself. The Attending Physician will be notified. If the Attending Physician disagrees with the necessity for consultation, the matter shall be brought immediately to the President of the Medical Staff for final decision and direction.

15.2.3 In the event that a practitioner on the call roster does not respond to consultative (ED/Inpatient/Outpatient) requests, the Chair of the Department involved shall be notified, and it is his responsibility to see that adequate consultation is obtained. If the Chair of the Department is unable to be contacted, the President of the Medical Staff will assume this responsibility.

15.3 Consultation Report

15.3.1 Each Consultant shall examine the patient and complete a consultation report within twenty-four (24) hours. The report shall contain his findings and recommendations and shall be made a part of the patient's medical record.

15.3.2 Each consultation report shall show evidence of a review of the patient's record, pertinent physical findings, conclusions or impressions, and subsequent recommendations. When

treatment involves operative procedures, the Consultant shall record consultation notes prior to surgery, patient's condition permitting.

15.4 Care and Treatment of Patients

Each patient's Consulting Physician shall be and remain the patient's Consulting Physician and shall remain responsible for the specialty care of each patient he treats in the Hospital until the patient is discharged, the responsibility for the specialty care and treatment of the patient is transferred to another Practitioner, or the patient no longer requires the specialty services of the Consulting Physician.

16.0 MEDICATIONS

16.1 Formulary

- 16.1.1 The AdventHealth Formulary and Therapeutics Committee develops and maintains a standardized master formulary and monitors the use of non-formulary items.
- 16.1.2 The Hospital Pharmacy and Therapeutics Committee will be responsible for determining a facility formulary. The facility formulary may only contain items on the standardized master formulary. Practitioners may prescribe medications from the facility formulary.
- 16.1.3 If a Practitioner requests a medication that is not on the facility master formulary, the Hospital Pharmacy and Therapeutics Committee will review supporting evidence for use of the medication at the Hospital.
- 16.1.4 If the Hospital Pharmacy and Therapeutics Committee determines that the medication should be added to the facility formulary, then the Hospital Pharmacy and Therapeutics Committee will determine whether the item exists on the standardized master formulary. If the item exists on the standardized master formulary, then the Hospital Pharmacy and Therapeutics Committee will recommend adding the item to the facility formulary; however, if the item does not exist on the standardized master formulary, then the Hospital Pharmacy and Therapeutics Committee may submit an appeal, with supporting documentation and/or additional considerations, to the AdventHealth Formulary and Therapeutics Committee for review.

16.2 Use and Discontinuation of Medication Orders

- 16.2.1 Only medications prescribed by a Practitioner may be administered in the Hospital.
- 16.2.2 A Practitioner shall indicate the medication, dosage, route, and duration of administration of a medication in the medication order.
- 16.2.3 All medication orders must comply with policies established with the Pharmacy and Therapeutic Committee.

17.0 PRONOUNCEMENT OF DEATH AND AUTOPSIES

17.1 Autopsies

- 17.1.1 It is the responsibility of each Attending Physician to ensure that deaths which are within the jurisdiction of the Medical Examiner are reported to the Tarrant County Medical Examiner's Office.
- 17.1.2 It shall be the responsibility of each Attending Physician to obtain autopsies when appropriate. Medical Staff Members may refer to current hospital autopsy criteria for guidelines in determining when autopsies are appropriate.
- 17.1.3 The Department of Pathology will perform (or refer to an appropriate institution) appropriate autopsies which are not within the jurisdiction of the Medical Examiner. An autopsy shall not be performed without written authorization as required by Texas law.
- 17.1.4 When an autopsy is performed, the provisional anatomic diagnoses shall be recorded in the medical record within three (3) days and the complete report shall be made part of the medical record within sixty (60) days, unless exceptions for special studies are established by the Medical Executive Committee.

18.0 HEALTH INFORMATION MANAGEMENT

18.1 Medical Record Entries

18.1.1 Information entered in a patient's medical record shall accurately and succinctly document the patient's care and treatment in the Hospital. Medical Record documentation shall include paper, electronic and/or computerized patient information. Each Attending Physician shall include in a patient's medical record the following information: chief complaint; medical history; physical examination; description of medical condition; preliminary diagnosis; medical care and/or surgical treatment; operative report; progress notes; consultation and other reports; laboratory and x-ray reports; final diagnosis; discharge summary; and an autopsy report, if applicable.

18.1.2 All entries shall reflect actual observations and clinical opinions. Entries regarding matters unrelated to the care and treatment of the patient shall not be made in a patient's medical record. Each entry must be dated, timed, and authenticated by electronic signature, written signature, or written initials. The physician shall authenticate all portions of the medical record for which he is responsible including entries made by specified professional personnel under his supervision. Signature stamps shall not be used.

18.1.3 Removal of Medical Record Entries - Entries made in the medical record shall not be removed, deleted, altered or tampered with in any way, except that amendments, correction of errors and late entries may be made in accordance with the Hospital's policies and procedures.

18.1.4 Correction of Errors

When a correction to a paper-based medical record is necessary, the original entry shall be marked through with a single line, initialed, and the correct entry subsequently made, dated and authenticated. Corrections to computerized/electronic records shall be made in accordance with Hospital policies and procedures. Errors shall be corrected in all mediums (e.g., paper and electronic) in which the record is maintained.

18.1.5 Symbols and Abbreviations

Legends of abbreviations that are not approved are posted at the appropriate locations. The legends shall be periodically updated and approved by the Medical Executive Committee and maintained in Health Information Management. Inappropriate usage of abbreviations will be referred to the committee reviewing Clinical Pertinence.

18.1.6 Inappropriate entries

18.1.6.1 Examples of inappropriate entries include, but are not limited to:

18.1.6.1.1 Entries that are "copied and pasted" electronically without updating the clinical information; and

18.1.6.1.2 Entries that are accusatory, inflammatory, and/or demean the care or character of a patient, another provider, or the Hospital.

18.1.6.2 All inappropriate entries shall be referred to the Centralized Performance Improvement Committee.

18.2 Medical History and Physical Examination Report

18.2.1 Admission, Readmission within 30 Days

- 18.2.1.1 A complete admission history and physical (H&P) examination must be written, dictated or transcribed and entered into the EMR no more than thirty (30) days before or twenty-four (24) hours after inpatient admission or registration, but prior to surgery or a procedure requiring anesthesia. An H&P completed more than thirty (30) days before admission is not acceptable.
- 18.2.1.2 For patients receiving surgical or procedural services where scanning documents immediately into the EMR is impractical due to urgency of the procedure or lack of scanning equipment in the department, the H&P must be present in paper form in the procedural chart and updated if required as per Subsection 18.2.1.3 below.
- 18.2.1.3 Updated H&Ps
 - 18.2.1.3.1 When the H&P is completed before admission, an update note is required within twenty-four (24) hours of admission, but prior to surgery or a procedure requiring anesthesia.
 - 18.2.1.3.2 The update notes shall include any changes in the patient's condition since the time the H&P was performed that may be significant for the planned course of treatment. Otherwise, the Practitioner shall document that the history and physical was reviewed, the patient was examined, and no change has occurred in the patient's condition since the history and physical was completed.
- 18.2.1.4 If a patient is readmitted within 30 days after discharge with the same or related problem, an interval H&P is acceptable with an update note.
- 18.2.1.5 An H&P completed by a practitioner who is not a Member of the Medical Staff may be used and included in the patient's medical record provided it is co- signed and updated by the admitting Practitioner.
- 18.2.1.6 History and physicals completed by ED Practitioners cannot be substituted for the admission H&P. The admitting or attending Practitioner must document the complete H&P examination.
- 18.2.1.7 Consultations may be used as an H&P exam if they are documented and entered in the medical record within twenty-four (24) hours after the patient's admission or registration but prior to surgery or procedure requiring anesthesia. When a consultation is used it must meet the content requirements for an H&P.
- 18.2.1.8 H&Ps may be performed and documented by Oral and Maxillofacial Surgeons on the Medical Staff who also are Physicians.

- 18.2.1.9 Podiatrists may co-admit patients, perform, and document the H&P relating to the surgical procedure if granted the delineated privileges to do so.
- 18.2.2 Prior to Surgery or Procedure Requiring Anesthesia
 - 18.2.2.1 The patient's H&P examination and the results of any indicated diagnostic tests must be entered into the procedural chart before surgery or other procedure requiring anesthesia is performed.
 - 18.2.2.2 When the H&P examination and pre-anesthesia evaluation are not completed and in the EMR before an operation or other procedure involving anesthesia, the procedure shall be delayed until documentation is completed except in the case of an emergency. In such an emergency, the primary surgeon or Practitioner performing the procedure shall document that any delay to record the H&P would create a risk of harm to the patient, and the primary surgeon or Practitioner shall document in the EMR, prior to the procedure, a progress or admission note describing a brief history and appropriate physical findings and the preoperative diagnosis.
- 18.2.3 Outpatients and Observation
 - 18.2.3.1 An abbreviated H&P shall be documented for observation patients and outpatients receiving a procedure requiring anesthesia.
 - 18.2.3.2 The H&P must be documented and entered in the EMR within twenty-four (24) hours after the patient is placed in observation and prior to the procedure requiring anesthesia.
 - 18.2.3.3 The content of the abbreviated H&P shall contain:
 - 18.2.3.3.1 Date of assessment;
 - 18.2.3.3.2 Chief complaint;
 - 18.2.3.3.3 History of present illness;
 - 18.2.3.3.4 Medications;
 - 18.2.3.3.5 Allergies;
 - 18.2.3.3.6 Relevant past medical history;
 - 18.2.3.3.7 Relevant social and family history;
 - 18.2.3.3.8 Targeted physical exam relevant to the chief complaint and/or procedure;
 - 18.2.3.3.9 Diagnosis/clinical impression/conclusions; and

18.2.3.3.10 Plan of treatment/course of actions.

18.2.4 Content of History and Physical

18.2.4.1 The H&P must meet hospital guidelines as to content and timeliness and shall contain at least the following relevant information regardless of format, e.g. recorded in a transcribed report, entered in the EMR or doctor's office record:

18.2.4.1.1 Date of assessment;

18.2.4.1.2 Chief complaint;

18.2.4.1.3 History of present illness;

18.2.4.1.4 Medications;

18.2.4.1.5 Allergies;

18.2.4.1.6 Past medical history including previous surgery;

18.2.4.1.7 Past social history;

18.2.4.1.8 Family history;

18.2.4.1.9 Review of systems;

18.2.4.1.10 Vital signs;

18.2.4.1.11 Physical examination;

18.2.4.1.12 Diagnosis/clinical impression/conclusions; and

18.2.4.1.13 Plan of treatment/course of actions.

18.2.5 Obstetrical Records

18.2.5.1 The obstetrical record shall include a complete prenatal record.

18.2.5.2 The history and physical must be on the record within twenty-four (24) hours of admission but prior to surgery or a procedure requiring anesthesia.

18.2.5.3 For women who have not received prenatal care before the onset of labor, the H&P must be completed within twenty-four (24) hours after admission but prior to surgery or a procedure requiring anesthesia.

18.3 Orders

18.3.1 Practitioner's Responsibilities

18.3.1.1 Each Practitioner will complete and sign orders regarding the care and treatment of the patient. A verbal order shall only be used when it is not feasible to provide a written order due to an emergent situation. Telephone orders may only be

performed when the physician does not have access to a computer. The physician (or a covering physician) giving a verbal or telephone order shall authenticate the verbal or telephone order by signing, dating, and timing the order within ninety-six (96) hours. Verbal or telephone orders shall only be provided to qualified Hospital personnel

18.3.1.2 When a patient is transferred from the care of one Practitioner to another, the receiving Practitioner shall review the orders.

18.3.2 Personnel Authorized to Receive Verbal Orders

A Practitioner may dictate orders to hospital personnel who are licensed, registered, or certified professionals acting within their scope and individual job description, including the following personnel:

- 18.3.2.1 Registered Nurses;
- 18.3.2.2 Registered Pharmacists;
- 18.3.2.3 Licensed Physical Therapists;
- 18.3.2.4 Licensed Vocational Nurses;
- 18.3.2.5 Certified Respiratory Therapists;
- 18.3.2.6 Registered Dietitians;
- 18.3.2.7 Certified Physician Assistants;
- 18.3.2.8 Certified Registered Nurse Anesthetists;
- 18.3.2.9 Licensed Advanced Nurse Practitioners;
- 18.3.2.10 Registered Radiologic Technologists; and
- 18.3.2.11 Other personnel authorized by the MEC and Board of Directors.

Verbal orders received and documented by approved hospital personnel must be subsequently countersigned by the ordering Physician within ninety-six (96) hours.

18.3.3 Orders per Policy: A person authorized to receive verbal orders may also enter Orders per Policy as approved by the MEC which must be subsequently countersigned by the Attending Physician within ninety-six (96) hours.

18.3.4 Cancellation of Orders: Prior to transfer of a patient to a different level of care, the Attending Physician shall review the patient's orders. When a patient is transferred to Surgery, MICU or CVICU, all orders will be canceled automatically and must be reordered if they are to be continued.

18.3.5 Standing Orders: Standing Orders shall not be used.

18.4 Progress Notes

- 18.4.1 Progress notes shall provide a chronological record of a patient's care and treatment in the Hospital. Progress notes shall be recorded at the time of observation. Each clinical problem and related orders, test results and care and treatment of a patient shall be described in the patient's progress notes.
- 18.4.2 Progress notes shall be recorded daily or more frequently as the patient's condition warrants. Each progress note shall be dated, timed and signed.
- 18.4.3 In the event of death, the final progress note shall include the immediate cause of death, if known, and the final diagnosis.
- 18.4.4 Entries by Other Personnel: A Practitioner may authorize other personnel with appropriate Clinical Privileges to enter progress notes on his behalf. Each Practitioner authorizing such entries shall review and sign them within twenty-four (24) hours.
- 18.4.5 Interventional pharmacists shall enter notes in the progress notes. Each progress note shall be dated and signed by the pharmacist and does not have to be countersigned.

18.5 Completion of Reports Prior to Procedures Utilizing Moderate Sedation by Non-Anesthesiology Personnel

- 18.5.1 The Practitioner performing the procedure shall be responsible for ensuring that the following are in the patient's medical record prior to the induction of moderate sedation, unless the patient's medical condition does not permit:
 - 18.5.1.1 Preoperative diagnosis recorded, dated, and signed by the responsible Practitioner;
 - 18.5.1.2 A history and physical examination report;
 - 18.5.1.3 Pre-sedation assessment note(s);
 - 18.5.1.4 Consultation report(s), if indicated; and
 - 18.5.1.5 Properly executed informed consent(s).
- 18.5.2 If an emergent condition does not allow usual documentation, this shall be stated in the record.

18.6 Operative Report

- 18.6.1 Each primary surgeon or other Practitioner performing a surgery or procedure involving anesthesia shall create a complete operative report or post-operative progress note before the patient is transferred to the next level of care, except when the Practitioner performing the operation or procedure accompanies the patient from the operating suite to the next unit or area of care in which case the report can be created in the new unit or area of care.
- 18.6.2 A complete operative report shall include:

- 18.6.2.1 Name(s) of the primary surgeon(s) and his assistant(s) (even

when performing those tasks under supervision);

- 18.6.2.2 Date and time of the surgery;
 - 18.6.2.3 Procedures performed and description/technique for each procedure;
 - 18.6.2.4 Operative findings;
 - 18.6.2.5 Type of anesthesia administered;
 - 18.6.2.6 Complications, if any;
 - 18.6.2.7 Estimated blood loss;
 - 18.6.2.8 Specimens removed;
 - 18.6.2.9 Pre- and post-operative diagnosis; and
 - 18.6.2.10 Prosthetic devices, grafts, tissues, transplants, or devices implanted, if any.
- 18.6.3 When the operative report is not immediately available in the medical record, an immediate post-operative progress note must be documented in the medical record before the patient leaves the post anesthesia recovery area. The complete operative report must be documented and entered in the medical record within twenty-four (24) hours of completion of the procedure.
- 18.6.4 If the complete operative report is documented in the medical record at the time or before the patient leaves the post anesthesia recovery area, an immediate post-op progress note is not required.
- 18.6.5 The immediate post-operative progress note shall include:
- 18.6.5.1 Name(s) of the primary surgeon(s) and his assistant(s);
 - 18.6.5.2 Procedures performed;
 - 18.6.5.3 Name of each procedure and findings;
 - 18.6.5.4 Estimated blood loss;
 - 18.6.5.5 Specimens removed; and
 - 18.6.5.6 Post-operative diagnosis

18.7 Anesthesia Reports

- 18.7.1 All anesthesia reports/forms relating to drug administration will be completed and appropriately documented in the medical record immediately following the end of the case.
- 18.7.2 Discrepancy resolution and correction of documentation is the ultimate responsibility of the anesthesiologist.

18.7.3 The anesthesia report shall include written documentation of at least the following:

- 18.7.3.1 The pre-anesthesia evaluation of the patient performed by the anesthesiologist or CRNA, with appropriate documentation, including evaluation of the patient's previous drug history and anesthesia experience as well as any potential anesthesia problems. A pre-anesthesia evaluation completed within thirty (30) days of admission may be updated. The updated pre-anesthesia assessment must be completed within forty-eight (48) hours prior to surgery. If this evaluation is done by a CRNA, the documentation shall be reviewed and countersigned by the anesthesiologist responsible for the case prior to induction.
- 18.7.3.2 Documentation of the reevaluation of the patient immediately before moderate or deep sedation and before anesthesia induction.
- 18.7.3.3 A record of all events taking place during induction of, maintenance of and emergence from moderate or deep sedation or anesthesia, including dosage and duration of all anesthetic agents, other drugs, intravenous fluids and blood or blood fractions.
- 18.7.3.4 Post-anesthetic note(s) after the patient recovers from moderate or deep sedation or anesthesia, including at least one (1) note describing the presence or absence of anesthesia-related complications.

18.8 Discharge Summary

- 18.8.1 The discharge summary must be entered into the medical record within seventy-two (72) hours after discharge.
- 18.8.2 A discharge summary shall be documented for all patients hospitalized over forty-eight (48) hours, including normal obstetrical deliveries and normal newborn infants and must contain:
 - 18.8.2.1 Final diagnoses;
 - 18.8.2.2 Significant findings;
 - 18.8.2.3 Procedures and treatments;
 - 18.8.2.4 Events of the patient's hospitalization;
 - 18.8.2.5 Condition at discharge;
 - 18.8.2.6 Diet at discharge;
 - 18.8.2.7 Medications at discharge;
 - 18.8.2.8 Recommendations and arrangements for future care; and
 - 18.8.2.9 The discharge summary is to be completed within seventy-two (72) hours of discharge. A final progress note may be substituted for the discharge summary in the case of a short stay patient with problems of a minor nature

who required less than a forty-eight (48) hour period of hospitalization, but must include the elements outlined above to be accepted in the absence of a discharge summary.

- 18.8.3 For patients hospitalized under forty-eight (48) hours, a final progress note may serve as a discharge summary and must contain:
 - 18.8.3.1 The outcome of the treatment, procedures, or surgery;
 - 18.8.3.2 Case disposition;
 - 18.8.3.3 Provisions for follow-up care;
 - 18.8.3.4 Final diagnosis; and
 - 18.8.3.5 Completion of the Short Stay Discharge Summary template is sufficient for patients who are hospitalized for less than forty-eight (48) hours and outpatients who had surgery.
- 18.8.4 Discharge Summaries completed by PAs and APPs must be reviewed and countersigned by the supervising Practitioner.
- 18.8.5 A concise discharge summary is documented and provides information to other caregivers and facilitates continuity of care will include:
 - 18.8.5.1 Reason for hospitalization;
 - 18.8.5.2 Significant findings, procedures performed and care, treatment, and services provided;
 - 18.8.5.3 The patient's condition at discharge; and
 - 18.8.5.4 Information to the patient and family as appropriate, to include medications and durable medical equipment or other devices, provisions for follow-up care, final diagnosis and disposition.

18.9 Informed Consent

- 18.9.1 Each patient's medical record shall contain evidence of the patient's informed consent in accordance with the Hospital Policy on Informed Consent and all applicable laws.
- 18.9.2 The patient's physician is responsible for (a) disclosing to the patient, or the person authorized to consent for the patient, the need for, risk of, and alternatives to blood transfusion when blood or blood components may be needed, and the risks and hazards of any non-listed medical treatment and surgical procedures to be performed by the physician; (b) obtaining the consent in accordance with the Texas Medical Disclosure Panel recommendations (c) documenting in the medical record that risks, benefits, alternatives (including not performing the procedure) and potential complications were discussed with the patient and/or the person authorized to consent for the patient; and (d) discussing sedation and anesthesia options, and risks with the patient and family prior to administration and obtaining consent.

18.10 Coding Queries

- 18.10.1 A coding query may be initiated to a Practitioner to clarify documentation in the medical record.
- 18.10.2 Coding queries must be responded to within seven (7) days after receiving the query in the physician in-basket in the electronic medical record.
- 18.10.3 It is the expectation that the medical staff member respond to the query by either documenting a progress note in the EMR clarifying documentation or declining the query and stating the reason for declination.
- 18.10.4 A trend of unanswered queries will be forwarded to the CPI committee.

18.11 Medical Record Completion and Enforcement

- 18.11.1 Once relinquishment has occurred, all available incomplete medical records must be completed prior to reinstatement of full Clinical Privileges. During relinquishment, each 14-day period that the available medical records remain incomplete shall be considered an additional automatic relinquishment of privileges.
- 18.11.2 If the Practitioner who has been automatically terminated under Section 18.11.10.3 desires to be a Medical Staff Member and/or Practitioner again, then he may apply as an initial Applicant. Any Applicant who desires to reapply for medical staff membership shall complete any and all incomplete medical records prior to being eligible to receive a credentialing request for application regardless of reason the Member is no longer on the medical staff.
- 18.11.3 Upon resignation of Membership and/or Clinical Privileges from the Medical Staff, the resignee must complete his medical records to the satisfaction of the Director of Health Information Management. Except in the case of extreme medical disability, the resignee who has not completed his medical records within sixty (60) days of his effective date of resignation, will be referred to the Medical Executive Committee. The Medical Executive Committee, except for good cause, will recommend to the Board that the resignee's file shall reflect that he resigned from the medical staff and that he has not completed his medical records.
- 18.11.4 In the event of automatic termination, the Chair of the Practitioner's affected member's Department will assign another Practitioner to provide hospital patient care. The wishes of the patient will be considered in choosing a substitute Practitioner.
- 18.11.5 Definitions
 - 18.11.5.1 Primary Suspension:
 - 18.11.5.1.1 Practitioners placed on Primary Suspension may not:
 - 18.11.5.1.1.1 Admit patients (except for previously scheduled admissions or elective surgery);
 - 18.11.5.1.1.2 Schedule elective surgery for

new inpatients or outpatients;

18.11.5.1.1.3 Treat ambulatory care patients in the hospital (except for previously scheduled admissions or elective surgery);

18.11.5.1.1.4 Administer anesthesia; and

18.11.5.1.1.5 Provide consultation to other Practitioners (unless on emergency call rotation).

18.11.5.1.2 The suspended Practitioner may admit emergent patients and may continue to provide care for all patients admitted prior to the date of suspension.

18.11.5.1.3 A Practitioner placed on Primary Suspension shall fulfill his emergency call rotation obligation.

18.11.5.2 Full Suspension:

18.11.5.2.1 Practitioners placed on Full Suspension may not:

18.11.5.2.1.1 Exercise any of his Clinical Privileges unless an exception is granted for taking call under Sec. 18.11.5.2.3 below.

18.11.5.2.2 The Practitioner must arrange for coverage of any patients currently receiving inpatient treatment.

18.11.5.2.3 An exception may be made, at the discretion of the President of the Medical Staff and CEO or their designees, to allow the suspended Practitioner to cover emergency call days scheduled prior to the suspension if the impact of removing the suspended Practitioner from the call schedule would create a risk to patient care or an undue burden on other Practitioners in that specialty. In such event, the suspended Practitioner may treat patients emergently in the ER and provide ongoing care in the case of required admission in response to calls, but all other full suspension restrictions shall remain in place. The Hospital President's decision not to exercise such discretion is not an adverse action under the Bylaws and does not entitle the Practitioner to a hearing or other procedural rights.

18.11.6 Primary Suspension for H&P, Operative Report and Discharge Summary delinquencies

- 18.11.6.1** History and Physicals shall be completed within twenty-four (24) hours of admission or registration, Operative Reports shall be completed within twenty- four (24) hours of completion of the procedure.
- 18.11.6.2** Discharge Summaries shall be completed within seventy-two (72) hours of discharge.
- 18.11.6.3** Practitioner will receive telephone notification of delinquencies on the next business day after the medical record entries were due (“Telephone Notice”).
- 18.11.6.4** If the H&Ps and/or Operative Reports are not completed by 8:00 a.m. on the first business day following the Telephone Notice, the Practitioner will be placed on Primary Suspension automatically.
- 18.11.6.5** If the Discharge Summaries are not completed by 8:00 a.m. on the third business day following telephone notification, the practitioner will be placed on Primary Suspension automatically.
- 18.11.6.6** The HIM department will send notice to the Practitioner (“Primary Suspension Notice”) via email (with receipt confirmed by the Practitioner sending a reply) and fax notifying him of the Primary Suspension and that Full Suspension will be imposed if delinquent entries are not completed within fourteen (14) days of imposition of Primary Suspension.
- 18.11.6.7** Notice will also be sent to the Hospital Medical Staff Office.
- 18.11.6.8** A Practitioner who remains on Primary Suspension for fourteen (14) days without completion of the delinquencies shall automatically be placed on Full Suspension. Notice will be sent to the Practitioner (“Suspension Notice,” as defined in Section 18.11.7.6 below) and to the Hospital Medical Staff Office via email or fax.

18.11.7 Full Suspension for All Delinquencies

- 18.11.7.1** All Medical Record entries shall be completed in the time frames set forth in these Rules and Regulations and/or Medical Staff policies. Records are considered complete when all required signatures, reports, dictations, response to coding queries and orders have been completed, timed, dated, and signed.
- 18.11.7.2** Any medical record entry not completed within seven (7) days after patient discharge shall be considered delinquent.
- 18.11.7.3** The notice will be faxed and emailed to the Practitioner on the seventh day following discharge, notifying the Practitioner of the delinquency(ies) and notifying him that he will be placed on Full Suspension automatically if delinquencies are not completed within the next seven (7) days, i.e. fourteen (14) days post-discharge (“First

Notice”).

- 18.11.7.4 Notice will also be sent to the Hospital Medical Staff Office.
- 18.11.7.5 Any medical records not completed by fourteen (14) days post-discharge shall result in the Practitioner automatically being placed on Full Suspension.
- 18.11.7.6 Notice shall be sent to the Practitioner (“Suspension Notice”) via email and fax notifying him of the Full Suspension and that automatic relinquishment of medical staff membership and clinical privileges may result if delinquent records are not completed in the time frames stated in Subsection 18.11.6 and 18.11.7. Notice will also be sent to the Medical Staff Office.

18.11.8 Reinstatement After Suspension

- 18.11.8.1 Once **Primary Suspension** is imposed, privileges may be reinstated only upon completion of all missing H&Ps, Operative Reports, and Discharge Summaries.
- 18.11.8.2 Once **Full Suspension** is imposed, privileges may be reinstated upon completion of all incomplete and delinquent medical records available to the Practitioner.
- 18.11.8.3 Reinstatement will occur upon re-analysis of incomplete records to ensure that all deficiencies have been completed. To facilitate reinstatement of privileges, it is recommended the Practitioner document the dictation job number in a progress note and contact the HIMS department.

18.11.9 Chart Availability

- 18.11.9.1 No Practitioner shall be suspended, and no suspension shall be continued for an incomplete medical record that is not available to the Practitioner for completion.
- 18.11.9.2 If there is a delay in the assignment of the deficiency to the Practitioner, the delay will be reflected in the timing of the suspension.

18.11.10 Repeated Violations

- 18.11.10.1 If the Practitioner has relinquished his privileges three (3) times during a calendar year, prior to reinstatement he must complete all medical records made available to him and then appear before the next regularly scheduled Credentials Committee. Failure to appear without good cause shall result in automatic termination of Medical Staff Membership and/or Clinical Privileges.
- 18.11.10.2 The Credentials Committee may recommend termination or any other appropriate action to the Medical Executive Committee.

18.11.10.3 A Practitioner's Medical Staff Membership and/or Clinical Privileges shall automatically be terminated for incomplete medical records if a Practitioner has automatically relinquished his privileges for incomplete medical records four (4) times during any one (1) calendar year. Written notice, which would include fax, e-mail or letter of automatic termination of a Practitioner's Medical Staff Membership and/or Clinical Privileges shall be given jointly by the Chief Executive Officer and the President of the Medical Staff, or their designees. Automatic termination pursuant to this section shall result in the Member's file reflecting that he was terminated from the Medical Staff.

18.11.11 Absences

18.11.11.1 Vacation and planned absence

18.11.11.1.1 Vacation or other planned absences do not excuse a Practitioner from medical record completion requirements.

18.11.11.1.2 To avoid suspension for records that become delinquent while the Practitioner is on vacation or planned absence, the Practitioner must notify HIMS or entity-based designee prior to the Practitioner's time off, and the following requirements are met:

18.11.11.1.2.1 Notify HIMS of the planned time off, including commencement and return dates, at least two (2) business days prior to the start of the planned time off; and

18.11.11.1.2.2 Complete all medical records that are available to the Practitioner as of forty-eight (48) hours prior to commencement of time off (example: If Practitioner's time off commences at 5 p.m. Friday, all records available to Practitioner at 5 p.m. the preceding Wednesday must be completed prior to the start of the time off).

18.11.11.1.3 Failure to complete H&Ps, Operative Reports and Discharge Summaries prior to the absence will NOT be excused under this section.

18.11.11.1.4 A Practitioner who has given the proper notification of planned time off will have five (5) business days following his return to complete any records that became delinquent during the planned time off.

18.11.11.1.5 If the delinquent records are not completed within five (5) business days of return, the Practitioner

will be placed on Full Suspension.

- 18.11.11.1.6 A Practitioner who takes planned time off without providing proper notification will be required to meet regular medical record completion requirements.

18.11.12 Unplanned Absence

A Practitioner who has an unplanned time off due to illness or a family emergency may be granted extra time to complete delinquent medical records at the sole discretion of the Medical Executive Committee or President of the Medical Staff or designee based on individual circumstances.

18.11.13 Advanced Practice Professionals

- 18.11.13.1 Practitioners approved to supervise PAs or APNs are responsible for the PAs or APNs to complete medical records according to the timeline outlined in the Rules and Regulations.
- 18.11.13.2 Failure of the PA or APN to timely complete medical records will result in the PA or APN being placed on suspension in accordance with the Medical Staff Bylaws or Rules and Regulations.
- 18.11.13.3 Failure of the PA or APN to timely complete medical records may result in the supervising Medical Staff Member being placed on suspension in accordance with Rules & Regulations or policy.

19.0 MEMBER AND PRACTITIONER CONDUCT

19.1 Medical Staff Member and Practitioner Conduct

All individuals in the Hospital shall be treated courteously, respectfully, and with dignity. Accordingly, all Medical Staff Members and Practitioners shall conduct themselves in a professional and cooperative manner while in the Hospital. Those Members or Practitioners failing to conduct themselves in the appropriate manner shall be subject to Corrective Action.

19.2 Disruptive Practitioners

19.2.1. If a Member or Practitioner fails to conduct himself appropriately, the matter shall be addressed in accordance with the following Rule and Regulation. It is the intention of the Medical Staff that this process will be carried out in a firm, fair, and equitable manner.

19.2.2 A single egregious incident such as physical or sexual harassment, assault, a fraudulent act, stealing, damaging hospital property, or inappropriate physical behavior may result in suspension of Membership and Clinical Privileges with due process.

19.2.3 The objective of this Rule and Regulation is to ensure optimum patient care by promoting a safe, cooperative, and professional health care environment, and to prevent or eliminate, to the extent possible, conduct that:

19.2.3.1 Disrupts the operation of the hospital;

19.2.3.2 Affects the ability of others to do their jobs;

19.2.3.3 Creates a hostile work environment for hospital employees or other medical staff members;

19.2.3.4 Interferes with an individual's ability to practice competently; or

19.2.3.5 Does not support a culture of safety and quality.

19.3 Definition of Disruptive Behavior

Unacceptable disruptive conduct may include, but is not limited to, behavior such as:

19.3.1 Attacks (verbal or physical) leveled at other Medical Staff Members, Practitioners, hospital personnel, or patients, that are personal, irrelevant, or beyond the bounds of fair professional conduct;

19.3.2 Impertinent and inappropriate comments (or illustrations) made in patient medical records or other official documents, impugning the quality of care in the hospital, or attacking Members, Practitioners, nurses, or hospital policies;

19.3.3 Non-constructive criticism that is addressed to its recipient in such a way as to intimidate, undermine confidence, belittle, or imply stupidity or incompetence;

19.3.4 Refusal to accept or disruptive acceptance of medical staff assignments or participation in committee or departmental affairs regarding anything but his or her own terms; or

- 19.3.5 Imposing idiosyncratic requirements on the nursing staff which have nothing to do with better patient care but serve only to burden the nurses with special techniques and procedures;
- 19.3.6 Profanity or similarly offensive language while in the Hospital and/or while speaking with nurses or other Hospital personnel;
- 19.3.7 Inappropriate physical contact with another individual that is threatening or intimidating;
- 19.3.8 Derogatory comments about the quality of care being provided by the Hospital, another Medical Staff Member, another Practitioner, or any other individual outside of appropriate Medical Staff and/or administrative channels.

19.4 The Professional Conduct Committee

The Professional Conduct Committee (PCC) is a Medical Staff Peer Review Committee and members shall be appointed by the President of the Medical Staff. Except as otherwise may be determined by the PCC, the Practitioner or Medical Staff's counsel shall not attend any of the PCC meetings. The PCC will consist of no less than three (3) members.

19.5 Referral to the Professional Conduct Committee

- 19.5.1 The individual who reports an incident shall be requested to document it via the electronic incident reporting system (Origami). If he does not wish to do so, the supervisor, PCC member or designee may document it, after attempting to ascertain the individual's reasons for declining and encouraging the individual to do so.
- 19.5.2 The documentation may include:
 - 19.5.2.1 The date and time of the incident;
 - 19.5.2.2 A factual description of the questionable behavior;
 - 19.5.2.3 The name of any person who may have been involved in the incident, including any patient or family member who may have witnessed the incident;
 - 19.5.2.4 The circumstances which precipitated the incident;
 - 19.5.2.4.1 The names of other witnesses to the incident;
 - 19.5.2.4.2 Consequences, if any, of the behavior as it relates to patient care, personnel, or Hospital operations;
 - 19.5.2.4.3 Any action taken to intervene in, or remedy, the incident; and,
 - 19.5.2.4.4 The name of the individual reporting the matter. (see Section 19.5.6 on disclosure.)
- 19.5.3 The documented information about the incident will be forwarded to the PCC. The Origami report may not be forwarded to the PCC.
- 19.5.4 The PCC or designee shall review the information and may meet with the individual who prepared it and/or any witnesses to the incident to ascertain the details of the incident.

- 19.5.5 If the PCC determines that an incident of inappropriate conduct has likely occurred, the PCC has several options available to it, including, but not limited to, the following:
- 19.5.5.1 Notify the Practitioner that a report has been received and invite the Practitioner to meet with one or more members of the PCC to discuss it;
 - 19.5.5.2 Send the Practitioner a written request for further information;
 - 19.5.5.3 Send the Practitioner a letter of guidance about the incident;
 - 19.5.5.4 Educate the Practitioner about administrative channels that are available for registering concerns about quality or services, if the Practitioner's conduct suggests that such concerns led to the behavior. Other sources of support may also be identified for the Practitioner, as appropriate;
 - 19.5.5.5 Have a PCC member(s), or the PCC as a group, meet with the Practitioner to counsel and educate the individual about the concerns and the necessity to modify the behavior in question.
 - 19.5.5.6 Referral to the President of the Medical Staff for action pursuant to Section 19.6.
- 19.5.6 The identity of an individual reporting inappropriate conduct will not be disclosed to the Practitioner without the express written consent of that individual, and only then if the PCC agrees in advance that it is appropriate to do so. If the reporting person's identity will be disclosed, the PCC will notify that individual prior to disclosure. In any case, the Practitioner should be advised that any retaliation against the person reporting a concern, whether the specific identity is disclosed or not, will be grounds for immediate referral to the President of the Medical Staff for further action pursuant to the Bylaws.
- 19.5.7 If the PCC prepares any documentation for a Practitioner's file regarding its efforts to address concerns with the Practitioner, the Practitioner shall be apprised of the outcome and given an opportunity to respond in writing. Any such response shall then be kept in the Practitioner's confidential file along with the original concern and the PCC's documentation.
- 19.5.8 If additional reports are received concerning a Practitioner, the PCC may either:
- 19.5.8.1 Continue to utilize the collegial and educational steps noted in this Section as long as it believes that there is still a reasonable likelihood that those efforts will resolve the concerns;
 - 19.5.8.2 Forward to the Centralized Performance Improvement Committee (CPI); or
 - 19.5.8.3 Refer for possible initiation of Professional Review Activity pursuant to the Medical Staff Bylaws.

19.6 Referral to the President of the Medical Staff

- 19.6.1 At any point, the PCC may refer the matter to the President of the Medical Staff (or designee) for review and action. The President of the Medical Staff shall be fully apprised of the actions taken by the PCC or others to address the concerns. When it

makes such a referral, the PCC may also suggest a recommended course of action.

- 19.6.2 The President of the Medical Staff, in conjunction with the Chief Executive Officer or designee, may take additional steps to address the concerns including, but not limited to, the following:
- 19.6.2.1 Require the Practitioner to meet with the full Medical Executive Committee or a designated subgroup;
 - 19.6.2.2 Require the Practitioner to meet with specified individuals (such as, but not limited to, including any combination of current or past medical staff leaders, outside consultant(s), the Board of Directors Chair, or other Board of Directors members);
 - 19.6.2.3 Issuance of a letter of guidance;
 - 19.6.2.4 Request that the Practitioner complete a behavior modification course as a performance improvement plan; and
 - 19.6.2.5 Request that the Practitioner agree to a “personal” code of conduct as a performance improvement plan and condition of continued Membership and/or Clinical Privileges.

The imposition of any of these actions does not entitle the Practitioner to a hearing or appeal.

- 19.6.3 The President of the Medical Staff may also direct that a matter be handled pursuant to the Physician Health Policy.
- 19.6.4 At any point, including but not limited to the Practitioner’s failure to enter into a voluntary performance improvement plan, the President of the Medical Staff may convene an Ad Hoc Committee to conduct an investigation or directly notify the Medical Executive Committee and/or Board of Directors if a Professional Review Activity is recommended.
- 19.6.5 The President of the Medical Staff and the CEO or designee(s) may initiate an Emergency Corrective Action in accordance with Medical Staff Bylaw 7.2.

19.7 Sexual Harassment

19.7.1 Definition

Sexual harassment is defined as any verbal and/or physical conduct of a sexual nature that is unwelcome and offensive to those individuals who are subjected to it or who witness it. Examples include, but are not limited to, the following:

- 19.7.1.1 Verbal: innuendoes, epithets, derogatory slurs, off-color jokes, propositions, graphic commentaries, threats, and/or suggestive or insulting sounds;
- 19.7.1.2 Visual/Non-Verbal: derogatory posters, cartoons, or drawings; suggestive objects or pictures; leering; and/or obscene gestures;

19.7.1.3 Physical: unwanted physical contact, including touching, interference with an individual's normal work movement, and/or assault;

19.7.1.4 Other: making or threatening retaliation as a result of an individual's negative response to harassing conduct.

19.7.2 Procedure to investigate a harassment complaint

19.7.2.1 If any individual working in the hospital has observed or been the victim of conduct that constitutes sexual harassment, they should follow the same process for reporting of inappropriate conduct listed in Section 19.5. Because of the unique legal implications surrounding sexual harassment, a single incident, which the PCC determines is likely to have occurred, will require the following actions:

19.7.2.1.1 A PCC meeting shall be held with the Practitioner to discuss the incident. If the Practitioner agrees to stop the conduct thought specifically to constitute sexual harassment, the meeting shall be followed up with a formal letter of admonition and warning to be placed in the confidential portion of the Practitioner's file. This letter shall also set forth those additional actions, if any, which result from the meeting.

19.7.2.1.2 If the Practitioner refuses to stop the conduct immediately, this refusal shall result in the matter being referred to the President of the Medical Staff for review pursuant to the Bylaws. In addition, a refusal to agree to immediately stop the conduct shall result in a formal written notification to the Practitioner that he or she will not be permitted to associate with anyone in the hospital until that agreement is obtained. Thus, the Practitioner shall not be permitted to enter the hospital. This action will not constitute a suspension of Clinical Privileges, even though the effect may be the same. During the fourteen (14) day period in which the disruptive Practitioner has been given notice of his exclusion from association with anyone at the Hospital, the Practitioner shall either: (a) provide a written agreement to the President of the Medical Staff that he will refrain from any further disruptive conduct or (b) attend the next regular or special called meeting of the Medical Executive Committee during the fourteen (14) day period to discuss possible actions that could be taken in the absence of such written agreement. Failure to satisfy either of the preceding alternatives may result in the imposition of suspension, the initiation of a Professional Review Action or both.

19.7.2.1.3 Any reports of retaliation or any further reports of sexual harassment, after the Practitioner has agreed to stop the improper conduct, shall result in an immediate review by the PCC. If the review results in a finding that further improper conduct took place, the PCC shall refer the matter to the President of the Medical Staff for a formal investigation or other steps in accordance with the Bylaws. Should the President of the Medical Staff make a recommendation that entitles the individual to

request a hearing under the Bylaws, the individual shall be provided with copies of all relevant reports so that he or she can prepare.

20.0 ADVANCED PRACTICE PROFESSIONALS (APP's)

20.1 General

Advanced Practice Professionals are health care providers who are not members of the Medical Staff and are qualified to provide health care services to patients in the Hospital in a discipline, which is needed and approved by the Board of Directors. Advanced Practice Professionals shall function and be subject to the provisions of the Medical Staff Bylaws, these Rules and Regulations and the policies of the Hospital as applicable to Advanced Practice Professionals and applicable law. The scope of services, which may be provided by the Advanced Practice Professionals, shall be determined in accordance with Hospital policy. Advanced Practice Professionals are required to obtain Clinical Privileges prior to practicing in the Hospital.

20.2 Categories and Activities of Advanced Practice Professionals

Advanced Practice Professionals are subject to varying degrees of supervision and direction by Medical Staff Members while practicing in this Hospital, even though Texas law may permit certain APPs to provide healthcare services without Physician direction or supervision. Each APP scope of practice is defined by the relevant Texas practice act and by the granting of Authorization to Act as described by the Medical Staff Bylaws. Practice Privileges may be more restrictive than the scope of practice allowed by the relevant Texas practice act, but they may not exceed it.

The term supervising practitioner includes either one or more individual Practitioners all of whom may supervise the APP. Any Member of the Active or Non-Voting Medical Staff is eligible to supervise and shall assume total responsibility for the performance of any APP used by him. Conduct of the APP may subject the Supervising Practitioner of that case to informal peer review activity, professional review activity, or professional review action. Should the relationship of the APP and the Supervising Practitioner be terminated, it shall be the responsibility of such Practitioner and/or the APP to immediately notify the Medical Staff Services department of such termination and the privileges of such an APP should be suspended immediately upon receipt of such notification.

Should the staff membership of the Supervising Practitioner be terminated, the privileges of the APP shall be suspended immediately upon such action. The APP shall have sixty (60) days in which to identify an alternative approved Medical Staff member to assume the responsibilities as Supervising Practitioner. If such alternative Medical Staff member is not identified, the privileges of the APP shall automatically terminate.

20.2.1 Categories

20.2.1.1 Certified Physician Assistant

The term "Physician Assistant" refers specifically to a person who is a graduate of an accredited physician assistant training program, who has current certification by the National Commission on Certification of Physician Assistants, and who has current active licensure with the Texas Medical Board as a physician assistant.

Texas regulations determine the number of physician assistants any one Medical Staff Member may sponsor or supervise.

A physician assistant may perform only those acts which may be assigned or delegated according to the laws of the State of Texas and specifically granted by the Board of Directors.

20.2.1.2 **Certified Registered Nurse Anesthetist (CRNA)**
CRNAs must conform to the scope of practice and standards set for them by the American Association of Nurse Anesthetists (AANA). A CRNA may perform only those acts that are approved by the laws of the State of Texas, and specifically granted by the Board of Directors.

20.2.1.3 **Certified Nurse Practitioner**
Certified Nurse Practitioners may perform only those functions that are within the scope of practice and are consistent with the Texas Nursing Practice Act, other laws and regulations of the state of Texas, and specifically granted by the Board of Directors.

20.3 Rules for All Advanced Practice Professionals

20.3.1 **Bound by Rules and Regulations and Policies:** all APPs, in connection with submitting their application, shall have access to Section 20 of the Rules and Regulations governing Advanced Practice Professionals at the Hospital and agree to be subject to and abide by such provisions.

20.3.2 While at the Hospital, all APPs shall be governed by the general policies of the Hospital, as well as by specific policies relating to delivery of services and conduct of care by APPs.

20.3.3 Physician or their APP shall round daily. The sponsoring physician is required to personally assess the patient at least once per hospitalization or more if requested to do so. If the patient is on active ventilatory non-invasive or invasive support or hemodynamic support such as intravenous inotrope or intravenous vasopressor support, the APP can round but the physician must also round daily.

20.3.4 The APP shall wear the hospital assigned identification tag at all times while on the Hospital premises. Such name tags shall bear the APP's name, professional designation or other appropriate title. Failure to wear such identification shall be grounds for disciplinary action.

20.3.5 The APP may be delegated the ability to order medicinal drugs and controlled substances for hospitalized patients as long as they have an active DEA, authority to do so by the Texas Board of Nursing and comply with all applicable state and federal laws and regulations.

20.3.6 Advanced Practice Professionals shall not be eligible to vote or hold office but may be requested to serve on Medical Staff committees.

20.4 PROCEDURES FOR AUTHORIZATION, RENEWAL AND REVOCATION

20.4.1 **Effect of Application**

20.4.1.1 By applying for Authorization/Renewal each Applicant:

- 20.4.1.1.1 agrees to notify the President of the Medical Staff Services and Chief Executive Officer via Medical Staff Services in writing IMMEDIATELY after receiving written or oral notice of any of the following:
 - 20.4.1.1.1.1 voluntary or involuntary termination, denial, suspension, revocation, limitation, refusal to renew or the surrender of his license to practice or his DEA permit to prescribe (if applicable);
 - 20.4.1.1.1.2 any sanctions by state or federal agency and any sanctions or exclusions by Medicare/Medicaid;
 - 20.4.1.1.1.3 taking a leave of absence or entering into a contract or agreement with another health care facility or professional society because of mental or physical health impairment or substance abuse; and
 - 20.4.1.1.1.4 agrees to report any changes in his physical or mental health that might affect his ability to practice medicine and agrees to submit to an examination.

Failure to notify the President of the Medical Staff Services and Chief Executive Officer via Medical Staff Services of any of these situations IMMEDIATELY may be grounds for disciplinary action, up to and including termination of his Authorization to Act. However, it is unnecessary to notify of (i) traffic offenses except those involving allegations of driving while intoxicated or under the influence, (ii) suspension of privileges for less than thirty (30) days based solely upon failure to complete medical records, (iii) filing of civil lawsuits which do not allege professional negligence; or (iv) inquiry letters from peer review organizations.

- 20.4.1.1.2 agrees to notify the President of the Medical Staff and Chief Executive Officer via Medical Staff Services in writing WITHIN 15 BUSINESS DAYS after receiving written or oral notice of any of the following:
 - 20.4.1.1.2.1 Initiation of an investigation or implementation of an agreed order, remedial plan, or any other action by any professional licensing agency or a professional certification board;
 - 20.4.1.1.2.2 Imposition of: (i) any disciplinary or corrective action (including probation), (ii) initiation of an investigation for purposes of possible corrective action, (iii) suspension, reduction or loss of clinical privileges, (iv) proctoring, monitoring or review for any reason other than FPPE applicable to new Practitioners or the exercise of newly granted clinical privileges, or (vi)

denial of appointment, reappointment or renewal of medical staff membership or clinical privileges at any other hospital or health care entity, but not including automatic action for delinquent medical records;

- 20.4.1.1.2.3 Resignation of clinical privileges or medical staff membership at any other hospital or health care facility;
- 20.4.1.1.2.4 Leave of absence, whether voluntary or involuntary, from another hospital or health care entity;
- 20.4.1.1.2.5 Filing of any report concerning the APP with the National Practitioner Data Bank;
- 20.4.1.1.2.6 Pending investigations, formal or informal actions, or sanctions, whether criminal or civil, by the Texas Medical Foundation, Medicare, Medicaid, or any other state or federal governmental program;
- 20.4.1.1.2.7 Filing of, or notice of claim, for any civil or administrative action alleging professional incompetence, professional negligence, or improper professional conduct or professional misconduct;
- 20.4.1.1.2.8 Judgment, settlement or dismissal of any claim for any civil or administrative actions alleging professional incompetence, professional negligence, or improper professional conduct or professional misconduct;
- 20.4.1.1.2.9 Voluntary or involuntary challenge, denial, limitation, suspension, revocation or relinquishment of membership in any medical/professional society or association or initiation of any action that would affect membership in such a society or association; and
- 20.4.1.1.2.10 Any conviction, guilty plea or deferred adjudication, or *nolo contendere* plea or filing of formal charges for a felony or misdemeanor (including DUI or PI) other than minor traffic violations, or any court-martial.

Failure to notify the President of the Medical Staff and Chief Executive Officer via Medical Staff Services of any of these situations WITHIN 15 BUSINESS DAYS may be grounds for disciplinary action, up to and including termination of his Authorization to Act. However, it is unnecessary to notify the Medical Executive Committee of (i) traffic offenses except those involving allegations of driving while intoxicated or under the influence, (ii) suspension of privileges for less than thirty (30) days based solely upon failure to complete medical records, (iii) filing of civil lawsuits which do not allege professional negligence; or (iv) inquiry letters from peer review organizations.

- 20.4.1.1.3 authorizes Texas Health Huguley Hospital, by its Medical Staff, agents or representatives to consult with representatives of other hospitals or

institutions and members of other medical staffs with which he is or has been associated and with all others who may have information regarding his experience and competence, his character and ethical qualifications, physical and mental health and ability to work cooperatively with others. He further requests and authorizes the release of information and documents, including medical records, subject to state or federal law, regarding any of his patients or his personal medical records, relating to his professional experience and competence, ethics, character, physical and mental health and other qualifications for Authorization and Practice Privileges, by representatives of this and other hospitals, or healthcare organizations, and their medical staffs, provided such information is given in good faith and without malice;

20.4.1.1.4 releases from liability all individuals and organizations who provide information to Texas Health Huguley Hospital and its Medical Staff, and further releases Texas Health Huguley Hospital, its affiliates and their successors, assigns and transferees and their directors, trustees, officers, employees, agents and independent contractors, and any Member or any other person who provides information to other hospitals, medical associations and other healthcare organizations, in good faith and without malice, concerning his professional experience and competence, ethics, character, health and other qualifications for Authorization and privileges; and

20.4.1.1.5 acknowledges that the agreements, authorizations and releases set forth in these Rules and Regulations are express conditions to his Authorization, Renewal, and to his exercise of Practice Privileges at Texas Health Huguley Hospital.

20.4.2 Supervision of Advanced Practice Professionals

Each APP must have a supervising Physician sponsor with current privileges. If there is more than one sponsoring Physician, one Physician shall be designated as the primary supervising Physician and required to submit attestations as to the competence of the APP and the obligations of the supervising Physician. All other Physicians utilizing the services of the APP are considered alternate supervising Physicians and are subject to the same obligations. All supervising Physicians are responsible to provide the required delegation, direction and/or supervision as set forth in the Bylaws, these Rules & Regulations, Hospital policy, and the APP's delineation of Clinical Privileges when using the services of the APP. Each supervising Physician retains full responsibility for the performance and care provided by the APP. The appropriate Department, through the Physician Performance Improvement Committee, shall monitor the performance of the Advanced Practice Professionals.

20.4.3 Renewal and Revocation

The Medical Executive Committee shall recommend that any Advanced Practice Professional's approval be terminated at any time when it is believed such APP's continued service at the Hospital may in any way disrupt or endanger good patient care, or that such termination is in the interest of the orderly administration of the Hospital.

The authorization of any APP may be revoked at any time by the President or Vice President of the Medical Staff when in the opinion of such person, the failure to take such action might in any way result in a threat to the health or welfare of any patient or other person or to the orderly administration of the Hospital.

20.4.4 Notice of Adverse Recommendation or Action

After being advised that an Advanced Practice Professional has not been approved, such approval has been lost, revoked or not renewed, Bylaws, Section 6.14.18 will be followed.

20.4.5 Time to Reapply After Termination: if the Advanced Practice Professional's approval has been terminated, he shall wait at least one (1) year before reapplying if his termination was involuntary.

20.4.6 Effect of Withdrawal of Application: an APP who withdraws an application for initial or renewal of Clinical Privileges after the application has been presented to the Medical Executive Committee but prior to a final decision by the Board of Directors, may not resubmit such application for a period of one (1) year from the date of the withdrawal.

20.4.7 Failure to Process Application: if an application was closed or not processed due to failure of the applicant to provide requested or required information within the time frame allotted, the APP is not eligible to submit another application for a period of one (1) year following the date of withdrawal from processing. A second similar event will preclude the applicant from applying again.

20.5 Temporary Clinical Privileges for APP Applicants

20.5.1 Subject to the APP Applicant meeting the conditions below, temporary Clinical Privileges may be granted only to APP Applicants with a pending application for initial appointment and only granted when there is an important patient care, treatment, or service need. In granting temporary Clinical Privileges, special requirements may be imposed in order to monitor and assess the quality of care rendered by the APP exercising such privileges.

20.5.2 After receipt of a Complete Application, including a request for specific temporary Clinical Privileges and in accordance with the conditions specified below, the Hospital President may grant an Advanced Practice Professional Temporary Clinical Privileges for a period not to exceed 120 days while awaiting Medical Executive Committee and Board of Directors approval once the following criteria is met:

20.5.2.1 Complete application;

20.5.2.2 Fully verified application;

20.5.2.3 Positive recommendation from the Department Chair;

20.5.2.4 Positive recommendation from the Credentials Chair;

20.5.2.5 Positive recommendation from the President of the Medical Staff; and

20.5.2.6 Approved by the Hospital Chief Executive Officer.

- 20.5.3 To be eligible for temporary privileges, the credentialing process must include: (1) primary source verification of the applicant's current state professional licensure, (2) relevant training and current competence at the time of granting privileges, (3) ability to perform the privileges requested, (4) a query and evaluation of the NPDB information, (5) no current or previously successful challenge to licensure or controlled substances registration, (6) no record of involuntary termination of allied health membership at another health care entity, and (7) no record of involuntary limitation, reduction, denial or loss of clinical privileges at another health care entity.
- 20.5.4 Authority of Department Chair. Advanced Practice Professionals with temporary Clinical Privileges shall be subject to the authority of the Chair of the Department to which assigned and special requirements of consultation and reporting may be imposed by that Chair.
- 20.5.5 Termination of Temporary Clinical Privileges. The Hospital CEO may, after consultation with the President of the Medical Staff, terminate any or all of an Advanced Practice Professional's temporary Clinical Privileges. If failure to act may result in imminent danger to the health of an individual, the termination (or a suspension) may be affected by any person entitled to impose summary Corrective Actions under Article 7 of the Medical Staff Bylaws. Temporary Clinical Privileges shall be automatically terminated on issuance of an unfavorable recommendation by the Medical Executive Committee or automatically modified to conform to the Medical Executive Committee's recommendation that the APP be granted Clinical Privileges which are different from the temporary Clinical Privileges.
- 20.5.6 No Procedural Rights of Review. The granting of temporary Clinical Privileges is a courtesy on the part of the Hospital. An APP is not entitled to any procedural rights afforded by these Rules and Regulations or otherwise as a result of granting temporary Clinical Privileges, a failure to grant temporary Clinical Privileges, or because of any termination or suspension of temporary Clinical Privileges such as with disaster or emergency privileges. However, if the APP was granted temporary privileges pending completion of his file to the MEC and Board, and his privileges are terminated due to competence or conduct issues, then procedural rights of review are granted under Bylaws Section 6.14.18.

21.0 MEDICAL STUDENTS/POST-GRADUATE TRAINEES

Medical students, physicians, podiatrists or dentists who are currently participating in an approved training program which has established a formal relationship with the Hospital, and who have a Member of the Medical Staff sponsoring such medical student/post-graduate trainee, may be permitted to participate in patient care at the Hospital under the supervision and direction of the sponsoring Member so long as such medical student/post-graduate trainee complies with the Hospital policies pertaining to medical student/post-graduate trainees. The sponsoring Member shall be responsible to require the medical student/post-graduate trainee to comply with all Medical Staff Bylaws, Rules and Regulations and Hospital policies as such that pertain to or involve medical student/post-graduate trainees. A medical student/post-graduate trainee is not a Member of the Medical Staff and shall not be entitled to any of the procedural rights afforded Members or Practitioners of the Medical Staff. The medical student/post-graduate trainee participates in patient care by permission of the Hospital, which may be modified, reduced, suspended or terminated at any time for any reason at the sole discretion of the CEO and/or the President of the Medical Staff.

22.0 MISCELLANEOUS

22.1 Hospital Disaster Plan

A plan for the care of mass casualties at the time of any major disaster, based upon the Hospital's capabilities in conjunction with other emergency facilities in the community, shall be reviewed and approved by the Medical Staff and the Board of Directors.

22.2 Medical Staff Application Fee

The Medical Executive Committee shall decide if and how medical staff leadership and/or members of specific committees shall be compensated. These funds will be raised primarily by medical staff application fees.

TEXAS HEALTH HUGULEY HOSPITAL

MEDICAL STAFF RULES AND REGULATIONS

ADOPTED by the Medical Staff on October 12, 2021

APPROVED by the Board of Directors on October 15, 2021

CAUSE NO. 342-329996-21

ERIN JONES, INDIVIDUALLY AND AS
LEGAL REPRESENTATIVE AND
NEXT FRIEND OF JASON JONES

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IN THE DISTRICT COURT

Plaintiff,

v.

OF TARRANT COUNTY, TEXAS

TEXAS HEALTH HUGULEY HOSPITAL,
FT. WORTH SOUTH, DR. JASON SEIDEN
JOHN DOES #1-5, JANE ROES #1-5

Defendants.

342ND JUDICIAL DISTRICT

**DEFENDANTS’ RESPONSE AND BRIEF IN OPPOSITION TO PLAINTIFF’S
REQUESTED INJUNCTION**

TO THE HONORABLE JUDGE OF SAID COURT:

COME NOW Texas Health Huguley, Inc. d/b/a Texas Health Huguley Hospital Fort Worth South (“Huguley Hospital”), incorrectly named in the style as Texas Health Huguley Hospital, Ft. Worth South, Jason Seiden, M.D., John Does #1-5, and Jane Roes #1-5, Defendants in the above-styled and numbered Cause, who make and file this their Response to Plaintiff’s Request for Preliminary Injunctive Relief and Brief in Support and would show the Court the following:

I. FACTUAL AND PROCEDURAL BACKGROUND

Because the Court held a hearing on Plaintiff’s request for injunctive relief on November 1 and November 2, 2021, Defendants provide a summary of the underlying facts herein, generally referenced from the evidence and testimony presented. Jason Jones was admitted to Huguley Hospital on September 28, 2021 for COVID-related care and treatment following his discharge against medical advice from a different hospital the previous day after he refused recommended treatment. At Huguley Hospital, Mr. Jones continued to refuse recommended COVID-related

care, and predictably deteriorated. He was intubated on October 7, 2021, remains intubated and ventilator-dependent to date. His condition is critical and his prognosis is poor.

Plaintiff, Mr. Jones' spouse, contacted an otolaryngologist in Houston, Texas named Mary Talley Bowden, M.D. ("Dr. Bowden") at some point during Mr. Jones' hospitalization at Huguley Hospital. Plaintiff found Dr. Bowden on the website of the Frontline COVID-19 Critical Care Alliance ("FLCCC"). Through a "telehealth" meeting between Dr. Bowden and Plaintiff, Dr. Bowden issued a prescription for Mr. Jones for a number of medications, including Ivermectin, that constitute the "protocol" treatment according to the FLCCC. Dr. Bowden is not a credentialed member of the Huguley Hospital medical staff. Prior to issuing the prescription, she did not examine Mr. Jones, was not provided any of Mr. Jones' medical records, did not know the acute clinical condition of Mr. Jones, did not know the results of any diagnostic studies for Mr. Jones, did not know the medications he was receiving at Huguley Hospital, and had not spoken with any of Mr. Jones' actual providers.

The physicians at Huguley Hospital refused to prescribe Ivermectin to Mr. Jones, and the hospital providers refused to administer Ivermectin to Mr. Jones in accordance with Dr. Bowden's prescriptions for multiple reasons, which include, but are not limited to: (1) Dr. Bowden is not a credentialed and vetted member of the Huguley Hospital medical staff; (2) Ivermectin is not a medication approved for the treatment of COVID-19 by the United States Food and Drug Administration ("FDA"); (3) Numerous authoritative bodies and government agencies either recommend against the use of Ivermectin to treat COVID-19 (FDA, United States Centers for Disease Control and Prevention; World Health Organization, Infectious Diseases Society of America, American Medical Association, American Pharmacists Association, American Society of Health-System Pharmacists, and others) or are expressly neutral pending clinical trials (National

Institutes of Health); and (4) Mr. Jones' current physicians at Huguley Hospital, including Defendant Jason Seiden, M.D., who is a board-certified critical care physician, the Medical Director of Huguley Hospital's Critical Care service, and one of the principal physicians responsible for the development of Huguley Hospital's COVID-19 protocol (the protocol Mr. Jones refused to allow be administered to him) exercising their own professional medical judgment that Ivermectin is (1) not indicated for Mr. Jones' acute clinical condition (he is in the fibrotic—most severe—phase of acute respiratory distress syndrome) and (2) potentially harmful due to the possible side effect of arrhythmia and Mr. Jones' ileus and gastroparesis (his gastrointestinal functions are slowed, thus large amounts of ground-up tablets would likely sit in his stomach/intestinal tract and potentially result in obstruction). Plaintiff thereafter retained counsel, who commenced the instant matter on her behalf.

On October 26, 2021, the 323rd Judicial District Court of Tarrant County, Texas granted an *ex parte* application for a temporary restraining order (“TRO”) requiring Huguley Hospital and, for all intents and purposes, everyone working in and for the hospital (including its attorneys), to administer Ivermectin to Mr. Jones. After being served with the TRO, Defendants filed an emergency motion to dissolve the TRO (the arguments contained therein adopted and incorporated by Defendants as if set forth verbatim herein), as well as a Petition for Writ of Mandamus in the Second Court of Appeals, along with an Emergency Motion to Stay the trial court proceedings. The Honorable Alex Kim of the 323rd Judicial District Court transferred the case *sua sponte* on Thursday, October 28, 2021. On Friday, October 29, 2021, the Honorable R. H. Wallace of the 48th Judicial District Court of Tarrant County, Texas dissolved the TRO, but set hearing on Plaintiff's Request for a Preliminary Injunction for Monday, November 1, 2021.

On Sunday, October 31, 2021, Plaintiff filed an objection to visiting Judge R. H. Wallace. The proceeding was thereafter transferred to this Court. The temporary injunction hearing commenced on the afternoon of November 1, 2021. That day and the following day, the Court heard testimony from Plaintiff, Defendant Jason Seiden, M.D., Mary Talley Bowden, M.D., Texas State Senator Bob Hall, and Huguley Hospital's Director of Medical Staff Services.

The Court concluded the temporary injunction hearing without arguments of counsel. At the time of this briefing, the Court has yet to issue an Order.

II. SUMMARY OF RESPONSE

Plaintiff's Request for injunctive relief should be denied *in toto* for the following reasons: First, Plaintiff has failed to state a valid cause of action and, necessarily, has also failed to show a probable right to relief. Second, the relief requested by Plaintiff is manifestly untenable; federal and Texas law and regulations, the standards of authoritative bodies and agencies, and Huguley Hospital's Bylaws and Rules and Regulations for the Medical Staff all prohibit the practice of medicine in the hospital by non-credentialed physicians. Not only is Dr. Bowden not credentialed, but she is also unqualified to provide acute critical care in a hospital intensive care unit to a patient who does not require otolaryngology care. Further, under no circumstances can Huguley Hospital permit a non-credentialed, unqualified practitioner administer medication according to the "protocol" of an unsanctioned, unaccredited non-profit "Alliance" to a patient with whom she has not examined and whose records she has not reviewed. Third, as a matter of general principle, courts reject attempts to override the exercise of medical judgment by health care providers. Fourth, the relief requested by Plaintiff is not to merely keep the status quo. Rather, it awards Plaintiff relief on the ultimate issue in this case without affording Defendants the due process right to present complete evidence and arguments in their defense.

III. ARGUMENT AND AUTHORITY

“A temporary injunction is an extraordinary remedy and does not issue as a matter of right.” *Walling v. Metcalfe*, 863 S.W.2d 56, 57 (Tex. 1993) (per curiam). “A temporary injunction’s purpose is to preserve the status quo of the litigation’s subject matter pending a trial on the merits.” *Butnaru v. Ford Motor Co.*, 84 S.W.3d 198, 204 (Tex. 2002). “A prohibitive injunction forbids conduct, whereas a mandatory injunction requires it.” *Tri-Star Petroleum Co. v. Tipperary Corp.*, 101 S.W.3d 583, 592 (Tex.App.—El Paso 2003, pet. denied). Under Texas law, mandatory injunctive relief “is proper only if a mandatory order is necessary to prevent irreparable injury or extreme hardship.” *Id.*; see also *Rhodia, Inc. v. Harris County*, 470 S.W.2d 415, 419 (Tex.Civ.App.—Houston [1st Dist.] 1971, no writ). In this case, Plaintiff requests mandatory injunctive relief, requiring Defendants to administer medication not otherwise prescribed.

A. Plaintiff has not stated a Valid Claim for Relief

To prevail on a request for injunctive relief, Plaintiff must plead and prove three specific elements: (1) a cause of action against the defendant; (2) a probable right to the relief sought; and (3) a probable, imminent, and irreparable injury in the interim.” *Butnaru v. Ford Motor Co.*, 84 S.W.3d 198, 204 (Tex. 2002). Plaintiff requests a declaratory judgment that gives her a legal right to dictate treatment determinations for her husband by requiring Defendants to administer a medication prescribed by a non-credentialed and wholly unqualified provider.

Under the Uniform Declaratory Judgments Act, the only subject matter for relief permitted is that of “[a] person interested under a deed, will, written contract, or other writings constituting a contract or whose rights, status, or other legal relations are affected by a statute, municipal ordinance, contract, or franchise.” Tex. Civ. Prac. & Rem. Code § 37.004(a). Such persons may have determined any question of construction or validity arising under the instrument, statute,

ordinance, contract, or franchise and obtain a declaration of rights, status, or other legal relations thereunder. *Id.* In this case, Plaintiff has not pleaded any *valid* interest under a deed, will, written contract, or other writing constituting a contract, nor has she pleaded that her rights (or those of her husband) are affected by any statute, municipal ordinance, contract, or franchise. Instead, Plaintiff alleges that she seeks a declaration determining the rights of the parties under a nebulously-referenced “Patient/Physician contract” and the “hypocritic [sic] Oath.”

Plaintiff does not articulate on her reference to a “Patient/Physician contract.” She has not presented any contract to the Court for examination or inspection; there are no allegations about the terms of this phantom “contract,” nor is there any information in Plaintiff’s Petition or Application from which the Court could decipher what rights any party has or does not have that can be declared. Moreover, Plaintiff herself has testified that there is no written contract that requires Defendants to administer medications to Mr. Jones according to her wishes. Plaintiff does not present any competent evidence that declining to administer Ivermectin to Mr. Jones constitutes a violation or breach of the “Patient/Physician contract,” nor does she present any evidence that declining to provide Ivermectin constitutes medically improper care. The pleading is unequivocally defective. It is as if Plaintiff, knowing that to provide the Court jurisdiction to consider her request for relief under the Uniform Declaratory Judgments Act required some contract or other writing to underlie the requested relief, included “Patient/Physician contract” merely to state magical words to avoid a plea to the jurisdiction.

Plaintiff also seeks declaratory relief as to her “authority” as the “Wife” of Mr. Jones. There is no subject matter of relief available under the Uniform Declaratory Judgments Act for relief based upon the mere spousal relationship. Giving Plaintiff the benefit of the doubt, perhaps she means to state that she has the legal authority to act as medical power of attorney for her

husband, and thus her requests related to his care should be honored by his health care providers. Even this ground falls short of providing the Court jurisdiction. Plaintiff has failed to cite to any authority recognizing a patient's (or the patient's agent's) legal right to force a physician or health care provider to comply with the patient's treatment request even if the physician or health care provider believes such treatment is not medically appropriate.

Plaintiff also conclusively asserts that "Defendants have violated Texas and federal law by denying Mr. Jones his legal right to make rational treatment decisions and choices." She does not, however, state what Texas and federal laws her pleadings refer to, much less point the Court to a law that gives Mr. Jones and/or his "Wife" and their supposed "legal right to make rational treatment decisions and choices" legal priority over Defendants' legal and countervailing rights to make treatment decisions based upon the exercise of their own reasonable and prudent medical judgment. In other words, even if Mr. Jones had a legal right to take Ivermectin, there is no authority, nor could Plaintiff ever cite to any, that such a "right" compels a physician or health care provider to administer it to him.

Plaintiff further alleges that Defendants have violated Plaintiff's "right to exercise informed consent to accept and/or decline proposed treatment." Not only is this not a proper subject matter for declaratory relief, but Plaintiff's reliance on informed consent as a concept is misplaced and makes no logical sense. Mr. Jones cannot, by definition, exercise informed consent for a medication that he is not being administered. Informed consent relates to a patient's rights to know the risks and hazards of certain care and treatment before the care and treatment takes place. It does not give patients the legal right to demand care and treatment from a physician or substitute their own judgment for that of a physician or health care provider. By definition, the concept of informed consent is inapplicable.

As a corollary matter, Defendants are not even aware whether Plaintiff has any standing to bring this action. Plaintiff has produced no evidence that she holds a valid Power of Attorney for Mr. Jones, or that she has ever been designated as attorney-in-fact for her husband, much less appointed a guardian to seek relief on his behalf. The Court should require Plaintiff to show authority prior to any consideration of the merits of her request for relief.

At any rate, it is notable that there is no recognized, valid, cause of action against a hospital for failing to administer a drug that is outside the standard of care, in Texas or any other state. *See*, for example, *DeMarco v. Christiana Care Health Servs., Inc.*, No. CV 2021-0804-MTZ, 2021 WL 4343661 (Del. Ch. Sept. 24, 2021). The Court in *Demarco* addressed essentially the same issue as in this case. That Court denied a TRO finding that “[u]nder the present standard of care, healthcare providers have no duty to administer ivermectin to a COVID-19 patient” and that refusing to administer ivermectin did not breach the physician, patient relationship. *Id.* at 9. The same is true here. There is no cause of action in Texas against health care providers for failure to administer a medication that is outside of the standard of care, a circumstance Plaintiff essentially admits in her pleadings and which was produced in testimony at the temporary injunction hearing. Because there is no valid cause of action, there cannot be a probable right to relief.

B. Texas and Federal Law Prohibit Plaintiff’s Requested Relief

At the temporary injunction hearing, upon Defendants’ request the Court took judicial notice of, and admitted, numerous enacted Texas and federal statutes and regulations that govern the provision of medical and nursing care in a hospital that participates with the Centers for Medicare and Medicaid Services (*See* Exhibits 11 – 26, inclusive from the hearing record). The Court also admitted Defendants’ Exhibits 9 and 10, Huguley Hospital’s Bylaws for the Medical Staff and Rules and Regulations of the Medical Staff, respectively.

During the temporary injunction hearing, Dr. Bowden acknowledged in testimony that physicians providing medical care to hospitalized patients must be properly credentialed by the hospital, and that she is not a credentialed physician at Huguley Hospital. Tandra Cobern, the hospital's Director of Medical Staff Services, testified to the credentialing process, which mirrors that required by the CMS Conditions of Participation and Joint Commission standards. Ms. Cobern further testified that even physicians applying for temporary privileges, a vetting protocol is followed and that, in the event even temporary privileges are granted, practitioner's privileges are limited to the scope of their medical competence. Dr. Bowden is an otolaryngologist. Were she to be granted temporary privileges, they would not extend to, or permit her to provide care for, Mr. Jones. According to Ms. Cobern, Mr. Jones is in a "closed unit"—the MICU." He is not a patient in need of otolaryngology care. Further, were Mr. Jones to develop the need for otolaryngology care, the hospital is already equipped with ear, nose, and throat specialists on its medical staff. Cumulatively, the evidence demonstrates how Plaintiff's requested injunction is manifestly untenable.

C. Courts Reject the Substitution of Independent Medical Judgment

Here, rather than preserving the status quo, Plaintiff is requesting an order granting mandatory injunctive relief, *i.e.* affirmative action which contravenes the status quo. She seeks an order requiring Defendants to administer a medication that is currently not prescribed by any licensed physician that is credentialed by Huguley Hospital, and which is inconsistent with not only the patient's physicians but also the standard of care. As such, any order granting relief would require the surrender of the patient's physicians' clinical judgment to that of another physician that is not credentialed in the hospital and, by definition, has not adequately examined the patient, as

well as to the judgment of the Court, which is not a licensed physician with any legal authority in this context to dictate a patient's plan of care.

Texas courts have recognized that mandatory injunctions are tenuous when what is interfered with is the independent medical judgment of health care providers. Courts have “disavowed any attempt to second-guess the propriety or adequacy of a particular course of treatment” because it is “a question of sound professional judgment.” *Muniz v. Texas Dep’t of Crim. Just.*, 2008 WL 2764518 at *3 (Tex.App.—Corpus Christi Jul. 17, 2008, no pet.) (rejecting request for preliminary injunction ordering defendants to provide patient operation—“Courts should not intervene upon allegations of mere negligence, mistake, or difference of opinion”). Federal courts have also held that “judges are not ‘better qualified than appropriate professionals’ to make decisions relating to the physical and mental health of patients and that, to the extent possible, ‘interference by the federal judiciary with the internal operations of...institutions...should be “minimized.”” *Costa v. Bazron*, 464 F.Supp. 3d 132, 141 (D.D.C. 2020) (quoting *Youngberg v. Romeo*, 457 U.S. 307, 322-23 (1982)); *See also Youngberg*, 457 U.S. at 323 (“[W]e emphasize that courts must show deference to the judgment exercised by a qualified professional”—“[T]here certainly is no reason to think that judges or juries are better qualified than appropriate professionals in making such decisions.”); *Bowring v. Godwin*, 551 F.2d 44, 48 (4th Cir. 1977) (“[W]e disavow any attempt to second-guess the propriety or adequacy of a particular course of treatment. Along with other aspects of health care, this remains a question of sound professional judgment. The courts will not intervene upon allegations of mere negligence, mistake or difference of opinion.”).

Here, Plaintiff requests the Court override proper deference to the independent, professional, and clinical judgment of the patient's health care providers; relief which would

equally fail to give the same deference to the exercise of medical judgment that previous federal and state courts have given. Defendants have exercised clinical judgment, including with respect to the patient's plan of care. Any order requiring them to administer a certain medication overriding that judgment would be an abuse of discretion.

D. An Injunction should not Grant Ultimate Relief

To further demonstrate the perversion of Texas injunctive relief doctrine that Plaintiff has employed in this case, there is the problem that injunctive relief is designed and intended to enforce the status quo while an underlying dispute is adjudicated. Here, Plaintiff is seeking injunctive relief requiring Defendants to administer a medication, but the ultimate relief she is requesting in the underlying proceeding is to require Defendants to administer a medication.

In granting or refusing a temporary injunction, the trial court is vested with broad discretion to determine only one issue: whether the party requesting temporary relief is entitled to preservation of the status quo of the subject matter pending a trial on the merits. *Tex. Dep't of Public Safety v. Martin*, 882 S.W.2d 476 (Tex. App.—Beaumont 1994, no writ). An order granting injunctive relief that does not set forth the act to be restrained with sufficient specificity is void. *Hoist Litruck Mfg., Inc v. Carruth-Doggett, Inc.*, 485 S.W.3d 120, 123 (Tex. App.—Houston [14th Dist.] 2016, no pet.). Here, the proposed order granting the temporary injunction cannot possibly meet this standard—it does more than merely keep the status quo, it orders Defendants to take action that is not in any way related to the claim for declaratory relief. And, the action being ordered has nothing to do with keeping the status quo pending a trial on the merits. Rather, it awards Plaintiff relief on the ultimate issue in the case without affording Defendants the due process right to present complete evidence and arguments in their defense.

Keeping the status quo in this case is properly characterized as keeping the ultimate subject of the litigation, Mr. Jones, alive. Defendants have gone through extraordinary efforts to do so—recall Dr. Seiden’s testimony that he saved Mr. Jones’ life twice just in the last week by emergently inserting tubes in his chest cavity to clear trapped air caused by multiple collapsed lungs. Obviously, this case presents profoundly regrettable circumstances, as the Court itself remarked during the temporary injunction hearing.

IV. STATUS SINCE TEMPORARY INJUNCTION HEARING

Toward the conclusion of the temporary injunction hearing, the Court intimated that, in light of her testimony as to her willingness to personally provide medical care to Mr. Jones, Dr. Bowden should be permitted to apply for temporary privileges to Huguley Hospital, and further intimated that such should be reflected in some manner in a proposed order. Defendant represents to the Court that following the hearing, Dr. Bowden commenced the process for requesting temporary privileges at Huguley Hospital. The standard protocol is being adjudicated as it would for any applicant for credentials, without unnecessary delay as instructed by the Court.

Defendant is compelled, however, to repeat and restate the substance of Ms. Cobern’s testimony. Dr. Bowden is an otolaryngologist, and her training is in otolaryngology care. Were she to be granted temporary privileges, the hospital’s Bylaws and Rules and Regulations would necessarily limit her scope of practice to otolaryngology. Mr. Jones is not in need of otolaryngology care. He is in the fibrotic phase of acute respiratory distress syndrome and his condition no longer includes COVID viremia.

V. CONCLUSION

At the conclusion of the temporary injunction hearing, the Court seemed to contemplate an order permitting Dr. Bowden to apply for temporary privileges at Huguley Hospital. She has

already commenced that process even without an order from the Court, making an order to that effect superfluous.

Defendants have no other option than to ask that the Court deny Plaintiff's requested relief in its entirety. There are legal reasons, medical reasons, and public policy reasons. Legally, Plaintiff has not stated a valid cause of action, and thus cannot show a probable right to relief. Further, injunctive relief should not award ultimate relief. Medically, any order requiring health care providers to do some act in contravention of their own independent professional medical judgment, particularly one that is not recommended by numerous authoritative bodies and government agencies, is anathema to the obligation of physicians and health care providers to act in the best interests of patients. Even still, federal and state law requires patient care in the hospital to be administered by qualified, credentialed practitioners—something Dr. Bowden is not. Moreover, by her own testimony, Dr. Bowden never saw the patient, was not provided his medical records, had no knowledge of his acute care and clinical condition (what medications he was on and the results of diagnostic studies), and issued a prescription not by exercising professional medical judgment based specifically on an appropriate assessment of the patient and plan of care (which is required by law), but on the treatment “protocol” of an unsanctioned, unaccredited “Alliance.” Conceptually, this circumstance is intolerably inconsistent with prudent clinical practice.

With respect to public policy, an order by the Court that does anything but deny Plaintiff's requested relief in its entirety would set a dangerous precedent where patients unhappy with providers who will not administer precisely the care or treatment they demand can simply file a lawsuit and seek injunctive relief to override professional medical judgment by judicial fiat. With all due respect to the Court, this seems a profoundly problematic road to go down.

VI. PRAYER

WHEREFORE, PREMISES CONSIDERED, Defendants pray the Court deny Plaintiff injunctive relief and for all other and further relief, both general and special, at law or in equity, to which Defendants may show themselves to be justly entitled.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was served on counsel for the Plaintiff on the 4th day of November, 2021 via e-service.

/s/ Joshua D. Ross
Joshua D. Ross

Automated Certificate of eService

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TEX181-115413

November 5, 2021

VIA E-FILE AND EMAIL

Honorable Kimberly Fitzpatrick
Judge, 342nd Judicial District Court
Tarrant County, Texas
100 North Calhoun Street
Fort Worth, Texas 76196
kfitzpatrick@tarrantcounty.com

Re: *Erin Jones et al v. Texas Health Huguley, Inc. et al*; Cause No. 342-329996-21

Dear Judge Fitzpatrick:

Per the telephone conference with the Court and counsel of the parties late this afternoon, please accept this letter brief that outlines the various manners in which the granting of privileges or temporary privileges to Mary Talley Bowden, M.D. for the sole purpose of prescribing and administering Ivermectin to patient Jason Jones at Texas Health Huguley Hospital would violate both federal and state law. Like any regulatory framework, those which govern the licensure and operations of hospitals are complex and technical. Nevertheless, the framework set forth below constitutes the unequivocal law, violations of which can, and sometimes shall, result in the suspension or revocation of a hospital's operating license.

I am compelled to note that there is no judicial exception to the applicability, and enforceability, of the law as set forth below. The Court, quite clearly, has exercised considerable reflection about this case. The circumstances are heartbreaking; of that there is no doubt. I would be remiss if I failed to convey to the Court, but especially to Ms. Jones, that Defendants' collective posture on this matter is in no manner intended to suggest that the value of Mr. Jones' life to his spouse and his family is limited, or that the passionate efforts of Plaintiff's counsel are anything but founded on good faith and the sanctity of life. The mission of Texas Health Huguley is "Extending the Healing Ministry of Christ." We all mourn for this regrettable situation.

However, "the law is reason free from passion"—Aristotle. Thus, while it is difficult sometimes to suspend the dutiful application of the law to an unfortunate case, fidelity to the rule of law remains necessary.

I am further compelled to repeat the obvious—while Dr. Bowden is a licensed Texas physician, she is clearly unqualified for the care the Court contemplates she would provide. That Plaintiff has represented her ready willingness to release Defendants from liability (although there is no evidence to support her legal capacity to do so), Defendants’ legal and ethical obligations are to exercise independent professional medical judgment. A physician in a hospital may prescribe medication for a patient, but before it is administered a pharmacist has to be willing to dispense the medication, and a nurse has to be willing to carry out the physician’s order. While this letter brief focuses mostly on the law as applied to hospitals, pharmacists and nurses are subject to substantially similar, if not identical legal and ethical limitations of their respective practices. The purpose of this note is to convey to the Court that the order proposed by Plaintiff would likely lead the parties back to further court intervention if the hospital pharmacists are unwilling to dispense Ivermectin in accordance with Dr. Bowden’s order, or if the nurses invoke the safe harbor provisions of Chapter 303 of the Texas Occupations Code and corresponding regulations that protect a nurse from discipline for being asked to perform an act that the nurse believes violates a nurse’s duty to a patient and/or could result in a violation of the Texas Nursing Practice Act. *See* Tex. Occ. Code §§ 303.0015 and 303.005(b) and 22 T.A.C. § 217.20.

Defendants offered, and the Court admitted, several provisions of Title 42 of the Code of Federal Regulations, which provide the law colloquially referred to as the “CMS Conditions of Participation.” I have briefed, generally, the federal rules multiple times since the commencement of this proceeding, so they will not be duplicatively recited herein. Succinctly, there is no dispute that federal law requires hospitals to form medical staffs that are governed by bylaws and rules and regulations, the membership of which are determined by its members and credentialing committees. Texas Health Huguley’s Medical Staff Services Director, Tandra Cobern, testified that the Conditions of Participation are mirrored by the Bylaw and Rules of Regulations of the hospital, as well as standards promulgated by The Joint Commission, the independent non-profit organization that accredits and certifies more than 22,000 health care organizations and programs in the United States, and that is the oldest and largest standards-setting accrediting body in health care. Texas law, as shown below, also mirrors the Conditions of Participation.

Chapter 133 of Title 25 of the Texas Administrative Code provides Texas law regarding hospital licensing, the violation of which may result in the revocation of licensure. *See* 25 T.A.C. § 133.121 (failure to comply with any provision of 25 Texas Administrative Code, Chapter 133 may result in denial, suspension, or revocation of a license or administrative penalty); *see also* Tex. Health & Safety Code § 241.053. A hospital’s license may be suspended or revoked also for failing to comply with any provision of Texas Health and Safety Code Chapters 241 or 311. 25 T.A.C. § 133.121(1)(A). In adopting rules for hospitals, “conditions of participation for certification under Title XVIII of the Social Security Act (42 U.S.C. § 1395 et seq.) and the standards of The Joint Commission are used “to achieve consistency with those conditions and standards.” Tex. Health & Safety Code § 241.026(b).

25 Texas Administrative Code § 133.41(f) outlines the rules and responsibilities of the “Governing body” of a hospital, which is “responsible for the organization, management, control, and operation of the hospital, including appointment of the medical staff.” 25 T.A.C. § 133.41(f)(1). The governing body must be formally organized in accordance with written bylaws.

Id. at (f)(2). The medical staff of a hospital must have bylaws, rules, and regulations which are implemented and enforced. *Id.* at (f)(4)(A) (emphasis added); *see also* Exhibits 9 and 10 of the hearing record, Texas Health Huguley’s Bylaws and Rules and Regulations for the Medical Staff, respectively. Further, the governing body “shall determine, in accordance with state law and with the advice of medical staff, which categories of practitioners are eligible candidates for appointment to the medical staff. 25 T.A.C. § 133.41(f)(4)(F). “The medical staff shall examine credentials of candidates for medical staff membership and make recommendations to the governing body on the appointment of the candidate. *Id.* at (k)(1)(B); *see also* Tex. Health & Safety Code § 241.101. Moreover, the governing body “shall be responsible for and ensure that any policies and procedures adopted by the governing body to implement the requirements of this chapter shall be implemented and enforced.” 25 T.A.C. § 133.41(f)(4)(F)(I) (emphasis added).

“A hospital’s bylaw requirements for staff privileges may require a physician...to document the person’s current clinical competency and professional training and experience in the medical procedures for which privileges are requested.” *Id.* at (f)(4)(F)(IV). Texas law requires that a credentials committee review an applicant’s request for privileges. “A hospital’s credentials committee shall act expeditiously and without unnecessary delay when a licensed physician...submits a completed application for medical staff membership or privileges.” *Id.* at (f)(4)(F)(VIII). A hospital’s medical staff “shall adopt, implement, and enforce bylaws, rules, and regulations to carry out its responsibilities.” *Id.* at (k)(3). Medical staff bylaws “shall describe the qualifications to be met by a candidate in order for the medical staff to recommend that the candidate be appointed by the governing body. *Id.* at (k)(3)(D). Bylaws should also “include criteria for determining the privileges to be granted and a procedure for applying the criteria to individuals requesting privileges.” *Id.* at (k)(3)(E). Physicians are not permitted to perform “acts that are beyond the scope of the respective license held.” Tex. Health & Safety Code § 241.102(a) (emphasis added). Physicians are not entitled to membership or privileges on a medical staff. *Id.* at (d). All physicians must recognize the limitations of their ability and shall not offer services outside the provider’s scope of practice or use techniques that exceed their professional competency. 25 T.A.C. § 448.202. Providers “shall provide adequate and appropriate services consistent with best practices and industry standards. 25 T.A.C. § 448.201.

With respect to the administration of medications, hospitals may only prepare and administer drugs and biologicals “in accordance with federal and state laws, the orders of the individuals granted privileges by the medical staff, and accepted standards of practice.” *Id.* at (o)(4) (emphasis added). The prescription and administration of medications that are non-therapeutic violates the Texas Medical Practice Act. Tex. Occ. Code § 164.053(a)(5). Similar restrictions govern the practice of nurses and pharmacists (25 T.A.C. § 133.41(q); *see also* 25 T.A.C. § 448.1001(b) (“Prescription medication shall be used only for therapeutic and medical purposes and shall be administered as prescribed by an appropriately licensed professional”).

Texas Health Huguley’s Bylaws (Ex. 9, § 4.2.2.1), in accordance with federal and state law as shown above, outline the members and duties of its Credentials Committee. Note that the voting members of the Committee are physicians on the Medical Staff. *Id.* Texas Health Huguley’s physicians are not employed by the hospital, and as such are not under the hospital’s control. The Credentials Committee reviews “all Applications and Requests for Clinical Privileges and requests

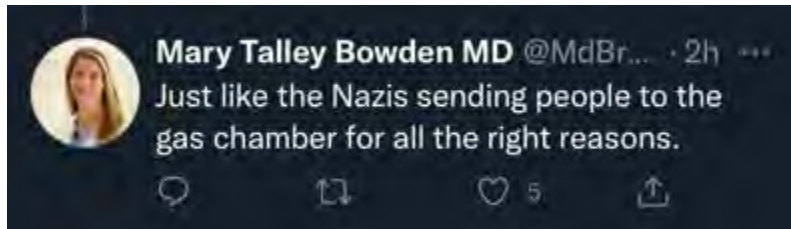
for advancement and making recommendations to the Medical Executive Committee regarding such Application and requests. *Id.* at § 4.2.2.2.1.

Texas Health Huguley's Medical Staff's members must "[a]bide by the Medical Staff Bylaws, Rules and Regulations, the Hospital's policies and procedures, regulatory requirements (*i.e.* the above-referenced Texas Administrative Code provisions and the CMS Conditions of Participation), and the professional code of ethics of the Member's profession. *Id.* at § 5.4.1. Members of the Medical Staff must be competent. *Id.* at § 5.5.2. Temporary privileges, what Plaintiff is requesting the Court to order Texas Health Huguley to provide to Dr. Bowden, are governed by Section 6.12 of the Bylaws. To be granted temporary privileges, the President of the Medical Staff, Chair of the Credentials Committee, and the Department Chair must endorse the Applicant, and an Applicant's request "may be granted *only* when there is an important patient care, treatment or service need." *Id.* at § 6.12.2. There is no need for an otolaryngologist to be granted temporary privileges at Texas Health Huguley. The Rules and Regulations of the Medical Staff, including the qualifications for Medical Staff Membership and Clinical Privileges are set forth in Exhibit 10 of the hearing record at sections 8 through 10, inclusive.

Conclusion

Viewed in the abstract, the circumstances present here are unprecedented. The patient at-issue is critically-ill in the Intensive Care Unit, a closed unit of the hospital limited to "intensivists" such as Defendant Jason Seiden, M.D., a board-certified critical care physician who is the Medical Director of the hospital's Critical Care service, and who was a principal in forming the hospital's COVID-19 protocol. Dr. Bowden, an ear, nose, and throat doctor in Houston, several hundred miles away, wishes to have the Court force the hospital to allow her to prescribe and administer a medication that nearly every authoritative body or government agency recommends against, based on nothing but her own anecdotal representation to the Court that she is qualified to do so.

Conversely, the Texas Health Huguley Credentialing Committee Vice Chair, President of the Texas Health Huguley Medical Staff, and the Department of Surgery Chair (which oversees otolaryngology services in the hospital), all non-employed physicians who are not under the hospital's control **and who are not parties to this proceeding**, reviewed Dr. Bowden's qualifications and found her wanting. The process was conducted in accordance with the hospital's Bylaws and Rules and Regulations, which, of course, are required by federal and state law in order for the hospital to retain licensure. The suggestion that the result of Dr. Bowden's privileges request was due to anything but a lack of qualifications to be involved in the care of a fibrotic acute respiratory distress syndrome patient who does not need otolaryngology care is mere hyperbolic conjecture. Despite such, Dr. Bowden herself seems to think it appropriate to post the below on her Twitter account:



It is regrettable that the medical care of a very sick individual descends so rapidly into radicalism. This from the doctor who issued a prescription of approximately a dozen medications, for which she did not evaluate the contraindications, to a patient she never saw, and for whom she never had the medical records, medication history, diagnostic study history, or a single conversation with the treating providers, based on nothing but a telephone call with the patient's wife and the treatment protocol of an unaccredited and unsanctioned organization that has pilfered money from desperate families since the COVID pandemic began. This is the doctor Plaintiff wishes for the Court to substitute the judgment of a Medical Staff President, Credentialing Committee Vice Chair, and Department Chair for judicial fiat. Defendants simply cannot stand idly by.

Thank you for your consideration of this very important matter.

Very truly yours,

Joshua D. Ross

The Honorable Kimberly Fitzpatrick

November 5, 2021

Page 6

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November 7, 2021

VIA E-FILE AND EMAIL

Honorable Kimberly Fitzpatrick
Judge, 342nd Judicial District Court
100 North Calhoun Street
Fort Worth, Texas 76196
kfitzpatrick@tarrantcounty.com

Re: Erin Jones et al v. Texas Health Huguley, Inc. et al; Cause No. 342-329996-21

Dear Judge Fitzpatrick:

I am in receipt of Mr. Ross' letter to the Court dated November 5, 2021 and offer this letter in response thereto.

Your Honor presided over a hearing for a temporary injunction on Tuesday, November 2, 2021. The Court had an opportunity to review and consider the written submissions of the parties, the arguments of counsel, and heard the testimony of witnesses for the plaintiff and defendant. Thereafter, Your Honor made a ruling.

Mr. Ross' letter is nothing but an attempt to re-argue this matter. Defendants had their opportunity to present their arguments on November 2nd, and while they continue to argue, we have a 48-year-old husband and father of six children, dying.

If in fact the mission of Texas Health Huguley is "Extending the Healing Ministry of Christ", as set forth in Mr. Ross' letter, then Defendants would stop delaying and administer this life saving medication.

Judge Kim signed the TRO in this matter on October 25, 2021. It has been two weeks and Mr. Jones remains a patient in Defendant's hospital on a ventilator, in a medically induced coma, continuing to die. The arrogance of Defendants by refusing to comply with Judge Kim's Court Order, and again refusing to comply with Your Honor's Decision, is astounding.

Defendants attempt to re-argue this matter and provide misleading information to the Court that federal and state laws will be violated by allowing temporary admission of a Board-Certified Doctor to administer a medication. This is simply not true. No laws are violated, in fact, CMS is waiving requirements under 42 CFR §482.22(a)(1)-(4) regarding the credentialing and privileging process due to covid-19. Therefore, Defendant is actually *required* to waive the credentialing process for Dr. Bowden in administering medication to Jason Jones.

Mr. Ross further argues in his letter that somehow there will be legal and ethical violations pertaining to a pharmacist who has to be willing to dispense the medication, and a nurse who has to be willing to carry out the physician's order. Again, false information is being provided to the Court. Please recall that Your Honor heard testimony at the hearing that the prescription for Ivermectin has been filled by a licensed pharmacist, and further, the Nurse working under Dr. Bowden has willingly, knowingly and voluntarily agreed to carry out the physician's order.

Lastly, Mr. Ross argues that "Temporary privileges, what Plaintiff is requesting the Court to order Texas Health Huguley to provide to Dr. Bowden, are governed by Section 6.12 of the Bylaws. To be granted temporary privileges, the President of the Medical Staff, Chair of the Credentials Committee, and the Department Chair must endorse the Applicant, and an Applicant's request "may be granted *only* when there is an important patient care, treatment or service need." *Id.* at § 6.12.2. There is no need for an otolaryngologist to be granted temporary privileges at Texas Health Huguley".

There is **no need?** The Administration at Defendant Hospital has forbidden their Doctors and Nurses to administer Ivermectin. **Their prohibition confers the need.** In addition, there is no question that this involves an **important patient care, treatment or service**". Not only is it important, but it is a matter of life and death.

We dispute that the bi-laws are violated. However, this issue was heard on November 2nd, and this Court ordered that temporary hospital privileges be granted in spite of the hospital by-laws.

We cannot forget that the issue here is the Defendants refusal to allow a lifesaving medication to an individual close to death.

Thank you.

Very truly yours,
RALPH C. LORIGO

VIA EMAIL

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March 20, 2020

Stephen G. Wohleb
Texas Hospital Association
1108 Lavaca Street
Suite 700
Austin, Texas 78701

Dear Mr. Wohleb:

This is in response to your inquiry to the Centers for Medicare & Medicaid Services (CMS). You submitted a request for Waivers under Section 1135 of the Social Security Act related to the COVID-19 Emergency on behalf of all Medicare-participating hospitals in Texas.

As you may be aware on March 13, 2020, the President of the United States issued a proclamation that the COVID-19 outbreak in the United States constitutes a national emergency by the authorities vested in him by the Constitution and the laws of the United States, including sections 201 and 301 of the National Emergencies Act (50 U.S.C. 1601 et seq.), and consistent with section 1135 of the Social Security Act (Act). On March 13, 2020, pursuant to section 1135(b) of the Act, the Secretary of the United States Department of Health and Human Services waived or modified certain requirements of titles XVIII, XIX, and XXI of the Act as a result of the consequences of the 2019 Novel Coronavirus (previously referred to as 2019-nCoV, now as COVID-19) pandemic. These waivers and modifications take effect as of 6PM Eastern Standard Time on March 15, 2020, with a retroactive effective date of March 1, 2020. The following link will list the applicable blanket 1135 waivers approved as part of the March 13, 2020, National Declaration of Emergency, pursuant to section 1135 of the Social Security Act, to address the challenges posed by COVID-19: <https://www.cms.gov/files/document/covid19-emergency-declaration-health-care-providers-fact-sheet.pdf>.

In response to the Texas Hospital Association requests not addressed as part of the blanket authorization, CMS' responses are as follows:

1. Suspend section 1867 of the Social Security Act (the Emergency Medical Treatment and Labor Act, or EMTALA) to allow hospitals to screen or triage patients at a location offsite from the hospital's campus. THA understands that CMS has issued guidance permitting hospitals to set up alternate locations to perform medical screening examinations. In an effort to prevent the transmission of COVID-19, hospitals should be permitted to screen in off campus hospital-controlled sites to afford additional flexibility. [See current CMS guidance on EMTALA and COVID-19](#). In addition, waive EMTALA sanctions for transfer of unstable patient as necessitated by public health emergency.

- This allows more flexibility to separate patients in order to prevent the spread of COVID-19 without risking an EMTALA violation. CMS' EMTALA guidance is very helpful, but this would be the most thorough form of protection.

CMS Response: This question is being forwarded to the Office of Administrator's (OA) Committee for review.

2. Waivers related to conditions and requirements of participation, certification requirements and preapproval requirements.
 - This is a general waiver, but it allows a hospital that is unable to meet a condition of participation or other requirement due to COVID-19 to request a waiver from CMS.

CMS Response: This question is being forwarded to the Office of Administrator's (OA) Committee for review.

3. Waiver of 42 C.F.R. § 482.22(a) so that physicians whose privileges will expire, and new physicians can be full medical staff/governing body review and approval.

- This removes some red tape to onboarding additional physicians or renewing the credentials of existing physicians.

CMS Response: As long as physicians are licensed to practice medicine, this waiver request is approved.

4. Waive the requirement under Section 1812(f) of the Social Security Act for a 3-day hospital stay prior to coverage of a skilled nursing facility stay.
 - This allows hospitals to discharge patients to long term care more quickly to make room for more acute patients.

CMS Response: Waiver request approved.

5. Waive discharge planning requirements so that hospitals can discharge patients who no longer need acute care to post-acute providers that can accept them in an efficient manner to free beds for acutely ill patients. See 42 C.F.R. §§ 482.43(a)(8); 485.642(a)(8).
 - This allows patients to be discharged and self-quarantined more quickly.

CMS Response: This question is being forwarded to the Office of Administrator's (OA) Committee for review.

6. Waive 42 C.F.R. 485.620, which sets a 25-bed limit and 96-hour stay limitation for critical access hospitals.
 - This allows a critical access hospital to treat or isolate a greater number of patients if a transfer is otherwise unwarranted.

CMS Response: Waiver request approved. Please also reference Blanket Waivers for COVID-19 at <https://www.cms.gov/files/document/covid19-emergency-declaration-health-care-providers-fact-sheet.pdf>

7. Allow hospitals to treat medical/surgical patients in non-PPS hospitals (e.g. long-term care hospitals) and/or units (e.g. rehabilitation). This would ensure that psychiatric or rehab units can be utilized for acute care, and that acute care is paid as acute care.
 - This allows hospitals to flex their space to use it more efficiently, which can be important for patient isolation.

CMS Response: Waiver request approved. Please also reference Blanket Waivers for COVID-19 at <https://www.cms.gov/files/document/covid19-emergency-declaration-health-care-providers-fact-sheet.pdf>

8. Waive 42 C.F.R. § 482.41 so non-hospital buildings/space can be used for patient care, provided sufficient safety and comfort is provided for patients and staff.
 - This ensures that hospitals can designate alternate sites for patient care without running into issues.

CMS Response: Waiver request approved.

9. Waive sanctions under section 1877(g) of the Social Security Act (relating to limitations on physician referral).
 - In the event of an outbreak, this removes a liability concern for referring patients to the closest or most appropriate care setting.

CMS Response: Waiver request approved.

10. Pursuant to Section 1135(b)(7) of the Social Security Act, waive sanctions and penalties arising from noncompliance with the following provisions of the HIPAA privacy regulations: (a) the requirements to obtain a patient's agreement to speak with family members or friends or to honor a patient's request to opt out of the facility directory (as set forth in 45 C.F.R. § 164.510); (b) the requirement to distribute a notice of privacy practices (as set forth in 45 C.F.R. R. § 164.520); and (c) the patient's right to request privacy restrictions or confidential communications (as set forth in 45 C.F.R. § 164.522).
 - Suspending these portions of HIPAA contemplates an influx of patients and provides the flexibility needed to share information about infection and treat patients more efficiently.

CMS Response: This will be referred to the Office of Civil Rights.

11. Waive limitations under Section 1851(i) of the Social Security Act on payment for health care items and services furnished to Medicare Advantage enrollees by non-network providers.

- This removes the complication of Medicare Advantage network participation to ensure full payment to out-of-network providers while responding to COVID-19.

CMS Response: This will be referred to the Dallas/Denver Drug and Health Plan Operations Group. Forwarded on March 19, 2020.

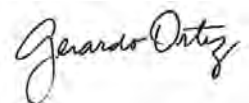
12. Permit home health agencies to temporarily perform initial assessments and determine patients' homebound status remotely or by record review. See 42 C.F.R. § 484.55(a).

- This prevents vulnerable patients from coming into contact with individuals with COVID- 19.

CMS Response: This question is being forwarded to the Office of Administrator's (OA) Committee for review.

If you have questions or concerns regarding this correspondence, please send inquiries to our corporate mailbox, RODALDSC@cms.hhs.gov, or contact Gerardo Ortiz, Division Director, at (214) 767-6341 or by e-mail at gerardo.ortiz@cms.hhs.gov.

Sincerely,



Gerardo Ortiz
Division Director, CMS – Dallas
Survey & Operations Group (SOG)

Cc: Jean Moody Williams, CCSQ
Sandra Pace, CCSQ

COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers

The Administration is taking aggressive actions and exercising regulatory flexibilities to help healthcare providers contain the spread of 2019 Novel Coronavirus Disease (COVID-19). CMS is empowered to take proactive steps through 1135 waivers as well as, where applicable, authority granted under section 1812(f) of the Social Security Act (the Act) and rapidly expand the Administration's aggressive efforts against COVID-19. As a result, the following blanket waivers are in effect, with a retroactive effective date of March 1, 2020 through the end of the emergency declaration. For general information about waivers, see Attachment A to this document. **These waivers DO NOT require a request to be sent to the 1135waiver@cms.hhs.gov mailbox or that notification be made to any of CMS's regional offices.**

Flexibility for Medicare Telehealth Services

- **Eligible Practitioners.** Pursuant to authority granted under the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) that broadens the waiver authority under section 1135 of the Social Security Act, the Secretary has authorized additional telehealth waivers. CMS is waiving the requirements of section 1834(m)(4)(E) of the Act and 42 CFR § 410.78 (b)(2) which specify the types of practitioners that may bill for their services when furnished as Medicare telehealth services from the distant site. The waiver of these requirements expands the types of health care professionals that can furnish distant site telehealth services to include all those that are eligible to bill Medicare for their professional services. This allows health care professionals who were previously ineligible to furnish and bill for Medicare telehealth services, including physical therapists, occupational therapists, speech language pathologists, and others, to receive payment for Medicare telehealth services.
- **Audio-Only Telehealth for Certain Services.** Pursuant to authority granted under the CARES Act, CMS is waiving the requirements of section 1834(m)(1) of the ACT and 42 CFR § 410.78(a)(3) for use of interactive telecommunications systems to furnish telehealth services, to the extent they require use of video technology, for certain services. This waiver allows the use of audio-only equipment to furnish services described by the codes for audio-only telephone evaluation and management services, and behavioral health counseling and educational services (see designated codes <https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes>). Unless provided otherwise, other services included on the Medicare telehealth services list must be furnished using, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner.

Hospitals, Psychiatric Hospitals, and Critical Access Hospitals (CAHs), including Cancer Centers and Long-Term Care Hospitals (LTCHs)

- **Emergency Medical Treatment & Labor Act (EMTALA).** CMS is waiving the enforcement of section 1867(a) of the Act. This will allow hospitals, psychiatric hospitals, and critical access hospitals (CAHs) to screen patients at a location offsite from the hospital's campus to prevent the spread of COVID-19, so long as it is not inconsistent with a state's emergency preparedness or pandemic plan.
- **Verbal Orders.** CMS is waiving the requirements of 42 CFR §482.23, §482.24 and §485.635(d)(3) to provide additional flexibility related to verbal orders where read-back verification is required, but authentication may occur later than 48 hours. This will allow more efficient treatment of patients in surge situations. Specifically, the following requirements are waived:
 - §482.23(c)(3)(i) - If verbal orders are used for the use of drugs and biologicals (except immunizations), they are to be used infrequently.
 - §482.24(c)(2) - All orders, including verbal orders, must be dated, timed, and authenticated promptly by the ordering practitioner or by another practitioner who is responsible for the care of the patient.
 - §482.24(c)(3) - Hospitals may use pre-printed and electronic standing orders, order sets, and protocols for patient orders. This would include all subparts at §482.24(c)(3).
 - §485.635(d)(3) - Although the regulation requires that medication administration be based on a written, signed order, this does not preclude the CAH from using verbal orders. A practitioner responsible for the care of the patient must authenticate the order in writing as soon as possible after the fact.
- **Reporting Requirements.** CMS is waiving the requirements at 42 CFR §482.13(g) (1)(i)-(ii), which require that hospitals report patients in an intensive care unit whose death is caused by their disease, but who required soft wrist restraints to prevent pulling tubes/IVs, no later than the close of business on the next business day. Due to current hospital surge, CMS is waiving this requirement to ensure that hospitals are focusing on increased patient care demands and increased patient census, provided any death where the restraint may have contributed is still reported within standard time limits (i.e., close of business on the next business day following knowledge of the patient's death).
- **Patient Rights.** CMS is waiving requirements under 42 CFR §482.13 **only for hospitals that are considered to be impacted by a widespread outbreak of COVID-19.** Hospitals that are located in a state which has widespread confirmed cases (i.e., 51 or more confirmed cases*) as updated on the CDC website, CDC States Reporting Cases of COVID-19, at <https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html>, would not be required to meet the following requirements:

- §482.13(d)(2) - With respect to timeframes in providing a copy of a medical record.
- §482.13(h) - Related to patient visitation, including the requirement to have written policies and procedures on visitation of patients who are in COVID-19 isolation and quarantine processes.
- §482.13(e)(1)(ii) - Regarding seclusion.

*The waiver flexibility is based on the number of confirmed cases as reported by CDC and will be assessed accordingly when COVID-19 confirmed cases decrease.

- **Sterile Compounding.** CMS is waiving requirements (also outlined in USP797) at 42 CFR §482.25(b)(1) and §485.635(a)(3) in order to allow used face masks to be removed and retained in the compounding area to be re-donned and reused during the same work shift in the compounding area only. This will conserve scarce face mask supplies. CMS will not review the use and storage of face masks under these requirements.
- **Detailed Information Sharing for Discharge Planning for Hospitals and CAHs.** CMS is waiving the requirement 42 CFR §482.43(a)(8), §482.61(e), and §485.642(a)(8) to provide detailed information regarding discharge planning, described below:
 - The hospital, psychiatric hospital, and CAH must assist patients, their families, or the patient's representative in selecting a post-acute care provider by using and sharing data that includes, but is not limited to, home health agency (HHA), skilled nursing facility (SNF), inpatient rehabilitation facility (IRF), and long-term care hospital (LTCH) quality measures and resource use measures. The hospital must ensure that the post-acute care data on quality measures and resource use measures is relevant and applicable to the patient's goals of care and treatment preferences.
 - CMS is maintaining the discharge planning requirements that ensure a patient is discharged to an appropriate setting with the necessary medical information and goals of care as described in 42 CFR §482.43(a)(1)-(7) and (b).
- **Limiting Detailed Discharge Planning for Hospitals.** CMS is waiving all the requirements and subparts at 42 CFR §482.43(c) related to post-acute care services so as to expedite the safe discharge and movement of patients among care settings, and to be responsive to fluid situations in various areas of the country. CMS is maintaining the discharge planning requirements that ensure a patient is discharged to an appropriate setting with the necessary medical information and goals of care as described in 42 CFR §482.43(a)(1)-(7) and (b). CMS is waiving the more detailed requirement that hospitals ensure those patients discharged home and referred for HHA services, or transferred to a SNF for post-hospital extended care services, or transferred to an IRF or LTCH for specialized hospital services, must:
 - §482.43(c)(1): Include in the discharge plan a list of HHAs, SNFs, IRFs, or LTCHs that are available to the patient.

- §482.43(c)(2): Inform the patient or the patient’s representative of their freedom to choose among participating Medicare providers and suppliers of post-discharge services.
- §482.43(c)(3): Identify in the discharge plan any HHA or SNF to which the patient is referred in which the hospital has a disclosable financial interest, as specified by the Secretary, and any HHA or SNF that has a disclosable financial interest in a hospital under Medicare.
- **Medical Staff.** CMS is waiving requirements under 42 CFR §482.22(a)(1)-(4) to allow for physicians whose privileges will expire to continue practicing at the hospital and for new physicians to be able to practice before full medical staff/governing body review and approval to address workforce concerns related to COVID-19. CMS is waiving §482.22(a) (1)-(4) regarding details of the credentialing and privileging process. **(Please also refer to Practitioner Locations Blanket Waiver listed below.)**
- **Medical Records.** CMS is waiving requirements under 42 CFR §482.24(a) through (c), which cover the subjects of the organization and staffing of the medical records department, requirements for the form and content of the medical record, and record retention requirements, and these flexibilities may be implemented so long as they are not inconsistent with a state’s emergency preparedness or pandemic plan. CMS is waiving §482.24(c)(4)(viii) related to medical records to allow flexibility in completion of medical records within 30 days following discharge from a hospital. This flexibility will allow clinicians to focus on the patient care at the bedside during the pandemic.
- **Flexibility in Patient Self Determination Act Requirements (Advance Directives).** CMS is waiving the requirements at sections 1902(a)(58) and 1902(w)(1)(A) of the Act (for Medicaid); 1852(i) of the Act (for Medicare Advantage); and 1866(f) of the Act and 42 CFR §489.102 (for Medicare), which require hospitals and CAHs to provide information about their advance directive policies to patients. CMS is waiving this requirement to allow staff to more efficiently deliver care to a larger number of patients.
- **Physical Environment.** CMS is waiving certain physical environment requirements under the Medicare conditions of participation at 42 CFR §482.41 and 42 CFR §485.623 to allow for increased flexibilities for surge capacity and patient quarantine at hospitals, psychiatric hospitals, and critical access hospitals (CAHs) as a result of COVID-19. CMS will permit facility and non-facility space that is not normally used for patient care to be utilized for patient care or quarantine, provided the location is approved by the state (ensuring that safety and comfort for patients and staff are sufficiently addressed) and is consistent with the state’s emergency preparedness or pandemic plan. This allows for increased capacity and promotes appropriate cohorting of COVID-19 patients. States are still subject to obligations under the integration mandate of the Americans with Disabilities Act, to avoid subjecting persons with disabilities to

unjustified institutionalization or segregation¹.

- **Telemedicine.** CMS is waiving the provisions related to telemedicine at 42 CFR §482.12(a) (8)–(9) for hospitals and §485.616(c) for CAHs, making it easier for telemedicine services to be furnished to the hospital’s patients through an agreement with an off-site hospital. This allows for increased access to necessary care for hospital and CAH patients, including access to specialty care.
- **Physician Services.** CMS is waiving requirements under 42 CFR §482.12(c)(1)–(2) and §482.12(c)(4), which requires that Medicare patients be under the care of a physician. This waiver may be implemented so long as it is not inconsistent with a state’s emergency preparedness or pandemic plan. This allows hospitals to use other practitioners to the fullest extent possible.
- **Anesthesia Services.** CMS is waiving requirements under 42 CFR §482.52(a)(5), §485.639(c) (2), and §416.42 (b)(2) that a certified registered nurse anesthetist (CRNA) is under the supervision of a physician in paragraphs §482.52(a)(5) and §485.639(c)(2). CRNA supervision will be at the discretion of the hospital and state law. This waiver applies to hospitals, CAHs, and Ambulatory Surgical Centers (ASCs). These waivers will allow CRNAs to function to the fullest extent of their licensure, and may be implemented so long as they are not inconsistent with a state’s emergency preparedness or pandemic plan.
- **Utilization Review.** CMS is waiving certain requirements under 42 CFR §482.1(a)(3) and 42 CFR §482.30 which address the statutory basis for hospitals and includes the requirement that hospitals participating in Medicare and Medicaid must have a utilization review plan that meets specified requirements.
 - CMS is waiving the entire utilization review condition of participation Utilization Review (UR) at §482.30, which requires that a hospital must have a UR plan with a UR committee that provides for a review of services furnished to Medicare and Medicaid beneficiaries to evaluate the medical necessity of the admission, duration of stay, and services provided. These flexibilities may be implemented so long as they are not inconsistent with a state’s emergency preparedness or pandemic plan. Removing these administrative requirements will allow hospitals to focus more resources on providing direct patient care.
- **Written Policies and Procedures for Appraisal of Emergencies at Off Campus Hospital**

¹Please note that consistent with the integration mandate of Title II of the ADA and the *Olmstead vs LC* decision, States are obligated to offer/ provide discharge planning and/or case management/ transition services, as appropriate, to individuals who are removed from their Medicaid home and community based services under these authorities during the course of the public health emergency as well as to individuals with disabilities who may require these services in order to avoid unjustified institutionalization or segregation. Transition services/ case management and/or discharge planning would be provided to facilitate these individuals in their return to the community when their condition and public health circumstances permit.

Departments. CMS is waiving 42 CFR §482.12(f)(3), emergency services, with respect to surge facilities **only**, such that written policies and procedures for staff to use when evaluating emergencies are not required for surge facilities. This removes the burden on facilities to develop and establish additional policies and procedures at their surge facilities or surge sites related to the assessment, initial treatment, and referral of patients. These flexibilities may be implemented so long as they are not inconsistent with a state’s emergency preparedness or pandemic plan.

- **Emergency Preparedness Policies and Procedures.** CMS is waiving 42 CFR §482.15(b) and §485.625(b), which requires the hospital and CAH to develop and implement emergency preparedness policies and procedures, and §482.15(c)(1)–(5) and §485.625(c)(1)–(5) which requires that the emergency preparedness communication plans for hospitals and CAHs to contain specified elements with respect to the surge site. The requirement under the communication plan requires hospitals and CAHs to have specific contact information for staff, entities providing services under arrangement, patients’ physicians, other hospitals and CAHs, and volunteers. This would not be an expectation for the surge site. This waiver applies to both hospitals and CAHs, and removes the burden on facilities to establish these policies and procedures for their surge facilities or surge sites.
- **Quality Assessment and Performance Improvement Program.** CMS is waiving 42 CFR §482.21(a)–(d) and (f), and §485.641(a), (b), and (d), which provide details on the scope of the program, the incorporation, and setting priorities for the program’s performance improvement activities, and integrated Quality Assurance & Performance Improvement programs (for hospitals that are part of a hospital system). These flexibilities, which apply to both hospitals and CAHs, may be implemented so long as they are not inconsistent with a state’s emergency preparedness or pandemic plan. We expect any improvements to the plan to focus on the Public Health Emergency (PHE). While this waiver decreases burden associated with the development of a hospital or CAH QAPI program, the requirement that hospitals and CAHs maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program will remain. This waiver applies to both hospitals and CAHs.
- **Nursing Services.** CMS is waiving the requirements at 42 CFR §482.23(b)(4), which requires the nursing staff to develop and keep current a nursing care plan for each patient, and §482.23(b)(7), which requires the hospital to have policies and procedures in place establishing which outpatient departments are not required to have a registered nurse present. These waivers allow nurses increased time to meet the clinical care needs of each patient and allow for the provision of nursing care to an increased number of patients. In addition, we expect that hospitals will need relief for the provision of inpatient services and as a result, the requirement to establish nursing-related policies and procedures for outpatient departments is likely of lower priority. These flexibilities apply to both hospitals and CAHs §485.635(d)(4), and may be implemented so long as they are not inconsistent with a state’s emergency preparedness or

pandemic plan.

- **Food and Dietetic Services.** CMS is waiving the requirement at paragraph 42 CFR §482.28(b) (3), which requires providers to have a current therapeutic diet manual approved by the dietitian and medical staff readily available to all medical, nursing, and food service personnel. Such manuals would not need to be maintained at surge capacity sites. These flexibilities may be implemented so long as they are not inconsistent with a state’s emergency preparedness or pandemic plan. Removing these administrative requirements will allow hospitals to focus more resources on providing direct patient care.
- **Respiratory Care Services.** CMS is waiving the requirements at 42 CFR §482.57(b)(1) that require hospitals to designate in writing the personnel qualified to perform specific respiratory care procedures and the amount of supervision required for personnel to carry out specific procedures. These flexibilities may be implemented so long as they are not inconsistent with a state’s emergency preparedness or pandemic plan. Not being required to designate these professionals in writing will allow qualified professionals to operate to the fullest extent of their licensure and training in providing patient care.
- **Expanded Ability for Hospitals to Offer Long-term Care Services (“Swing-Beds”) for Patients Who do not Require Acute Care but do Meet the Skilled Nursing Facility (SNF) Level of Care Criteria as Set Forth at 42 CFR 409.31.** Under section 1135(b)(1) of the Act, CMS is waiving the requirements at 42 CFR 482.58, “*Special Requirements for hospital providers of long-term care services (“swing-beds”)*” subsections (a)(1)-(4) “*Eligibility*”, to allow hospitals to establish SNF swing beds payable under the SNF prospective payment system (PPS) to provide additional options for hospitals with patients who no longer require acute care but are unable to find placement in a SNF.

In order to qualify for this waiver, hospitals must:

- Not use SNF swing beds for acute level care.
- Comply with all other hospital conditions of participation and those SNF provisions set out at 42 CFR 482.58(b) to the extent not waived.
- Be consistent with the state’s emergency preparedness or pandemic plan.

Hospitals must call the CMS Medicare Administrative Contractor (MAC) enrollment hotline to add swing bed services. The hospital must attest to CMS that:

- They have made a good faith effort to exhaust all other options;
- There are no skilled nursing facilities within the hospital’s catchment area that under normal circumstances would have accepted SNF transfers, but are currently not willing

to accept or able to take patients because of the COVID-19 public health emergency (PHE);

- The hospital meets all waiver eligibility requirements; and
- They have a plan to discharge patients as soon as practicable, when a SNF bed becomes available, or when the PHE ends, whichever is earlier.

This waiver applies to all Medicare enrolled hospitals, except psychiatric and long term care hospitals that need to provide post-hospital SNF level swing-bed services for non-acute care patients in hospitals, so long as the waiver is not inconsistent with the state's emergency preparedness or pandemic plan. The hospital shall not bill for SNF PPS payment using swing beds when patients require acute level care or continued acute care at any time while this waiver is in effect. This waiver is permissible for swing bed admissions during the COVID-19 PHE with an understanding that the hospital must have a plan to discharge swing bed patients as soon as practicable, when a SNF bed becomes available, or when the PHE ends, whichever is earlier.

- **Medicare Graduate Medical Education (GME) Affiliation Agreement (updated 5/24/21):** Due to the COVID-19 Public Health Emergency (PHE), under the authority of section 1135(b)(5) of the Social Security Act (the Act), CMS is extending the submission deadline for both new Medicare GME affiliation agreements and amendments to existing Medicare GME affiliation agreements to January 1, 2022. CMS previously waived the July 1 submission deadline under 42 CFR 413.79(f)(1) for new Medicare GME affiliation agreements and the June 30 deadline under the May 12, 1998 Health Care Financing Administration Final Rule (63 FR 26318, 26339, 26341) for amendments of existing Medicare GME affiliation agreements. That is, during the COVID-19 PHE, instead of requiring that new Medicare GME affiliation agreements be submitted to CMS and the MACs by July 1, 2020 (for the academic year starting July 1, 2020), and that amendments to Medicare GME affiliation agreements be submitted to CMS and the MACs by June 30, 2020 (for the academic year ending June 30, 2020), CMS allowed hospitals to submit new and/or amended Medicare GME affiliation agreements as applicable to CMS and the MACs by January 1, 2021.

As a result of the continuation of the COVID-19 PHE effective April 21, 2021, new Medicare GME affiliation agreements must be submitted by January 1, 2022 (for the academic year starting July 1, 2021) and amended Medicare GME affiliation agreements must be submitted by January 1, 2022 (for the academic year ending June 30, 2021). As under existing procedures, hospitals should email new and/or amended agreements to CMS at Medicare_GME_Affiliation_Agreement@cms.hhs.gov, and indicate in the subject line whether the affiliation agreement is a new one or an amended one.

- **CAH Personnel Qualifications.** CMS is waiving the minimum personnel qualifications for clinical nurse specialists at paragraph 42 CFR §485.604(a)(2), nurse practitioners at paragraph §485.604(b)(1)–(3), and physician assistants at paragraph §485.604(c)(1)–(3). Removing these Federal personnel requirements will allow CAHs to employ individuals in these roles who meet state licensure requirements and provide maximum staffing flexibility. These flexibilities should be implemented so long as they are not inconsistent with a state’s emergency preparedness or pandemic plan.
- **CAH Staff Licensure.** CMS is deferring to staff licensure, certification, or registration to state law by waiving 42 CFR §485.608(d) regarding the requirement that staff of the CAH be licensed, certified, or registered in accordance with applicable federal, state, and local laws and regulations. This waiver will provide maximum flexibility for CAHs to use all available clinicians. These flexibilities may be implemented so long as they are not inconsistent with a state’s emergency preparedness or pandemic plan.
- **CAH Status and Location.** CMS is waiving the requirement at 42 CFR §485.610(b) that the CAH be located in a rural area or an area being treated as being rural, allowing the CAH flexibility in the establishment of surge site locations. CMS is also waiving the requirement at §485.610(e) regarding the CAH’s off-campus and co-location requirements, allowing the CAH flexibility in establishing temporary off-site locations. In an effort to facilitate the establishment of CAHs without walls, these waivers will suspend restrictions on CAHs regarding their rural location and their location relative to other hospitals and CAHs. These flexibilities may be implemented so long as they are not inconsistent with a state’s emergency preparedness or pandemic plan.
- **CAH Length of Stay.** CMS is waiving the requirements that CAHs limit the number of beds to 25, and that the length of stay be limited to 96 hours under the Medicare conditions of participation for number of beds and length of stay at 42 CFR §485.620.
- **Temporary Expansion Locations:** For the duration of the PHE related to COVID-19, CMS is waiving certain requirements under the Medicare conditions of participation at 42 CFR §482.41 and §485.623 (as noted elsewhere in this waiver document) and the provider-based department requirements at §413.65 to allow hospitals to establish and operate as part of the hospital any location meeting those conditions of participation for hospitals that continue to apply during the PHE. This waiver also allows hospitals to change the status of their current provider-based department locations to the extent necessary to address the needs of hospital patients as part of the state or local pandemic plan. This extends to any entity operating as a hospital (whether a current hospital establishing a new location or an Ambulatory Surgical Center (ASC) enrolling as a hospital during the PHE pursuant to a streamlined enrollment and survey and certification process) so long as the relevant location meets the conditions of participation and other requirements not waived by CMS. This waiver will enable hospitals to meet the needs of Medicare beneficiaries.

- **Responsibilities of Physicians in Critical Access Hospitals (CAHs).** 42 CFR § 485.631(b)(2). CMS is waiving the requirement for CAHs that a doctor of medicine or osteopathy be physically present to provide medical direction, consultation, and supervision for the services provided in the CAH at § 485.631(b)(2). CMS is retaining the regulatory language in the second part of the requirement at § 485.631(b)(2) that a physician be available “through direct radio or telephone communication, or electronic communication for consultation, assistance with medical emergencies, or patient referral.” Retaining this longstanding CMS policy and related longstanding subregulatory guidance that further described communication between CAHs and physicians will assure an appropriate level of physician direction and supervision for the services provided by the CAH. This will allow the physician to perform responsibilities remotely, as appropriate. This also allows CAHs to use nurse practitioners and physician assistants to the fullest extent possible, while ensuring necessary consultation and support as needed.
- **Postponement of Application Deadline to the Medicare Geographic Classification Review Board** *(New since 7/29 Release)*. Per requirements at section 1886(d)(10)(C)(ii) of the Social Security Act (the Act) and 42 CFR 412.256(a)(2), September 1, 2020 is the deadline to submit an application to the Medicare Geographic Classification Review Board (MGCRB) for FY 2022 reclassifications. These provisions require applications to be filed through OH CDMS (<https://www.cms.gov/Regulations-and-Guidance/Review-Boards/MGCRB/Electronic-Filing>) not later than the first day of the 13-month period preceding the Federal fiscal year for which reclassification is requested.

Due to the COVID-19 Public Health Emergency (PHE), under the authority of section 1135(b)(5) of the Act, CMS is postponing the September 1 deadline until 15 days after the public display date of the FY 2021 IPPS/LTCH final rule by the Office of the Federal Register.

- **Long Term Care Hospitals - Site Neutral Payment Rate Provisions.** Also as required by section 3711(b) of the CARES Act, during the Public Health Emergency (PHE) due to COVID-19, the Secretary has waived section 1886(m)(6) of the Social Security Act relating to certain site neutral payment rate provisions for long-term care hospitals (LTCHs).
 - Section 3711(b)(1) of the CARES Act waives the payment adjustment under section 1886(m)(6)(C)(ii) of the Act for LTCHs that do not have a discharge payment percentage (DPP) for the period that is at least 50 percent during the COVID-19 public health emergency period. Under this provision, for the purposes of calculating an LTCH’s DPP, all admissions during the COVID-19 public health emergency period will be counted in the numerator of the calculation, that is, LTCH cases that were admitted during the COVID-19 public health emergency period will be counted as discharges paid the LTCH PPS standard Federal payment rate.
 - Section 3711(b)(2) of the CARES Act provides a waiver of the application of the site neutral payment rate under section 1886(m)(6)(A)(i) of the Act for those LTCH admissions that are in response to the public health emergency and occur during the

COVID-19 public health emergency period. Under this provision, all LTCH cases admitted during the COVID-19 public health emergency period will be paid the relatively higher LTCH PPS standard Federal rate. A new LTCH PPS Pricer software package will be released in April 2020 to include this temporary payment policy effective for claims with an admission date occurring on or after January 27, 2020 and continuing through the duration of the COVID-19 public health emergency period. Claims received on or after April 21, 2020, will be processed in accordance with this waiver. Claims received April 20, 2020, and earlier will be reprocessed.

- **Conditions of Participation (CoP) for COVID-19 Vaccinations. *(New since 12/1/20 Release)***. Under the authority afforded by Section 1135 of the Social Security Act, for the duration of the Public Health Emergency, CMS is modifying the following regulation:

§ 482.23 Condition of participation: Nursing services.

(c) Standard: Preparation and administration of drugs.

(3) With the exception of influenza and pneumococcal vaccines, which may be administered per physician-approved hospital policy after an assessment of contraindications, orders for drugs and biologicals must be documented and signed by a practitioner who is authorized to write orders in accordance with State law and hospital policy, and who is responsible for the care of the patient.

To allow for hospital and community administration of COVID-19 vaccines, the following highlighted language is being incorporated into this regulation for the duration of the PHE:

§ 482.23 Condition of participation: Nursing services.

(c) Standard: Preparation and administration of drugs.

(3) With the exception of influenza, pneumococcal, and COVID-19 vaccines (either currently approved by the FDA or authorized under an FDA Emergency Use Authorization), which may be administered per physician-approved hospital policy after an assessment of contraindications, orders for drugs and biologicals must be documented and signed by a practitioner who is authorized to write orders in accordance with State law and hospital policy, and who is responsible for the care of the patient.

Hospitals Classified as Sole Community Hospitals (SCHs)

- CMS is waiving certain eligibility requirements at 42 CFR § 412.92(a) for hospitals classified as

SCHs prior to the PHE. Specifically, CMS is waiving the distance requirements at paragraphs (a), (a)(1), (a)(2), and (a)(3) of 42 CFR § 412.92, and is also waiving the “market share” and bed requirements (as applicable) at 42 CFR § 412.92(a)(1)(i) and (ii). CMS is waiving these requirements for the duration of the PHE to allow these hospitals to meet the needs of the communities they serve during the PHE, such as to provide for increased capacity and promote appropriate cohorting of COVID-19 patients. MACs will resume their standard practice for evaluation of all eligibility requirements after the conclusion of the PHE period.

Hospitals Classified as Medicare-Dependent, Small Rural Hospitals (MDHs)

- For hospitals classified as MDHs prior to the PHE, CMS is waiving the eligibility requirement at 42 CFR § 412.108(a)(1)(ii) that the hospital has 100 or fewer beds during the cost reporting period, and the eligibility requirement at 42 CFR § 412.108(a)(1)(iv)(C) that at least 60 percent of the hospital's inpatient days or discharges were attributable to individuals entitled to Medicare Part A benefits during the specified hospital cost reporting periods. CMS is waiving these requirements for the duration of the PHE to allow these hospitals to meet the needs of the communities they serve during the PHE, such as to provide for increased capacity and promote appropriate cohorting of COVID-19 patients. MACs will resume their standard practice for evaluation of all eligibility requirements after the conclusion of the PHE period.

Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

- **Certain Staffing Requirements.** 42 CFR 491.8(a)(6). CMS is waiving the requirement in the second sentence of § 491.8(a)(6) that a nurse practitioner, physician assistant, or certified nurse-midwife be available to furnish patient care services at least 50 percent of the time the RHC operates. CMS is not waiving the first sentence of § 491.8(a)(6) that requires a physician, nurse practitioner, physician assistant, certified nurse-midwife, clinical social worker, or clinical psychologist to be available to furnish patient care services at all times the clinic or center operates. This will assist in addressing potential staffing shortages by increasing flexibility regarding staffing mixes during the PHE.
- **Physician Supervision of NPs in RHCs and FQHCs.** 42 CFR 491.8(b)(1). We are modifying the requirement that physicians must provide medical direction for the clinic's or center's health care activities and consultation for, and medical supervision of, the health care staff, only with respect to medical supervision of nurse practitioners, and only to the extent permitted by state law. The physician, either in person or through telehealth and other remote communications, continues to be responsible for providing medical direction for the clinic or center's health care activities and consultation for the health care staff, and medical supervision of the remaining health care staff. This allows RHCs and FQHCs to use nurse practitioners to the fullest extent possible and allows physicians to direct their time to more critical tasks.

- **Temporary Expansion Locations.** CMS is waiving the requirements at 42 CFR §491.5(a)(3)(iii) which require RHCs and FQHCs be independently considered for Medicare approval if services are furnished in more than one permanent location. Due to the current PHE, CMS is temporarily waiving this requirement removing the location restrictions to allow flexibility for existing RHCs/FQHCs to expand services locations to meet the needs of Medicare beneficiaries. This flexibility includes areas which may be outside of the location requirements 42 CFR §491.5(a)(1) and (2) but will end when the HHS Secretary determines there is no longer a PHE due to COVID-19.

Housing Acute Care Patients in the IRF or Inpatient Psychiatric Facility (IPF) Excluded Distinct Part Units

- CMS is waiving requirements to allow acute care hospitals to house acute care inpatients in excluded distinct part units, such as excluded distinct part unit IRFs or IPFs, where the distinct part unit's beds are appropriate for acute care inpatients. The Inpatient Prospective Payment System (IPPS) hospital should bill for the care and annotate the patient's medical record to indicate the patient is an acute care inpatient being housed in the excluded unit because of capacity issues related to the disaster or emergency.

Care for Excluded Inpatient Psychiatric Unit Patients in the Acute Care Unit of a Hospital

- CMS is allowing acute care hospitals with excluded distinct part inpatient psychiatric units to relocate inpatients from the excluded distinct part psychiatric unit to an acute care bed and unit as a result of a disaster or emergency. The hospital should continue to bill for inpatient psychiatric services under the Inpatient Psychiatric Facility Prospective Payment System for these patients and annotate the medical record to indicate the patient is a psychiatric inpatient being cared for in an acute care bed because of capacity or other exigent circumstances related to the COVID-19 emergency. This waiver may be utilized where the hospital's acute care beds are appropriate for psychiatric patients and the staff and environment are conducive to safe care. For psychiatric patients, this includes assessment of the acute care bed and unit location to ensure those patients at risk of harm to self and others are safely cared for.

Care for Excluded Inpatient Rehabilitation Unit Patients in the Acute Care Unit of a Hospital

- CMS is allowing acute care hospitals with excluded distinct part inpatient rehabilitation units that, as a result of a disaster or emergency, need to relocate inpatients from the excluded distinct part rehabilitation unit to an acute care bed and unit as a result of this PHE. The hospital should continue to bill for inpatient rehabilitation services under the inpatient rehabilitation facility prospective payment system for these patients and annotate the medical

record to indicate the patient is a rehabilitation inpatient being cared for in an acute care bed because of capacity or other exigent circumstances related to the disaster or emergency. This waiver may be utilized where the hospital's acute care beds are appropriate for providing care to rehabilitation patients and such patients continue to receive intensive rehabilitation services.

Flexibility for Inpatient Rehabilitation Facilities Regarding the “60 Percent Rule”

- CMS is allowing IRFs to exclude patients from the freestanding hospital's or excluded distinct part unit's inpatient population for purposes of calculating the applicable thresholds associated with the requirements to receive payment as an IRF (commonly referred to as the “60 percent rule”) if an IRF admits a patient solely to respond to the emergency and the patient's medical record properly identifies the patient as such. In addition, during the applicable waiver time period, we would also apply the exception to facilities not yet classified as IRFs, but that are attempting to obtain classification as an IRF.

Inpatient Rehabilitation Facility – Intensity of Therapy Requirement (“3-Hour Rule”)

- As required by section 3711(a) of the Coronavirus Aid, Relief, and Economic Security (CARES) Act, during the COVID-19 public health emergency, the Secretary has waived 42 CFR § 412.622(a)(3)(ii) which provides that payment generally requires that patients of an inpatient rehabilitation facility receive at least 15 hours of therapy per week. This waiver clarifies information provided in “Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency” (CMS-1744-IFC). (85 Federal Register 19252, 19287, April 6, 2020). The information in that rulemaking (CMS-1744-IFC) about Inpatient Rehabilitation Facilities was contemplated prior to the passage of the CARES Act.

Extension for Inpatient Prospective Payment System (IPPS) Wage Index Occupational Mix Survey Submission

- CMS collects data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program. Completed 2019 Occupational Mix Surveys, Hospital Reporting Form CMS-10079, for the Wage Index Beginning FY 2022, were initially due to the Medicare Administrative Contractors (MACs) on the Excel hospital reporting form available at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files.html> by July 1, 2020. CMS granted an extension for hospitals nationwide affected by COVID-19 until August 3, 2020. Due to continued COVID related concerns from hospitals about meeting this deadline, CMS is further extending this deadline to September 3, 2020. Hospitals must submit their occupational mix surveys along with complete supporting documentation to their MACs by no later than September 3, 2020. Hospitals may then submit revisions to their occupational mix surveys to their MACs, if needed,

by no later than September 10, 2020.

Supporting Care for Patients in Long-Term Care Acute Hospitals (LTCHs)

- CMS has determined it is appropriate to issue a blanket waiver to long-term care hospitals (LTCHs) where an LTCH admits or discharges patients in order to meet the demands of the emergency from the 25-day average length of stay requirement at § 412.23(e)(2), which allows these hospitals to participate in the LTCH PPS. In addition, during the applicable waiver time period, CMS has determined it is appropriate to issue a blanket waiver to hospitals not yet classified as LTCHs, but seeking classification as an LTCH, to exclude patient stays where the hospital admits or discharges patients in order to meet the demands of the emergency from the 25-day average length of stay requirement, which must be met in order for these hospitals to be eligible to participate in the LTCH PPS. Hospitals should add the “DR” condition code to applicable claims.

Care for Patients in Extended Neoplastic Disease Care Hospitals

- CMS is allowing extended neoplastic disease care hospitals to exclude inpatient stays where the hospital admits or discharges patients in order to meet the demands of the emergency from the greater than 20-day average length of stay requirement, which allows these facilities to be excluded from the hospital inpatient prospective payment system and paid an adjusted payment for Medicare inpatient operating and capital-related costs under the reasonable cost-based reimbursement rules as authorized under Section 1886(d)(1)(B)(vi) of the Act and §42 CFR 412.22(i).

Comprehensive Care for Joint Replacement (CJR) Model: Due to the COVID-19 public health emergency, the appeals timeline for the Comprehensive Care for Joint Replacement (CJR) model Performance Year (PY) 3 final and PY 4 initial reconciliation reports is modified for participant hospitals. Specifically, CMS is modifying participant hospital deadlines set forth at 42 CFR §510.310(a)(1)-(2), for (a) all participant hospitals that owe repayment to CMS for PY 3 final reconciliation and PY 4 initial reconciliation; and (b) upon request, any participant hospital that is eligible for a reconciliation payment for PY 3 final reconciliation and PY 4 initial reconciliation. The regulations provide that unless the participant hospital provides written notice of a calculation error, CMS deems the CJR reconciliation report to be final 45 calendar days after it is issued and that CMS responds to the notice of calculation error if it is received within 45 calendar days of the issuance of the reconciliation report.

We are modifying the participant hospital deadlines to permit the participant hospital 120 calendar days after the reconciliation report is issued to appeal a determination that such hospital owes repayment to CMS, or upon request, to appeal a determination that such hospital is eligible for a reconciliation payment. If a notice of calculation error is received by CMS within the 120-day period, then consistent with the existing regulation, CMS responds in writing within 30 calendar

days to either confirm that there was an error in the calculation or verify that the calculation is correct, although CMS reserves the right to an extension upon written notice to the participant hospital.

Hospitals receiving a reconciliation payment that do not request a 120-day appeal period have 45 days to provide a notice of calculation error. Unless the participant hospital provides written notice of the calculation error, CMS deems the CJR reconciliation report to be final 45 calendar days after it is issued, and proceeds with the payment.

Long-Term Care Facilities and Skilled Nursing Facilities (SNFs) and/or Nursing Facilities (NFs)

- **3-Day Prior Hospitalization.** Using the authority under Section 1812(f) of the Act, CMS is waiving the requirement for a 3-day prior hospitalization for coverage of a SNF stay, which provides temporary emergency coverage of SNF services without a qualifying hospital stay, for those people who experience dislocations, or are otherwise affected by COVID-19. In addition, for certain beneficiaries who recently exhausted their SNF benefits, it authorizes renewed SNF coverage without first having to start a new benefit period (this waiver will apply only for those beneficiaries who have been delayed or prevented by the emergency itself from commencing or completing the process of ending their current benefit period and renewing their SNF benefits that would have occurred under normal circumstances).
- **Reporting Minimum Data Set.** CMS is waiving 42 CFR 483.20 to provide relief to SNFs on the timeframe requirements for Minimum Data Set assessments and transmission.
- ~~**Staffing Data Submission.** CMS is waiving 42 CFR 483.70(q) to provide relief to long term care facilities on the requirements for submitting staffing data through the Payroll Based Journal system. (Terminated effective 6/25/2020)~~
- **Waive Pre-Admission Screening and Annual Resident Review (PASARR).** CMS is waiving 42 CFR 483.20(k), allowing nursing homes to admit new residents who have not received Level 1 or Level 2 Preadmission Screening. Level 1 assessments may be performed post-admission. On or before the 30th day of admission, new patients admitted to nursing homes with a mental illness (MI) or intellectual disability (ID) should be referred promptly by the nursing home to State PASARR program for Level 2 Resident Review.
- **Physical Environment.** CMS is waiving requirements related at 42 CFR 483.90, specifically the following:
 - Provided that the state has approved the location as one that sufficiently addresses safety and comfort for patients and staff, CMS is waiving requirements under § 483.90 to allow for a non-SNF building to be temporarily certified and available for use by a

- SNF in the event there are needs for isolation processes for COVID-19 positive residents, which may not be feasible in the existing SNF structure to ensure care and services during treatment for COVID-19 are available while protecting other vulnerable adults.
- CMS believes this will also provide another measure that will free up inpatient care beds at hospitals for the most acute patients while providing beds for those still in need of care. CMS will waive certain conditions of participation and certification requirements for opening a NF if the state determines there is a need to quickly stand up a temporary COVID-19 isolation and treatment location.
 - CMS is also waiving requirements under 42 CFR 483.90 to temporarily allow for rooms in a long-term care facility not normally used as a resident's room, to be used to accommodate beds and residents for resident care in emergencies and situations needed to help with surge capacity. Rooms that may be used for this purpose include activity rooms, meeting/conference rooms, dining rooms, or other rooms, as long as residents can be kept safe, comfortable, and other applicable requirements for participation are met. This can be done so long as it is not inconsistent with a state's emergency preparedness or pandemic plan, or as directed by the local or state health department.
- **Resident Groups.** CMS is waiving the requirements at 42 CFR 483.10(f)(5), which ensure residents can participate in-person in resident groups. This waiver would only permit the facility to restrict in-person meetings during the national emergency given the recommendations of social distancing and limiting gatherings of more than ten people. Refraining from in-person gatherings will help prevent the spread of COVID-19.
 - **Training and Certification of Nurse Aides.** CMS is waiving the requirements at 42 CFR 483.35(d) (with the exception of 42 CFR 483.35(d)(1)(i)), which require that a SNF and NF may not employ anyone for longer than four months unless they met the training and certification requirements under § 483.35(d). CMS is waiving these requirements to assist in potential staffing shortages seen with the COVID-19 pandemic. To ensure the health and safety of nursing home residents, CMS is not waiving 42 CFR § 483.35(d)(1)(i), which requires facilities to not use any individual working as a nurse aide for more than four months, on a full-time basis, unless that individual is competent to provide nursing and nursing related services. We further note that we are not waiving § 483.35(c), which requires facilities to ensure that nurse aides are able to demonstrate competency in skills and techniques necessary to care for residents' needs, as identified through resident assessments, and described in the plan of care.
 - **Physician Visits in Skilled Nursing Facilities/Nursing Facilities.** CMS is waiving the requirement in 42 CFR 483.30 for physicians and non-physician practitioners to perform in-person visits for nursing home residents and allow visits to be conducted, as appropriate, via telehealth options.
 - **Resident Roommates and Grouping.** CMS is waiving the requirements in 42 CFR 483.10(e) (5),

(6), and (7) solely for the purposes of grouping or cohorting residents with respiratory illness symptoms and/or residents with a confirmed diagnosis of COVID-19, and separating them from residents who are asymptomatic or tested negative for COVID-19. This action waives a facility's requirements, under 42 CFR 483.10, to provide for a resident to share a room with his or her roommate of choice in certain circumstances, to provide notice and rationale for changing a resident's room, and to provide for a resident's refusal a transfer to another room in the facility. This aligns with CDC guidance to preferably place residents in locations designed to care for COVID-19 residents, to prevent the transmission of COVID-19 to other residents.

- **Resident Transfer and Discharge.** CMS is waiving requirements in 42 CFR 483.10(c)(5); 483.15(c)(3), (c)(4)(ii), (c)(5)(i) and (iv), (c)(9), and (d); and § 483.21(a)(1)(i), (a)(2)(i), and (b)(2)(i) (with some exceptions) to allow a long term care (LTC) facility to transfer or discharge residents to another LTC facility solely for the following cohorting purposes:
 1. Transferring residents with symptoms of a respiratory infection or confirmed diagnosis of COVID-19 to another facility that agrees to accept each specific resident, and is dedicated to the care of such residents;
 2. Transferring residents without symptoms of a respiratory infection or confirmed to not have COVID-19 to another facility that agrees to accept each specific resident, and is dedicated to the care of such residents to prevent them from acquiring COVID-19; or
 3. Transferring residents without symptoms of a respiratory infection to another facility that agrees to accept each specific resident to observe for any signs or symptoms of a respiratory infection over 14 days.

Exceptions:

- These requirements are **only** waived in cases where the transferring facility receives confirmation that the receiving facility agrees to accept the resident to be transferred or discharged. Confirmation may be in writing or verbal. If verbal, the transferring facility needs to document the date, time, and person that the receiving facility communicated agreement.
- In § 483.10, we are only waiving the requirement, under § 483.10(c)(5), that a facility provide advance notification of options relating to the transfer or discharge to another facility. Otherwise, all requirements related to § 483.10 are not waived. Similarly, in § 483.15, we are only waiving the requirement, under § 483.15(c)(3), (c)(4)(ii), (c)(5)(i) and (iv), and (d), for the written notice of transfer or discharge to be provided before the transfer or discharge. This notice must be provided as soon as practicable.
- In § 483.21, we are only waiving the timeframes for certain care planning requirements

for residents who are transferred or discharged for the purposes explained in 1–3 above. Receiving facilities should complete the required care plans as soon as practicable, and we expect receiving facilities to review and use the care plans for residents from the transferring facility, and adjust as necessary to protect the health and safety of the residents the apply to.

- These requirements are also waived when the transferring residents to another facility, such as a COVID-19 isolation and treatment location, with the provision of services “under arrangements,” as long as it is not inconsistent with a state’s emergency preparedness or pandemic plan, or as directed by the local or state health department. In these cases, the transferring LTC facility need not issue a formal discharge, as it is still considered the provider and should bill Medicare normally for each day of care. The transferring LTC facility is then responsible for reimbursing the other provider that accepted its resident(s) during the emergency period.
 - If the LTC facility does not intend to provide services under arrangement, the COVID-19 isolation and treatment facility is the responsible entity for Medicare billing purposes. The LTC facility should follow the procedures described in 40.3.4 of the Medicare Claims Processing Manual (<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c06.pdf>) to submit a discharge bill to Medicare. The COVID-19 isolation and treatment facility should then bill Medicare appropriately for the type of care it is providing for the beneficiary. If the COVID-19 isolation and treatment facility is not yet an enrolled provider, the facility should enroll through the provider enrollment hotline for the Medicare Administrative Contractor that services their geographic area to establish temporary Medicare billing privileges.

We remind LTC facilities that they are responsible for ensuring that any transfers (either within a facility, or to another facility) are conducted in a safe and orderly manner, and that each resident’s health and safety is protected.

We also remind states that under 42 CFR 488.426(a)(1), in an emergency, the State has the authority to transfer Medicaid and Medicare residents to another facility.

- **Physician Services.** CMS is providing relief to long-term care facilities related to provision of physician services through the following actions:
 - **Physician Delegation of Tasks in SNFs.** 42 CFR 483.30(e)(4). CMS is waiving the requirement in § 483.30(e)(4) that prevents a physician from delegating a task when the regulations specify that the physician must perform it personally. This waiver gives physicians the ability to delegate any tasks to a physician assistant, nurse practitioner, or clinical nurse specialist who meets the applicable definition in 42 CFR 491.2 or, in the case of a clinical nurse specialist, is licensed as such by the State and is acting

within the scope of practice laws as defined by State law. We are temporarily modifying this regulation to specify that any task delegated under this waiver must continue to be under the supervision of the physician. This waiver does not include the provision of § 483.30(e)(4) that prohibits a physician from delegating a task when the delegation is prohibited under State law or by the facility's own policy.

- **Physician Visits.** 42 CFR 483.30(c)(3). CMS is waiving the requirement at § 483.30(c)(3) that all required physician visits (not already exempted in § 483.30(c)(4) and (f)) must be made by the physician personally. We are modifying this provision to permit physicians to delegate any required physician visit to a nurse practitioner (NPs), physician assistant, or clinical nurse specialist who is not an employee of the facility, who is working in collaboration with a physician, and who is licensed by the State and performing within the state's scope of practice laws.
- **Note to Facilities.** These actions will assist in potential staffing shortages, maximize the use of medical personnel, and protect the health and safety of residents during the PHE. We note that we are not waiving the requirements for the frequency of required physician visits at § 483.30(c)(1). As set out above, we have only modified the requirement to allow for the requirement to be met by an NP, physician assistant, or clinical nurse specialist, and via telehealth or other remote communication options, as appropriate. In addition, we note that we are not waiving our requirements for physician supervision in § 483.30(a)(1), and the requirement at § 483.30(d)(3) for the facility to provide or arrange for the provision of physician services 24 hours a day, in case of an emergency. It is important that the physician be available for consultation regarding a resident's care.
- **Quality Assurance and Performance Improvement (QAPI).** CMS is modifying certain requirements in 42 CFR §483.75, which require long-term care facilities to develop, implement, evaluate, and maintain an effective, comprehensive, data-driven QAPI program. Specifically, CMS is modifying §483.75(b)–(d) and (e)(3) to the extent necessary to narrow the scope of the QAPI program to focus on adverse events and infection control. This will help ensure facilities focus on aspects of care delivery most closely associated with COVID-19 during the PHE.
- **In-Service Training:** CMS is modifying the nurse aide training requirements at §483.95(g)(1) for SNFs and NFs, which requires the nursing assistant to receive at least 12 hours of in-service training annually. In accordance with section 1135(b)(5) of the Act, we are postponing the deadline for completing this requirement throughout the COVID-19 PHE until the end of the first full quarter after the declaration of the PHE concludes.
- **Detailed Information Sharing for Discharge Planning for Long-Term Care (LTC) Facilities.** CMS is waiving the discharge planning requirement in §483.21(c)(1)(viii), which requires LTC facilities to assist residents and their representatives in selecting a post-acute care provider using data, such as standardized patient assessment data, quality measures and

resource use. This temporary waiver is to provide facilities the ability to expedite discharge and movement of residents among care settings. CMS is maintaining all other discharge planning requirements, such as but not limited to, ensuring that the discharge needs of each resident are identified and result in the development of a discharge plan for each resident; involving the interdisciplinary team, as defined at 42 CFR §483.21(b)(2)(ii), in the ongoing process of developing the discharge plan address the resident's goals of care and treatment preferences.

- **Clinical Records.** Pursuant to section 1135(b)(5) of the Act, CMS is modifying the requirement at 42 CFR §483.10(g)(2)(ii) which requires long-term care (LTC) facilities to provide a resident a copy of their records within two working days (when requested by the resident). Specifically, CMS is modifying the timeframe requirements to allow LTC facilities ten working days to provide a resident's record rather than two working days.
- **Paid Feeding Assistants.** CMS is modifying the requirements at 42 CFR §§ 483.60(h)(1)(i) and 483.160(a) regarding required training of paid feeding assistants. Specifically, CMS is modifying the minimum timeframe requirements in these sections, which require this training to be a minimum of 8 hours. CMS is modifying to allow that the training can be a minimum of 1 hour in length. CMS is not waiving any other requirements under 42 CFR §483.60(h) related to paid feeding assistants or the required training content at 42 CFR §483.160(a)(1)-(8), which contains infection control training and other elements. Additionally, CMS is also not waiving or modifying the requirements at 42 CFR §483.60(h)(2)(i), which requires that a feeding assistant must work under the supervision of a registered nurse (RN) or licensed practical nurse (LPN).

Home Health Agencies (HHAs)

- **Requests for Anticipated Payment (RAPs).** CMS is allowing Medicare Administrative Contractors (MACs) to extend the auto-cancellation date of Requests for Anticipated Payment (RAPs) during emergencies.
- **Reporting.** CMS is providing relief to HHAs on the timeframes related to OASIS Transmission through the following actions below:
 - Extending the 5-day completion requirement for the comprehensive assessment to 30 days.
 - Waiving the 30-day OASIS submission requirement. Delayed submission is permitted during the PHE.
- **Initial Assessments.** CMS is waiving the requirements at 42 CFR §484.55(a) to allow HHAs to perform Medicare-covered initial assessments and determine patients' homebound status remotely or by record review. This will allow patients to be cared for in the best environment for

them while supporting infection control and reducing impact on acute care and long-term care facilities. This will allow for maximizing coverage by already scarce physician, and advanced practice clinicians, and allow those clinicians to focus on caring for patients with the greatest acuity.

- **Waive Onsite Visits for HHA Aide Supervision.** CMS is waiving the requirements at 42 CFR §484.80(h), which require a nurse to conduct an onsite visit every two weeks. This would include waiving the requirements for a nurse or other professional to conduct an onsite visit every two weeks to evaluate if aides are providing care consistent with the care plan, as this may not be physically possible for a period of time. This waiver is also temporarily suspending the 2-week aide supervision by a registered nurse for home health agencies requirement at §484.80(h)(1), but virtual supervision is encouraged during the period of the waiver.
- **Allow Occupational Therapists (OTs), Physical Therapists (PTs), and Speech Language Pathologists (SLPs) to Perform Initial and Comprehensive Assessment for all Patients.** CMS is waiving the requirements in 42 CFR § 484.55(a)(2) and § 484.55(b)(3) that rehabilitation skilled professionals may only perform the initial and comprehensive assessment when only therapy services are ordered. This temporary blanket modification allows any rehabilitation professional (OT, PT, or SLP) to perform the initial and comprehensive assessment for all patients receiving therapy services as part of the plan of care, to the extent permitted under state law, regardless of whether or not the service establishes eligibility for the patient to be receiving home care. The existing regulations at § 484.55(a) and (b)(2) would continue to apply; rehabilitation skilled professionals would not be permitted to perform assessments in nursing-only cases. We would continue to expect HHAs to match the appropriate discipline that performs the assessment to the needs of the patient to the greatest extent possible. Therapists must act within their state scope of practice laws when performing initial and comprehensive assessments, and access a registered nurse or other professional to complete sections of the assessment that are beyond their scope of practice. Expanding the category of therapists who may perform initial and comprehensive assessments provides HHAs with additional flexibility that may decrease patient wait times for the initiation of home health services.
- **12-hour Annual In-service Training Requirement for Home Health Aides.** CMS is modifying the requirement at 42 CFR §484.80(d) that home health agencies must assure that each home health aide receives 12 hours of in-service training in a 12-month period. In accordance with section 1135(b)(5) of the Act, we are postponing the deadline for completing this requirement throughout the COVID-19 PHE until the end of the first full quarter after the declaration of the PHE concludes. This will allow aides and the registered nurses (RNs) who teach in-service training to spend more time delivering direct patient care and additional time for staff to complete this requirement.
- **Detailed Information Sharing for Discharge Planning for Home Health Agencies.** CMS is waiving the requirements of 42 CFR §484.58(a) to provide detailed information regarding

discharge planning, to patients and their caregivers, or the patient's representative in selecting a post-acute care provider by using and sharing data that includes, but is not limited to, (another) home health agency (HHA), skilled nursing facility (SNF), inpatient rehabilitation facility (IRF), and long-term care hospital (LTCH) quality measures and resource use measures.

- This temporary waiver provides facilities the ability to expedite discharge and movement of residents among care settings. CMS is maintaining all other discharge planning requirements.
- **Clinical Records:** In accordance with section 1135(b)(5) of the Act, CMS is extending the deadline for completion of the requirement at 42 CFR §484.110(e), which requires HHAs to provide a patient a copy of their medical record at no cost during the next visit or within four business days (when requested by the patient). Specifically, CMS will allow HHAs ten business days to provide a patient's clinical record, instead of four.

Home Health Agencies (HHAs) and Hospice

- **Training and Assessment of Aides:** CMS is waiving the requirement at 42 CFR §418.76(h)(2) for Hospice and 42 CFR §484.80(h)(1)(iii) for HHAs, which require a registered nurse, or in the case of an HHA a registered nurse or other appropriate skilled professional (physical therapist/occupational therapist, speech language pathologist) to make an annual onsite supervisory visit (direct observation) for each aide that provides services on behalf of the agency. In accordance with section 1135(b)(5) of the Act, we are postponing completion of these visits. All postponed onsite assessments must be completed by these professionals no later than 60 days after the expiration of the PHE.
- **Quality Assurance and Performance Improvement (QAPI).** CMS is modifying the requirement at 42 CFR §418.58 for Hospice and §484.65 for HHAs, which requires these providers to develop, implement, evaluate, and maintain an effective, ongoing, hospice/HHA-wide, data-driven QAPI program. Specifically, CMS is modifying the requirements at §418.58(a)–(d) and §484.65(a)–(d) to narrow the scope of the QAPI program to concentrate on infection control issues, while retaining the requirement that remaining activities should continue to focus on adverse events. This modification decreases burden associated with the development and maintenance of a broad-based QAPI program, allowing the providers to focus efforts on aspects of care delivery most closely associated with COVID-19, and tracking adverse events during the PHE. The requirement that HHAs and hospices maintain an effective, ongoing, agency-wide, data-driven quality assessment and performance improvement program will remain.

Hospice

- **Waive Requirement for Hospices to Use Volunteers.** CMS is waiving the requirement at 42 CFR §418.78(e) that hospices are required to use volunteers (including at least 5% of patient care hours). It is anticipated that hospice volunteer availability and use will be reduced related to COVID-19 surge and potential quarantine.
- **Comprehensive Assessments.** CMS is waiving certain requirements at 42 CFR §418.54 related to updating comprehensive assessments of patients. This waiver applies the timeframes for updates to the comprehensive assessment found at §418.54(d). Hospices must continue to complete the required assessments and updates; however, the timeframes for updating the assessment may be extended from 15 to 21 days.
- **Waive Non-Core Services.** CMS is waiving the requirement for hospices to provide certain non-core hospice services during the national emergency, including the requirements at 42 CFR §418.72 for physical therapy, occupational therapy, and speech-language pathology.
- **Waived Onsite Visits for Hospice Aide Supervision.** CMS is waiving the requirements at 42 CFR §418.76(h), which require a nurse to conduct an onsite supervisory visit every two weeks. This would include waiving the requirements for a nurse or other professional to conduct an onsite visit every two weeks to evaluate if aides are providing care consistent with the care plan, as this may not be physically possible for a period of time.
- **Hospice Aide Competency Testing Allow Use of Pseudo Patients.** 42 CFR 418.76(c)(1). CMS is temporarily modifying the requirement in § 418.76(c)(1) that a hospice aide must be evaluated by observing an aide's performance of certain tasks with a patient. This modification allows hospices to utilize pseudo patients such as a person trained to participate in a role-play situation or a computer-based mannequin device, instead of actual patients, in the competency testing of hospice aides for those tasks that must be observed being performed on a patient. This increases the speed of performing competency testing and allows new aides to begin serving patients more quickly without affecting patient health and safety during the public health emergency (PHE).
- **12 hour Annual In-service Training Requirement for Hospice Aides.** 42 CFR 418.76(d). CMS is waiving the requirement that hospices must assure that each hospice aide receives 12 hours of in-service training in a 12 month period. This allows aides and the registered nurses (RNs) who teach in-service training to spend more time delivering direct patient care.
- **Annual Training.** CMS is modifying the requirement at 42 CFR §418.100(g)(3), which requires hospices to annually assess the skills and competence of all individuals furnishing care and provide in-service training and education programs where required. Pursuant to section 1135(b)(5) of the Act, we are postponing the deadline for completing this requirement

throughout the COVID-19 PHE until the end of the first full quarter after the declaration of the PHE concludes. This does not alter the minimum personnel requirements at 42 CFR §418.114. Selected hospice staff must complete training and have their competency evaluated in accordance with unwaived provisions of 42 CFR Part 418.

End-Stage Renal Dialysis (ESRD) Facilities

- **Training Program and Periodic Audits.** CMS is waiving the requirement at 42 CFR §494.40(a) related to the condition on Water & Dialysate Quality, specifically that on-time periodic audits for operators of the water/dialysate equipment are waived to allow for flexibilities.
- **Defer Equipment Maintenance & Fire Safety Inspections.** CMS is waiving the requirement at 42 CFR §494.60(b) for on-time preventive maintenance of dialysis machines and ancillary dialysis equipment. Additionally, CMS is also waiving the requirements under §494.60(d) which requires ESRD facilities to conduct on-time fire inspections. These waivers are intended to ensure that dialysis facilities are able to focus on the operations related to the Public Health Emergency.
- **Emergency Preparedness.** CMS is waiving the requirements at 42 CFR §494.62(d)(1)(iv) which requires ESRD facilities to demonstrate as part of their Emergency Preparedness Training and Testing Program, that staff can demonstrate that, at a minimum, its patient care staff maintains current CPR certification. CMS is waiving the requirement for maintenance of CPR certification during the COVID-19 emergency due to the limited availability of CPR classes.
- **Ability to Delay Some Patient Assessments.** CMS is not waiving subsections (a) or (c) of 42 CFR §494.80, but is waiving the following requirements at 42 CFR §494.80(b) related to the frequency of assessments for patients admitted to the dialysis facility. CMS is waiving the “on-time” requirements for the initial and follow up comprehensive assessments within the specified timeframes as noted below. This waiver applies to assessments conducted by members of the interdisciplinary team, including: a registered nurse, a physician treating the patient for ESRD, a social worker, and a dietitian. These waivers are intended to ensure that dialysis facilities are able to focus on the operations related to the Public Health Emergency. Specifically, CMS is waiving:
 - §494.80(b)(1): An initial comprehensive assessment must be conducted on all new patients (that is, all admissions to a dialysis facility), within the latter of 30 calendar days or 13 outpatient hemodialysis sessions beginning with the first outpatient dialysis session.
 - §494.80(b)(2): A follow up comprehensive reassessment must occur within 3 months after the completion of the initial assessment to provide information to adjust the patient’s plan of care specified in §494.90.

- **Time Period for Initiation of Care Planning and Monthly Physician Visits.** CMS is modifying two requirements related to care planning, specifically:
 - 42 CFR §494.90(b)(2): CMS is modifying the requirement that requires the dialysis facility to implement the initial plan of care within the latter of 30 calendar days after admission to the dialysis facility or 13 outpatient hemodialysis sessions beginning with the first outpatient dialysis session. This modification will also apply to the requirement for monthly or annual updates of the plan of care within 15 days of the completion of the additional patient assessments.
 - §494.90(b)(4): CMS is modifying the requirement that requires the ESRD dialysis facility to ensure that all dialysis patients are seen by a physician, nurse practitioner, clinical nurse specialist, or physician's assistant providing ESRD care at least monthly, and periodically while the hemodialysis patient is receiving in-facility dialysis. CMS is waiving the requirement for a monthly in-person visit if the patient is considered stable and also recommends exercising telehealth flexibilities, e.g. phone calls, to ensure patient safety.
- **Dialysis Home Visits to Assess Adaptation and Home Dialysis Machine Designation.** CMS is waiving the requirement at 42 CFR §494.100(c)(1)(i) which requires the periodic monitoring of the patient's home adaptation, including visits to the patient's home by facility personnel. For more information on existing flexibilities for in-center dialysis patients to receive their dialysis treatments in the home, or long-term care facility, reference QSO-20-19-ESRD.
- **Home Dialysis Machine Designation – Clarification.** The ESRD Conditions for Coverage (CFCs) do not explicitly require that each home dialysis patient have their own designated home dialysis machine. The dialysis facility is required to follow FDA labeling and manufacturer's directions for use to ensure appropriate operation of the dialysis machine and ancillary equipment. Dialysis machines must be properly cleaned and disinfected to minimize the risk of infection based on the requirements at 42 CFR §494.30 Condition: Infection Control if used to treat multiple patients.
- **Special Purpose Renal Dialysis Facilities (SPRDF) Designation Expanded.** CMS authorizes the establishment of SPRDFs under 42 CFR §494.120 to address access to care issues due to COVID-19 and the need to mitigate transmission among this vulnerable population. This will not include the normal determination regarding lack of access to care at §494.120(b) as this standard has been met during the period of the national emergency. Approval as a Special Purpose Renal Dialysis Facility related to COVID-19 does not require Federal survey prior to providing services.
- **Dialysis Patient Care Technician (PCT) Certification.** CMS is modifying the requirement at 42 CFR §494.140(e)(4) for dialysis PCTs that requires certification under a state certification program or a national commercially available certification program within 18 months of being hired as a dialysis PCT for newly employed patient care technicians. CMS is aware of the

challenges that PCTs are facing with the limited availability and closures of testing sites during the time of this crisis. CMS will allow PCTs to continue working even if they have not achieved certification within 18 months or have not met on time renewals.

- **Transferability of Physician Credentialing.** CMS is modifying the requirement at 42 CFR §494.180(c)(1) which requires that all medical staff appointments and credentialing are in accordance with state law, including attending physicians, physician assistants, nurse practitioners, and clinical nurse specialists. These waivers will allow physicians that are appropriately credentialed at a certified dialysis facility to function to the fullest extent of their licensure to provide care at designated isolation locations without separate credentialing at that facility, and may be implemented so long as they are not inconsistent with a state's emergency preparedness or pandemic plan.
- **Expanding Availability of Renal Dialysis Services to ESRD Patients.** CMS is waiving the following requirements related to Nursing Home residents:
 - **Furnishing Dialysis Services on the Main Premises:** ESRD requirements at 42 CFR §494.180(d) require dialysis facilities to provide services directly on its main premises or on other premises that are contiguous with the main premises. CMS is waiving this requirement to allow dialysis facilities to provide service to its patients who reside in the nursing homes, long-term care facilities, assisted living facilities and similar types of facilities, as licensed by the state (if applicable). CMS continues to require that services provided to these patients or residents are under the direction of the same governing body and professional staff as the resident's usual Medicare-certified dialysis facility. Further, in order to ensure that care is safe, effective and is provided by trained and qualified personnel, CMS requires that the dialysis facility staff: 1) furnish all dialysis care and services; 2) provide all equipment and supplies necessary; 3) maintain equipment and supplies in off-premises location; 4) and complete all equipment maintenance, cleaning and disinfection using appropriate infection control procedures and manufacturer's instructions for use.
- **Clarification for Billing Procedures.** Typically, ESRD beneficiaries are transported from a SNF/NF to an ESRD facility to receive renal dialysis services. In an effort to keep patients in their SNF/NF and decrease their risk of being exposed to COVID-19, ESRD facilities may temporarily furnish renal dialysis services to ESRD beneficiaries in the SNF/NF instead of the offsite ESRD facility. The in-center dialysis center should bill Medicare using Condition Code 71 (Full care unit. Billing for a patient who received staff-assisted dialysis services in a hospital or renal dialysis facility). The in-center dialysis center should also apply condition code DR to claims if all the treatments billed on the claim meet this condition or modifier CR on the line level to identify individual treatments meeting this condition. The ESRD provider would need to have their trained personnel administer the treatment in the SNF/ NF. In addition, the provider must follow the CFCs. In particular, under the CFCs is the requirement that to use a dialysis machine, the FDA-

approved labeling must be adhered to § 494.100 and it must be maintained and operated in accordance with the manufacturer's recommendations (§ 494.60) and follow infection control requirements at § 494.30.

Physical Environment for Multiple Providers/Suppliers

Inspection, Testing & Maintenance (ITM) under the Physical Environment Conditions of

Participation: CMS is waiving certain physical environment requirements for Hospitals, CAHs, inpatient hospice, ICF/IIDs, and SNFs/NFs to reduce disruption of patient care and potential exposure/transmission of COVID-19. The physical environment regulations require that facilities and equipment be maintained to ensure an acceptable level of safety and quality.

CMS will permit facilities to adjust scheduled inspection, testing and maintenance (ITM) frequencies and activities for facility and medical equipment.

• Specific Physical Environment Waiver Information:

- 42 CFR §482.41(d) for hospitals, §485.623(b) for CAH, §418.110(c)(2)(iv) for inpatient hospice, §483.470(j) for ICF/IID; and §483.90 for SNFs/NFs all require these facilities and their equipment to be maintained to ensure an acceptable level of safety and quality. CMS is temporarily modifying these requirements to the extent necessary to permit these facilities to adjust scheduled inspection, testing and maintenance (ITM) frequencies and activities for facility and medical equipment.
- 42 CFR §482.41(b)(1)(i) and (c) for hospitals, §485.623(c)(1)(i) and (d) for CAHs, §482.41(d)(1)(i) and (e) for inpatient hospices, §483.470(j)(1)(i) and (5)(v) for ICF/IIDs, and §483.90(a)(1)(i) and (b) for SNFs/NFs require these facilities to be in compliance with the Life Safety Code (LSC) and Health Care Facilities Code (HCFC). CMS is temporarily modifying these provisions to the extent necessary to permit these facilities to adjust scheduled ITM frequencies and activities required by the LSC and HCFC. The following LSC and HCFC ITM are considered critical are not included in this waiver:
 - Sprinkler system monthly electric motor-driven and weekly diesel engine-driven fire pump testing.
 - Portable fire extinguisher monthly inspection.
 - Elevators with firefighters' emergency operations monthly testing.
 - Emergency generator 30 continuous minute monthly testing and associated transfer switch monthly testing.
 - Means of egress daily inspection in areas that have undergone construction, repair, alterations, or additions to ensure its ability to be used instantly in case of emergency.
- 42 CFR §482.41(b)(9) for hospitals, §485.623(c)(7) for CAHs, §418.110(d)(6) for inpatient hospices, §483.470(e)(1)(i) for ICF/IIDs, and §483.90(a)(7) for SNFs/NFs require these

facilities to have an outside window or outside door in every sleeping room. CMS will permit a waiver of these outside window and outside door requirements to permit these providers to utilize facility and non-facility space that is not normally used for patient care to be utilized for temporary patient care or quarantine.

Specific Life Safety Code (LSC) for Multiple Providers - Waiver Information:

CMS is waiving and modifying particular waivers under 42 CFR §482.41(b) for hospitals; §485.623(c) for CAHs; §418.110(d) for inpatient hospice; §483.470(j) for ICF/IIDs and §483.90(a) for SNF/NFs. Specifically, CMS is modifying these requirements as follows:

- **Alcohol-based Hand-Rub (ABHR) Dispensers:** We are waiving the prescriptive requirements for the placement of alcohol based hand rub (ABHR) dispensers for use by staff and others due to the need for the increased use of ABHR in infection control. However, ABHRs contain ethyl alcohol, which is considered a flammable liquid, and there are restrictions on the storage and location of the containers. This includes restricting access by certain patient/resident population to prevent accidental ingestion. Due to the increased fire risk for bulk containers (over five gallons) those will still need to be stored in a protected hazardous materials area.

Referto: 2012 LSC, sections 18/19.3.2.6. In addition, facilities should continue to protect ABHR dispensers against inappropriate use as required by 42 CFR §482.41(b)(7) for hospitals; §485.623(c)(5) for CAHs; §418.110(d)(4) for inpatient hospice; §483.470(j)(5)(ii) for ICF/IIDs and §483.90(a)(4) for SNF/NFs.

- **Fire Drills:** Due to the inadvisability of quarterly fire drills that move and mass staff together, we will instead permit a documented orientation training program related to the current fire plan, which considers current facility conditions. The training will instruct employees, including existing, new or temporary employees, on their current duties, life safety procedures and the fire protection devices in their assigned area.

Referto: 2012 LSC, sections 18/19.7.1.6.

- **Temporary Construction:** CMS is waiving requirements that would otherwise not permit temporary walls and barriers between patients.

Referto: 2012 LSC, sections 18/19.3.3.2.

Intermediate Care Facility for Individuals with Intellectual Disabilities

- **Staffing Flexibilities.** CMS is waiving the requirements at 42 CFR §483.430(c)(4), which requires the facility to provide sufficient Direct Support Staff (DSS) so that Direct Care Staff (DCS) are not required to perform support services that interfere with direct client care. DSS perform activities such as cleaning of the facility, cooking, and laundry services. DSC perform activities

such as teaching clients appropriate hygiene, budgeting, or effective communication and socialization skills. During the time of this waiver, DCS may be needed to conduct some of the activities normally performed by the DSS. This will allow facilities to adjust staffing patterns, while maintaining the minimum staffing ratios required at §483.430(d)(3).

- **Suspension of Community Outings.** CMS is waiving the requirements at 42 CFR §483.420(a)(11) which requires clients have the opportunity to participate in social, religious, and community group activities. The federal and/or state emergency restrictions will dictate the level of restriction from the community based on whether it is for social, religious, or medical purposes. States may have also imposed more restrictive limitations. CMS is authorizing the facility to implement social distancing precautions with respect to on and off-campus movement. State and Federal restrictive measures should be made in the context of competent, person-centered planning for each client.
- **Suspend Mandatory Training Requirements.** CMS is waiving, in-part, the requirements at 42 CFR §483.430(e)(1) related to routine staff training programs unrelated to the public health emergency. CMS is not waiving 42 CFR §483.430(e)(2)-(4) which requires focusing on the clients' developmental, behavioral and health needs and being able to demonstrate skills related to interventions for inappropriate behavior and implementing individual plans. We are not waiving these requirements as we believe the staff ability to develop and implement the skills necessary to effectively address clients' developmental, behavioral and health needs are essential functions for an ICF/IID. CMS is also not waiving initial training for new staff hires or training for staff around prevention and care for the infection control of COVID-19. It is critical that new staff gain the necessary skills and understanding of how to effectively perform their role as they work with this complex client population and that staff understand how to prevent and care for clients with COVID-19.
- **Modification of Adult Training Programs and Active Treatment.** CMS recognizes that during the public health emergency, active treatment will need to be modified. The requirements at 42 CFR §483.440(a)(1) require that each client must receive a continuous active treatment program, which includes consistent implementation of a program of specialized and generic training, treatment, health services and related services.

CMS is waiving those components of beneficiaries' active treatment programs and training that would violate current state and local requirements for social distancing, staying at home, and traveling for essential services only. For example, although day habilitation programs and supported employment are important opportunities for training and socialization of clients at intermediate care facilities for individuals with developmental disabilities, these programs pose too high of a risk to staff and clients for exposure to a person with suspected or confirmed COVID-19. In accordance with §483.440(c)(1), any modification to a client's Individual Program Plan (IPP) in response to treatment changes associated with the COVID-19 crisis requires the approval of the interdisciplinary team. For facilities that have interdisciplinary team members

who are unavailable due to the COVID-19, CMS would allow for a retroactive review of the IPP under 483.440(f)(2) in order to allow IPPs to receive modifications as necessary based on the impact of the COVID-19 crisis.

Ambulatory Surgical Centers (ASCs)

- **Medical Staff.** 42 CFR 416.45(b). CMS is waiving the requirement at § 416.45(b) that medical staff privileges must be periodically reappraised, and the scope of procedures performed in the ASC must be periodically reviewed. This will allow for physicians whose privileges will expire to continue practicing at the ambulatory surgical center, without the need for reappraisal, and for ASCs to continue operations without performing these administrative tasks during the PHE. This waiver will improve the ability of ASCs to maintain their current workforce during the PHE.
- **Nursing Services.** 42 CFR 42 CFR §482.23(b)(1). For ASCs enrolling as hospitals during the PHE as part of the Hospitals Without Walls Program, CMS is waiving the particular requirement at 42 CFR §482.23(b)(1), which requires the hospital to have a licensed practical nurse or registered nurse on duty at all times. This waiver will only require ASCs enrolled as hospitals to provide 24-hour nursing services when there is a patient in the facility. This flexibility will allow ASCs enrolled as hospitals to provide nursing services on demand with a 24-7 on call service in the event a surgeon requests to admit a patient for a required surgical procedure. Waiver authority applies only to Federal requirements and does not supersede State requirements for licensure.

Community Mental Health Clinics (CMHCs)

- **Quality assessment and performance improvement (QAPI).** 42 CFR 485.917(a)-(d) We are modifying the requirements for CMHC's quality assessment and performance improvement (QAPI). Specifically, we are retaining the overall requirement that CMHC's maintain an effective, ongoing, CMHC-wide, data-driven QAPI program, while providing flexibility for CMHCs to use their QAPI resources to focus on challenges and opportunities for improvement related to the PHE by waiving the specific detailed requirements for the QAPI program's organization and content at § 485.917(a)-(d). Waiving the requirements related to the details of the QAPI program's organization and content will make it easier for CMHCs to reconfigure their QAPI programs, as needed, to adapt to specific needs and circumstances that arise during the PHE. These flexibilities may be implemented so long as they are consistent with a state's emergency preparedness or pandemic plan.
- **Provision of Services.** 42 CFR 485.918(b)(1)(iii). We are waiving the specific requirement at § 485.918(b)(1)(iii) that prohibits CMHCs from providing partial hospitalization services and other CMHC services in an individual's home so that clients can safely shelter in place during

the PHE while continuing to receive needed care and services from the CMHC. This waiver is a companion to recent regulatory changes

(<https://www.federalregister.gov/documents/2020/05/08/2020-09608/medicare-and-medicaid-programs-basic-health-program-and-exchanges-additional-policy-and-regulatory>)

that clarify how CMHCs should bill for services provided in an individual's home, and how such services should be documented in the medical record. While this waiver will now allow CMHCs to furnish services in client homes, including through the use of using telecommunication technology, CMHCs continue to be, among other things, required to comply with the non-waived provisions of 42 CFR Part 485, Subpart J, requiring that CMHCs: 1) assess client needs, including physician certification of the need for partial hospitalization services, if needed; 2) implement and update each client's individualized active treatment plan that sets forth the type, amount, duration, and frequency of the services; and 3) promote client rights, including a client's right to file a complaint.

- **40 Percent Rule.** 42 CFR 485.918(b)(1)(v) We are waiving the requirement at § 485.918(b)(1)(v) that a CMHC provides at least 40 percent of its items and services to individuals who are not eligible for Medicare benefits. Waiving the 40 percent requirement will facilitate appropriate timely discharge from inpatient psychiatric units and prevent admissions to these facilities because CMHCs will be able to provide PHP services to Medicare beneficiaries without restrictions on the proportion of Medicare beneficiaries that they are permitted to treat at a time. This will allow communities greater access to health services, including mental health services.

Ambulance Services

- **Medicare Ground Ambulance Data Collection System (*Modified since 11/25 Release*).** CMS is modifying the data collection period and data reporting period, as defined at 42 CFR § 414.626(a), for ground ambulance organizations (as defined at 42 CFR § 414.605) that were selected by CMS under 42 CFR § 414.626(c) to collect data beginning between January 1, 2020 and December 31, 2020 (year 1) and for ground ambulance organizations that were selected to collect data beginning between January 1, 2021 and December 31, 2021 (year 2) for purposes of complying with the data reporting requirements described at 42 CFR § 414.626. Under this modification, these ground ambulance organizations can select a new continuous 12-month data collection period that begins between January 1, 2022 and December 31, 2022, to collect data necessary to complete the Medicare Ground Ambulance Data Collection Instrument during their selected data collection period, and submit a completed Medicare Ground Ambulance Data Collection Instrument during the data reporting period that corresponds to their selected data collection period. CMS is modifying this data collection and reporting period to increase flexibilities for ground ambulance organizations that would otherwise be required to collect data in 2020-2021 so that they can focus on their operations and patient care.

- **Ambulance Treat in Place (New 5/5/2021).** Pursuant to authority granted under section 9832 of the American Rescue Plan Act of 2021, CMS is waiving the requirements under section 1861(s)(7) and section 1834(l) of the Act that an ambulance service include the transport of an individual to the extent necessary to allow payment for ground ambulance services furnished in response to a 911 call (or the equivalent in areas without a 911 call system) in cases in which an individual would have been transported to a destination permitted under Medicare regulations (as described in section 410.40 to title 42, Code of Federal Regulations (or successor regulations)) but such transport did not occur as a result of community-wide emergency medical service (EMS) protocols due to the public health emergency described in subsection (g)(1)(B).

For purposes of this waiver, community-wide EMS protocols are those established by state, local, or municipal authorities (including by a hospital, but only where a hospital has the requisite legal authority) in response to the COVID-19 PHE that govern the provision of ambulance services, and that require or allow, with patient consent, an ambulance provider or supplier to “treat in place” a patient who otherwise, but for the COVID-19 PHE, would have been transported to a Medicare covered destination (such as a hospital). Such protocols were/will be issued in written format, and such format that may have included, but is not limited to: state or local agency and official correspondence or electronic platforms that provided just-in-time updates to standard operative procedure or protocols. However, to the extent that a verbal protocol (such as from an individual hospital in a remote area) was/is in effect at the time of transport, we expect the verbal protocol to be fully documented. CMS will pay for treatment in place under this waiver in cases where the individual that would have been transported would have met the Medicare criteria for a medically necessary ground ambulance transport to the nearest appropriate facility that could have treated the patient’s condition, but such transport did not occur as a result of community-wide EMS protocols due to the COVID-19 PHE. The beneficiary’s condition must have required both the ambulance transportation itself and the level of service provided in order for the billed service to be considered medically necessary.

Under this waiver, ground ambulance services will be paid at the base rate that would have been paid under the fee schedule established under 1834(l) (excluding any mileage payment) if the individual had been so transported and, with respect to ambulance services furnished by a critical access hospital or an entity described in paragraph (8) of such section, at the amount that otherwise would be paid under such paragraph. Claims shall be submitted consistent with instructions, including the use of appropriate modifiers, and documentation to support medical necessity and the presence of a qualifying community-wide EMS protocol must be maintained and provided to CMS contractors for medical review upon request.

The deadline to submit claims for services that were furnished under this waiver between March 1, 2020 and May 5, 2021 is also modified. The deadline to submit such claims is May 5,

2022.

Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)

- When DMEPOS is lost, destroyed, irreparably damaged, or otherwise rendered unusable, CMS is allowing DME Medicare Administrative Contractors (MACs) to have the flexibility to waive replacements requirements such that the face-to-face requirement, a new physician's order, and new medical necessity documentation are not required. Suppliers must still include a narrative description on the claim explaining the reason why the equipment must be replaced and are reminded to maintain documentation indicating that the DMEPOS was lost, destroyed, irreparably damaged, or otherwise rendered unusable or unavailable as a result of the emergency.

Practitioner Locations

CMS is temporarily waiving requirements that out-of-state practitioners be licensed in the state where they are providing services when they are licensed in another state. CMS will waive the physician or non-physician practitioner licensing requirements when the following four conditions are met: 1) must be enrolled as such in the Medicare program; 2) must possess a valid license to practice in the state, which relates to his or her Medicare enrollment; 3) is furnishing services – whether in person or via telehealth – in a state in which the emergency is occurring in order to contribute to relief efforts in his or her professional capacity; and, 4) is not affirmatively excluded from practice in the state or any other state that is part of the 1135 emergency area.

- In addition to the statutory limitations that apply to 1135-based licensure waivers, an 1135 waiver, when granted by CMS, does not have the effect of waiving state or local licensure requirements or any requirement specified by the state or a local government as a condition for waiving its licensure requirements. Those requirements would continue to apply unless waived by the state. Therefore, in order for the physician or non-physician practitioner to avail him- or herself of the 1135 waiver under the conditions described above, the state also would have to waive its licensure requirements, either individually or categorically, for the type of practice for which the physician or non-physician practitioner is licensed in his or her home state.

Provider Enrollment

- **Non-Waiver CMS Action:** CMS has a toll-free hotline for physicians and non-physician practitioners and Part A certified providers and suppliers establishing isolation facilities to enroll and receive temporary Medicare billing privileges.
- Waive the following screening requirements:
 - Application Fee - (to the extent applicable).

Updated 5/24/21

- Criminal background checks associated with fingerprint-based criminal background checks (FCBC) (to the extent applicable) - 42 CFR §424.518.
- Site visits (to the extent applicable) - 42 CFR §424.517.
- Postpone all revalidation actions.
- Allow licensed providers to render services outside of their state of enrollment.
- Expedite any pending or new applications from providers.
- Allow physicians and other practitioners to render telehealth services from their home without reporting their home address on their Medicare enrollment while continuing to bill from their currently enrolled location.
- Allow opted-out physicians and non-physician practitioners to terminate their opt-out status early and enroll in Medicare to provide care to more patients.

Modification of 60-Day Limit for Substitute Billing Arrangements (Locum Tenens)

CMS is modifying the 60-day limit in section 1842(b)(6)(D)(iii) of the Social Security Act to allow a physician or physical therapist to use the same substitute for the entire time he or she is unavailable to provide services during the COVID-19 emergency plus an additional period of no more than 60 continuous days after the public health emergency expires. On the 61st day after the public health emergency ends (or earlier if desired), the regular physician or physical therapist must use a different substitute or return to work in his or her practice for at least one day in order to reset the 60-day clock. Without this flexibility, the regular physician or physical therapist generally could not use a single substitute for a continuous period of longer than 60 days, and would instead be required to secure a series of substitutes to cover sequential 60-day periods. The modified timetable applies to both types of substitute billing arrangements under Medicare fee-for-service (i.e., reciprocal billing arrangements and fee-for-time compensation arrangements (formerly known as locum tenens)).

Notes: Under the Medicare statute, only 1) physicians and 2) physical therapists who furnish outpatient physical therapy services in a health professional shortage area (HPSA), a medically underserved area (MUA), or a rural area can receive Medicare fee-for-service payment for services furnished by a substitute under a substitute billing arrangement. In addition, Medicare can pay for services under a substitute billing arrangement only when the regular physician or physical therapist is unavailable to provide the services. Finally, as provided by law, a regular physician or physical therapist who has been called or ordered to active duty as a member of a reserve component of the Armed Forces may continue to use the same substitute for an unlimited time even after the emergency ends.

Medicare Appeals in Fee for Service (FFS), Medicare Advantage (MA) and Part D

CMS is allowing Medicare Administrative Contractors (MACs) and Qualified Independent Contractors (QICs) in the FFS program pursuant to 42 CFR §405.942 and 42 CFR §405.962 (including for MA and Part D plans), as well as the MA and Part D Independent Review Entities (IREs) under 42 CFR §422.562, 42 CFR §423.562, 42 CFR §422.582 and 42 CFR §423.582, to allow extensions to file an appeal. CMS is allowing MACs and QICs in the FFS program under 42 CFR §405.950 and 42 CFR §405.966 and the MA and Part D IREs to waive requests for timeliness requirements for additional information to adjudicate appeals.

- CMS is allowing MACs and QICs in the FFS program under 42 CFR §405.910 and MA and Part D plans, as well as the MA and Part D IREs, to process an appeal even with incomplete Appointment of Representation forms as outlined under 42 CFR §422.561 and 42 CFR §423.560. However, any communications will only be sent to the beneficiary.
- CMS is allowing MACs and QICs in the FFS program under 42 CFR §405.950 and 42 CFR §405.966 (also including MA and Part D plans), as well as the MA and Part D IREs, to process requests for appeals that do not meet the required elements using information that is available as outlined within 42 CFR §422.561 and 42 CFR §423.560.
- CMS is allowing MACs and QICs in the FFS program under 42 CFR §405.950 and 42 CFR §405.966 (also including MA and Part D plans), as well as the MA and Part D IREs under 42 CFR §422.562 and 42 CFR §423.562 to utilize all flexibilities available in the appeal process as if good cause requirements are satisfied.

Medicaid and CHIP (as of 3/13/2020)

States and territories can request approval that certain statutes and implementing regulations be waived by CMS, pursuant to section 1135 of the Act. To assist states in this process, CMS released an 1135 Waiver Checklist to make it easier for states to receive federal waivers and implement flexibilities in their Medicaid and CHIP programs. States' use of this 1135 checklist will expedite their ability to apply for and receive approval for 1135 waivers that are now available under the President's national emergency declaration.

States and territories may submit a Section 1135 waiver request directly to their Center for Medicaid & CHIP Services (CMCS) state lead or Jackie Glaze, Acting Director, Medicaid & CHIP Operations Group, Center for Medicaid & CHIP Services at CMS by e-mail (Jackie.Glaze@cms.hhs.gov) or letter.

The following are examples of flexibilities that states and territories may seek through a Section 1135 waiver request:

- Waive prior authorization requirements in fee-for-service programs.

Updated 5/24/21

- Permits providers located out of state/territory to provide care to another state's Medicaid enrollee impacted by the emergency.
- Temporarily suspend certain provider enrollment and revalidation requirements to increase access to care.
- Temporarily waive requirements that physicians and other health care professionals be licensed in the state in which they are providing services, so long as they have an equivalent licensing in another state; and,
- Temporarily suspend requirements for certain pre-admission and annual screenings for nursing home residents.

States and territories are encouraged to assess their needs and request these available flexibilities, which are more completely outlined in the Medicaid and CHIP Disaster Response Toolkit. For more information and to access the toolkit and the [1135 waiver checklist](#), visit: <https://www.medicaid.gov/state-resource-center/disaster-response-toolkit/index.html>.

ATTACHMENT A

Blanket Waivers of Sanctions under the Physician Self-Referral Law (also known as the “Stark Law”)

CMS has issued blanket waivers of sanctions under section 1877(g) of the Act. The blanket waivers may be used now without notifying CMS. Individual waivers of sanctions under section 1877(g) of the Act may be granted upon request. For more information, visit:

<https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Spotlight>.

For resources and additional information on 1135 Waivers, please also visit:

- <https://www.cms.gov/About-CMS/Agency-Information/Emergency/EPRO/Current-Emergencies/Current-Emergencies-page>
- <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/1135-Waivers>

For questions, please email: 1135waiver@cms.hhs.gov

Blanket Waivers: Stafford Act, Public Health Emergency (PHE) and Section 1135 Waivers

Background

On March 13, 2020, the President issued an emergency declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121-5207 (the “Stafford Act”) to declare a national health emergency. The Secretary of the Department of Health and Human Services (the Secretary) is authorized to waive certain Medicare, Medicaid and Children’s Health Insurance Program (CHIP) program requirements and conditions of participation under Section 1135 of the Social Security Act once the President has declared an emergency through the Stafford Act² and the Secretary has declared a Public Health Emergency (PHE). The Secretary issued a PHE on January 31, 2020³. As a result of this authority, CMS can grant waivers that will ease certain requirements for affected providers as stated under Section 1135 of the Social Security Act⁴.

CMS can issue two types of waivers: blanket waivers and provider/supplier requested waivers. Specifics about the two types of waivers are outlined in detail below. Examples of these 1135 waivers or modifications include:

- Conditions of participation or other certification requirements
- Program participation and similar requirements
- Preapproval requirements
- Requirements that physicians and other health care professionals be licensed in the State in which they are providing services, so long as they have equivalent licensing in another State (this waiver is for purposes of Medicare, Medicaid, and CHIP reimbursement only – state law governs whether a non-Federal provider is authorized to provide services in the state without state licensure)
- Emergency Medical Treatment and Labor Act (EMTALA)
- Sanctions under the physician self-referral law (also known as the “Stark Law”)
- Performance deadlines and timetables may be adjusted (but not waived)
- Limitations on payment for health care items and services furnished to Medicare Advantage enrollees by non-network providers

² <https://www.whitehouse.gov/wp-content/uploads/2020/03/LetterFromThePresident.pdf>

³ <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>

⁴ <https://www.phe.gov/emergency/news/healthactions/section1135/Pages/covid19-13March20.aspx>

Waivers under Section 1135 of the Social Security Act typically end no later than the termination of the emergency period, or 60 days from the date the waiver or modification is first published. The Secretary can extend the waiver by notice for additional periods of up to 60 days, up to the end of the emergency period.

The 1135 waiver authority applies **only** to Federal requirements and **does not apply** to State requirements for licensure or conditions of participation.

In addition to the 1135 waiver authority, Section 1812(f) of the Social Security Act (the Act) authorizes the Secretary to provide for Skilled Nursing Facilities (SNF) coverage in the absence of a qualifying hospital stay, as long as this action does not increase overall program payments and does not alter the SNF benefit's "acute care nature" (that is, its orientation toward relatively short-term and intensive care).

Federally certified/approved providers must continue to operate under normal rules and regulations, unless they have sought and have been granted modifications under the waiver authority from specific requirements.

In addition, the Coronavirus Preparedness and Response Supplemental Appropriations Act, as signed into law by the President on March 6, 2020, includes a provision allowing the Secretary to waive certain Medicare telehealth payment requirements during the PHE the Secretary declared on January 31, 2020 to allow beneficiaries in all areas of the country to receive telehealth services, including at their home. Under the waiver, limitations on where Medicare patients are eligible for telehealth will be removed during the emergency. In particular, patients outside of rural areas, and patients in their homes will be eligible for telehealth services, effective for services starting March 6, 2020.⁵

⁵ <https://edit.cms.gov/files/document/medicare-telehealth-frequently-asked-questions-faqs-31720.pdf>

CMS Section 1135 Waiver Authority: Blanket Waivers, Provider/Supplier Individual Waivers, Medicaid and Special Waivers

Medicare Blanket Waivers

- **Approval:** CMS implements specific waivers or modifications under the 1135 authority on a “blanket” basis when a determination has been made that all similarly situated providers in the emergency area need such a waiver or modification. These waivers prevent gaps in access to care for beneficiaries impacted by the emergency. **Once approved these waivers apply automatically to all applicable providers and suppliers. Providers and suppliers do not need to apply for an individual waiver if a blanket waiver is issued by CMS.**
- **Claims Submission for Blanket Waivers:** When submitting claims covered by the blanket waivers, the “DR” (disaster-related) condition code should be used for institutional billing (i.e., claims submitted using the ASC X12 837 institutional claims format or paper Form CMS-1450). The “CR” (catastrophe/disaster-related) modifier should be used for Part B billing, both institutional and non-institutional (i.e., claims submitted using the ASC X12 837 professional claim format or paper Form CMS-1500 or, for pharmacies, in the NCPDP format). This requirement does not apply for purposes of compliance with waivers (blanket or individual) of sanctions under the physician self-referral law.

Medicare Provider/Supplier Individual Waivers

- **Approval:** Providers and suppliers can submit requests for individual 1135 waivers. These requests must include a justification for the waiver and expected duration of the modification requested. The State Survey Agency and CMS Survey Operations Group will review the provider’s request and make appropriate decisions, usually on a case-by-case basis. Providers and suppliers should keep careful records of beneficiaries to whom they provide services, in order to ensure that proper payment may be made. Providers are expected to come into compliance with any waived requirements prior to the end of the emergency period.
- With the exception of physician self-referral law waivers, the process for requesting an 1135 waiver is managed through the Survey Operations Group, and CMS locations, previously known as the CMS Regional Offices. More information on the process is located at <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/1135-Waivers>. The website includes contact information for each CMS location. Facilities should ensure to review the process and identify the appropriate contact based on the location of the facility.

Examples of Individual Requests for 1135 Waivers

An individual hospital may request a waiver of COPs related to doubling of single occupancy patient rooms or a waiver of the requirement to discharge to a specified location or situation.

Waiver Request Process

You **do not** have to make a request for a blanket waiver that has already been issued, and you **do not** have to notify CMS if you are taking action in accordance with a waiver during the time period in which the waiver is valid. If you are requesting an 1135 waiver outside of those outlined in this document or are already available at the CMS [Current Emergencies](#) page, please send your request or questions about a request to 1135waiver@cms.hhs.gov.

Medicaid Waivers

Approval

CMS works with the states and territories to respond to public health emergencies and disasters. States and territories have multiple strategies available to support Medicaid and CHIP Operations and enrollees in times of crisis. Some of these strategies are available without needing approval from CMS while some disaster-related and Public Health Emergency legal authorities include:

- Medicaid State Plan Amendments;
- CHIP Disaster Relief State Plan Amendments;
- Verification Plans;
- 1915(c) Waivers Appendix K;
- 1135 Waivers; and
- 1115 Demonstrations.

In Medicaid and CHIP, 1135 waivers can be used to implement a range of flexibilities. Some of these include: provider enrollment and participation; Medicaid prior authorization requirements; pre-admission screening and annual resident review (PASARR) Level I and Level II Assessments for 30 days; extend minimum data set authorizations for nursing facility and SNF residents; state fair hearing and appeal process timelines; and reporting and oversight. Under 1135 waivers, states also have flexibility on public notice, tribal consultation, and the effective dates of state plan amendment (SPA) submissions. For public notice, Section 1135 authority can be used to provide flexibility related to the need and timing for public notice associated with cost sharing, Alternative Benefit Plan (ABP) benefit and payment SPAs. Section 1135 authority can be used to provide flexibility related to the timing of tribal consultation including shortening consultation or conducting tribal consultation after submission of the SPA. For SPA submission dates, Section 1135 authority can be utilized to effectively permit states to submit a Medicaid SPA after the end of this quarter and still have an effective date retroactive to the date of the declaration by the Secretary of a Public Health Emergency.

In the event of a disaster or public health emergency, state Medicaid agencies should contact CMS for questions and waiver requests. More information on this process is located at:

<https://www.medicaid.gov/state-resource-center/disaster-response-toolkit/index.html>

Special Waivers

EMTALA:

Only two aspects of the EMTALA requirements can be waived under 1135 Waiver Authority: 1) Transfer of an individual who has not been stabilized, if the transfer arises out of an emergency or, 2) Redirection to another location (offsite alternate screening location) to receive a medical screening exam under a state emergency preparedness or pandemic plan. A waiver of EMTALA sanctions is effective only if actions under the waiver do not discriminate as to source of payment or ability to pay. Hospitals are generally able to manage the separation and flow of potentially infectious patients through alternate screening locations on the hospital campus.

Therefore, waivers to provide Medical Screening Examinations at an offsite alternate screening location not owned or operated by the hospital will be reviewed on a case-by-case basis. Please note, there is no waiver authority available for any other EMTALA requirement.

For the duration of the COVID-19 national emergency, CMS is waiving the enforcement of section 1867(a) of the Social Security Act (the Emergency Medical Treatment and Active Labor Act, or EMTALA). This will allow hospitals, psychiatric hospitals, and CAHs to screen patients at a location offsite from the hospital's campus to prevent the spread of COVID-19, in accordance with the state emergency preparedness or pandemic plan.

Individual Physician Self-Referral Law Waiver Requests:

CMS has issued blanket waivers of sanctions under the physician self-referral law. The blanket waivers may be used now without notifying CMS. For more information, visit: <https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Spotlight>.

Unlike other 1135 waiver requests, any requests for individual waivers of sanctions under the physician self-referral law related to COVID-19 will be handled by CMS Baltimore. Please send your request to 1877CallCenter@cms.hhs.gov and include the words "Request for 1877(g) Waiver" in the subject line of the email. All requests should include the following minimum information:

- Name and address of requesting entity;
- Name, phone number and email address of person designated to represent the entity;
- CMS Certification Number (CCN) or Taxpayer Identification Number (TIN);
- Nature of request.

Individual waivers may be granted only upon request and on a case-by-case basis and require specific details concerning the actual or proposed financial relationship between the referring physician(s) and the referred-to entity. Unless and until a waiver of sanctions under the physician self-referral law (i.e., a waiver of section 1877(g) of the Social Security Act) is granted to the requesting party(ies), such party(ies) must comply with section 1877 of the Social Security Act and the regulations at 42 CFR §411.350 et seq.

Helpful Website Resources

- **Approved 1135 Waivers:** <https://www.cms.gov/files/document/covid19-emergency-declaration-health-care-providers-fact-sheet.pdf>
- **Approved Telehealth Waivers:** <https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet>
- **1135 Waiver Request Information:** <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/1135-Waivers>
- **Medicare Fee-For-Service Additional Emergency and Disaster-Related Policies and Procedures That May Be Implemented Only With an §1135 Waiver:** <https://www.cms.gov/About-CMS/Agency-Information/Emergency/Downloads/MedicareFFS-EmergencyQsAs1135Waiver.pdf>
- **Blanket Waivers – Claims Submission:** <https://www.cms.gov/files/document/se20011.pdf>
- **Frequently Asked Questions – 1135 Waivers:** <https://www.cms.gov/About-CMS/Agency-Information/Emergency/Downloads/MedicareFFS-EmergencyQsAs1135Waiver.pdf>
- **Frequently Asked Questions – non-1135 Waivers:** [https://www.cms.gov/About-CMS/ Agency-Information/Emergency/Downloads/Consolidated Medicare FFS Emergency QsAs.pdf](https://www.cms.gov/About-CMS/Agency-Information/Emergency/Downloads/Consolidated_Medicare_FFS_Emergency_QsAs.pdf)
- **Medicaid Disaster Response Toolkit:** <https://www.medicare.gov/state-resource-center/disaster-response-toolkit/index.html>

CMS Oversight

CMS remains committed to ensuring continuity of oversight activities during a national public health emergency. We continue to work State Survey Agencies and accrediting organizations, charged with inspecting Medicare and Medicaid providers to ensure compliance with Federal requirements, to ensure these activities are prioritized to allow providers to focus on current health and safety threats and provide needed care to beneficiaries. We will continue to monitor program operations to support proper enrollment and accurate billing practices. CMS will coordinate our oversight activities with the OIG and GAO.



Federal & State Waivers

[Home](#) [Public Policy](#) > [Issues](#) > [Emergency Preparedness](#) > [Information For Texas Hospitals On COVID-19](#) > [Federal & State Waivers](#)

THA is working with state and federal leaders to waive certain regulatory requirements so that Texas hospitals can prioritize high quality, safe care during the declared state and federal disaster. The following provides the status of waivers of operational and financial requirements for Texas hospitals during the COVID-19 emergency.

THA updates the following list of state and federal waivers and their status everyday using a live Google Sheet. That means THA members can get the latest updates as soon as they are populated into the spreadsheet.

[See the Federal and State Waivers Spreadsheet](#) >>

[Return to COVID-19 Resource Center](#) >>

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State Advocacy

Federal Advocacy

Health Care Coverage Expansion

Flu Vaccination Resources

Issues

Surprise Billing

End of Life Issues

Behavioral/Mental Health

Maternal Health

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Federal Waivers

Category	Waiver Request	Status	Waiver Type	Approval Link	Applies To:
EMTALA	CMS is waiving the enforcement of section 1867(a) of the Social Security Act (the Emergency Medical Treatment and Active Labor Act, or EMTALA). This will allow hospitals, psychiatric hospitals, and critical access hospitals to screen patients at a location offsite from the hospital's campus to prevent the spread of COVID-19, in accordance with the state emergency preparedness or pandemic plan.	Approved 3/26/20 by CMS	Texas and Blanket	https://dnnsymkuj.blob.core.windows.net/portals/0/Issues/Emergency%20Readiness/TX-Texas_Hospital_Association-Waiver_Approval_Letter-3-26-2020.pdf?sr=b&si=DNNFileManagerPolicy&sig=y7SkK%2FGDStAjFDi8W7DE0fbZ2xo2fIM%2BlokVSatpNOK%3D https://www.cms.gov/files/document/covid-hospitals.pdf	Emergency Care Providers
Participation in Medicare and Medicaid	Waivers related to conditions and requirements of participation, certification requirements and preapproval requirements. This is a general waiver, but it allows a hospital that is unable to meet a condition of participation or other requirement due to COVID-19 to request a waiver from CMS.	This question is being forwarded to the Office of Administrator's Committee for review.	Texas		Medicare and Medicaid Providers
Medical Staff	42 C.F.R. §482.22(a) and §485.627(a).CMS is waiving these requirements to allow for physicians whose privileges will expire to continue practicing at the hospital or critical access hospital and for new physicians to be able to practice in the hospital or CAH before full medical staff/governing body review and approval.	Approved (as long as physicians are licensed). Update - Approved by CMS 3/26/20.	Texas and Blanket	https://dnnsymkuj.blob.core.windows.net/portals/0/Issues/Emergency%20Readiness/THA_1135_Waiver_Request_SW_03202020.pdf?sr=b&si=DNNFileManagerPolicy&sig=ETZ2EmpJJuDYSK%2FGDStAjFDi8W7DE0fbZ2xo2fIM%2BlokVSatpNOK%3D https://www.cms.gov/files/document/covid-hospitals.pdf https://dnnsymkuj.blob.core.windows.net/portals/0/Issues/Emergency%20Readiness/TX-Texas_Hospital_Association-Waiver_Approval_Letter-3-26-2020.pdf?sr=b&si=DNNFileManagerPolicy&sig=y7SkK%2FGDStAjFDi8W7DE0fbZ2xo2fIM%2BlokVSatpNOK%3D	Physicians

Federal Waivers

Category	Waiver Request	Status	Waiver Type	Approval Link	Applies To:
Skilled Nursing Facilities	Waive the requirement under Section 1812(f) of the Social Security Act for a 3-day hospital stay prior to coverage of a skilled nursing facility stay.	Approved 3/20/20	Texas	https://dnnsymkuj.blob.core.windows.net/portals/0/Issues/Emergency%20Readiness/THA_1135_Waiver_Request_SW_03202020.pdf?sr=b&si=DNNFileManagerPolicy&sig=ETZ2EmpJJuDYSK%2F9cxRnP8B5sTdUGe0szxktHuw2RF8%3D	Skilled Nursing Facilities
Discharge Planning	42 C.F.R. §482.43(c) CMS is waiving all the requirements and subparts related to post-acute care services, so as to expedite the safe discharge and movement of patients among care settings, and to be responsive to fluid situations in various areas of the country. CMS is waiving the requirement that for those patients discharged home and referred for HHA services, or for those patients transferred to a SNF for post-hospital extended care services, or transferred to an IRF or LTCH for specialized hospital services, the hospital must: <ul style="list-style-type: none"> o §482.43(c)(1) include in the discharge plan a list of HHAs, SNFs, IRFs, or LTCHs that are available to the patient. o §482.43(c)(2) must inform the patient or the patient's representative of their freedom to choose among participating Medicare providers and suppliers of post-discharge servicesand that, o §482.43(c)(3) The discharge plan must identify any HHA or SNF to which the patient is referred in which the hospital has a disclosable financial interest, as specified by the Secretary, and any HHA or SNF that has a disclosable financial interest in a hospital under Medicare. 	Approved by CMS 3/26/20	Texas and Blanket	https://dnnsymkuj.blob.core.windows.net/portals/0/Issues/Emergency%20Readiness/TX-Texas_Hospital_Association-Waiver_Approval_Letter-3-26-2020.pdf?sr=b&si=DNNFileManagerPolicy&sig=y7SkK%2FGDStAjFDi8W7DE0fbZ2xo2fIM%2BlokVSatpNOK%3D	Hospitals
Detailed Information Sharing for Discharge Planning for Hospitals and CAHs:	CMS is waiving the requirement to provide detailed information regarding discharge planning as outlined in 42 C.F.R. §482.43(a)(8), §482.61(e), and 485.642(a)(8), described below: The hospital, psychiatric hospital, and CAH must assist patients, their families, or the patient's representative in selecting a post-acute care provider by using and sharing data that includes, but is not limited to, HHA, SNF, IRF, or LTCH data on quality measures and data on resource use measures. The hospital must ensure that the post-acute care data on quality measures and data on resource use measures is relevant and applicable to the patient's goals of care and treatment preferences.	Approved 3/26/20 by CMS	Texas and Blanket	https://dnnsymkuj.blob.core.windows.net/portals/0/Issues/Emergency%20Readiness/TX-Texas_Hospital_Association-Waiver_Approval_Letter-3-26-2020.pdf?sr=b&si=DNNFileManagerPolicy&sig=y7SkK%2FGDStAjFDi8W7DE0fbZ2xo2fIM%2BlokVSatpNOK%3D	Hospitals and Critical Access Hospitals
Critical Access Hospitals	Waive 42 C.F.R. 485.620, which sets a 25-bed limit and 96-hour stay limitation for critical access hospitals.	Approved 3/30/20	Blanket Waiver	https://www.cms.gov/files/document/covid19-emergency-declaration-health-care-providers-fact-sheet.pdf	Critical Access Hospitals
Non-PPS Hospitals	Allow hospitals to treat medical/surgical patients in non-prospective payment system hospitals (e.g. long-term care hospitals) and/or units (e.g. rehabilitation). This would ensure that psychiatric or rehab units can be utilized for acute care, and that acute care is paid as acute care. This allows hospitals to flex their space to use it more efficiently, which can be important for patient isolation.	Approved 3/20/20	Blanket Waiver	https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf	Non-PPS Hospitals

Federal Waivers

Category	Waiver Request	Status	Waiver Type	Approval Link	Applies To:
Alternate Care Settings	Waive 42 C.F.R. § 482.41 so non-hospital buildings/space can be used for patient care, provided sufficient safety and comfort is provided for patients and staff. This ensures that hospitals can designate alternate sites for patient care without running into issues.	Approved 3/20/20	Texas	https://dnnsymkuj.blob.core.windows.net/portals/0/Issues/Emergency%20Readiness/THA_1135_Waiver_Request_SW_03202020.pdf?sr=b&si=DNNFileManagerPolicy&sig=ETZ2EmpJJuDYSK%2F9cxRnP8B5sTdUGe0szxktHuw2RF8%3D	Hospitals
Alternate Care Settings	Hospitals Able to Provide Inpatient Care in Temporary Expansion Sites: As part of the CMS Hospital Without Walls initiative, hospitals can provide hospital services in other healthcare facilities and sites not currently considered to be part of a healthcare facility or set up temporary expansion sites to help address the urgent need to increase capacity to care for patients. Previously, hospitals were required to provide services to patients within their hospital departments, and have shared concerns about capacity for treating patients during the COVID-19 Public Health Emergency, especially those requiring ventilator and intensive care services. CMS is providing additional flexibilities for hospitals to create surge capacity by allowing them to provide room and board, nursing, and other hospital services at remote locations or sites not considered part of a healthcare facility such as hotels or community facilities. This flexibility will allow hospitals to separate COVID-19 positive patients from other non-COVID-19 patients to help efforts around infection control and preservation of personal protective equipment (PPE). For example, for the duration of the Public Health Emergency, CMS is allowing hospitals to screen patients at offsite locations, furnish inpatient and outpatient services at temporary expansion sites. Hospitals would still be expected to control and oversee the services provided at an alternative location.	Approved 3/30/20	Blanket Waiver	https://www.cms.gov/files/document/covid-hospitals.pdf	Hospitals
HIPAA	Waive sanctions and penalties against a covered hospital that does not comply with the following provisions of the HIPAA Privacy Rule: <ul style="list-style-type: none"> • the requirements to obtain a patient's agreement to speak with family members or friends involved in the patient's care. See 45 CFR 164.510(b). • the requirement to honor a request to opt out of the facility directory. See 45 CFR 164.510(a). • the requirement to distribute a notice of privacy practices. See 45 CFR 164.520. • the patient's right to request privacy restrictions. See 45 CFR 164.522(a). • the patient's right to request confidential communications. See 45 CFR 164.522(b). The waiver became effective on March 15, 2020. When the Secretary issues such a waiver, it only applies: (1) in the emergency area identified in the public health emergency declaration; (2) to hospitals that have instituted a disaster protocol; and (3) for up to 72 hours from the time the hospital implements its disaster protocol. When the Presidential or Secretarial declaration terminates, a hospital must then comply with all the requirements of the Privacy Rule for any patient still under its care, even if 72 hours have not elapsed since implementation of its disaster protocol.	Approved by HHS 3/16/20 but only for up to 72 hours when a hospital operates under its disaster protocol.	Blanket Waiver	https://www.hhs.gov/sites/default/files/hipaa-and-covid-19-limited-hipaa-waiver-bulletin-508.pdf	Medicare and Medicaid Providers

Federal Waivers

Category	Waiver Request	Status	Waiver Type	Approval Link	Applies To:
Medicare and Medicaid Providers	Waive or modify only to the extent necessary, as determined by the Centers for Medicare & Medicaid Services: (a) certain conditions of participation, certification requirements, program participation or similar requirements; (b) requirements that physicians or other health care professionals hold licenses in the State in which they provide services, if they have an equivalent license from another State; (c) EMTALA sanctions for the direction or relocation of an individual to another location to receive medical screening pursuant to an appropriate state emergency preparedness plan or for the transfer of an individual who has not been stabilized if the transfer is necessitated by the circumstances of the declared Federal public health emergency for the COVID-19 pandemic; (d) Sanctions under section 1877(g) for self-referral under such conditions and in such circumstances as the Centers for Medicare & Medicaid Services determines appropriate; (e) Limitations on payments under section 1851(i) of the Act for health care items and services furnished to individuals enrolled in a Medicare Advantage plan by health care professionals or facilities not included in the plan's network.	Approved by US Department of Health and Human Services 3/13/20	Blanket Waiver	https://www.phe.gov/emergency/news/healthactions/section1135/Pages/covid19-13March20.aspx	Medicare and Medicaid Providers
Medicare and Medicaid Providers	Pursuant to Section 1135(b)(5), modification of deadlines and timetables and for the performance of required activities, but only to the extent necessary, as determined by the Centers for Medicare & Medicaid Services, to ensure that sufficient health care items and services are available to meet the needs of individuals enrolled in the Medicare, Medicaid and CHIP programs and to ensure that health care providers that furnish such items and services in good faith, but are unable to comply with one or more of these requirements as a result of the COVID-19 pandemic, may be reimbursed for such items and services and exempted from sanctions for such noncompliance, absent any determination of fraud or abuse.	Approved by US Department of Health and Human Services 3/13/20	Blanket Waiver	https://www.phe.gov/emergency/news/healthactions/section1135/Pages/covid19-13March20.aspx	Medicare and Medicaid Providers
Skilled Nursing Facilities	CMS is waiving the requirement at Section 1812(f) of the Social Security Act for a 3-day prior hospitalization for coverage of a skilled nursing facility stay provides temporary emergency coverage of SNF services without a qualifying hospital stay, for those people who need to be transferred as a result of the effect of a disaster or emergency. In addition, for certain beneficiaries who recently exhausted their SNF benefits, it authorizes renewed SNF coverage without first having to start a new benefit period.	Approved by CMS 3/30/20	Blanket Waiver	https://www.cms.gov/files/document/covid19-emergency-declaration-health-care-providers-fact-sheet.pdf	Skilled Nursing Facilities
Skilled Nursing Facilities	CMS is waiving 42 CFR 483.20 to provides relief to SNFs on the timeframe requirements for Minimum Data Set assessments and transmission.	Approved by CMS 3/30/20	Blanket Waiver	https://www.cms.gov/files/document/covid19-emergency-declaration-health-care-providers-fact-sheet.pdf	Skilled Nursing Facilities
Critical Access Hospitals	CMS is waiving the requirements that Critical Access Hospitals limit the number of beds to 25, and that the length of stay be limited to 96 hours.	Approved by CMS 3/30/20	Blanket Waiver	https://www.cms.gov/files/document/covid19-emergency-declaration-health-care-providers-fact-sheet.pdf	Critical Access Hospitals
Housing Acute Care Patients in Excluded Distinct Part Units	CMS is waiving requirements to allow acute care hospitals to house acute care inpatients in excluded distinct part units, where the distinct part unit's beds are appropriate for acute care inpatient. The Inpatient Prospective Payment System (IPPS) hospital should bill for the care and annotate the patient's medical record to indicate the patient is an acute care inpatient being housed in the excluded unit because of capacity issues related to the disaster or emergency.	Approved by CMS 3/30/20	Blanket Waiver	https://www.cms.gov/files/document/covid19-emergency-declaration-health-care-providers-fact-sheet.pdf	Acute Care Hospitals

Federal Waivers

Category	Waiver Request	Status	Waiver Type	Approval Link	Applies To:
DME	Where Durable Medical Equipment Prosthetics, Orthotics, and Supplies is lost, destroyed, irreparably damaged, or otherwise rendered unusable, contractors have the flexibility to waive replacements requirements such that the face-to-face requirement, a new physician's order, and new medical necessity documentation are not required. Suppliers must still include a narrative description on the claim explaining the reason why the equipment must be replaced and are reminded to maintain documentation indicating that the DMEPOS was lost, destroyed, irreparably damaged or otherwise rendered unusable or unavailable as a result of the emergency.	Approved by CMS 3/30/20	Blanket Waiver	https://www.cms.gov/files/document/covid19-emergency-declaration-health-care-providers-fact-sheet.pdf	Durable Medical Equipment Contractors
Care for Excluded Inpatient Psychiatric Unit Patients in the Acute Care Unit of a Hospital	CMS is waiving to allow acute care hospitals with excluded distinct part inpatient psychiatric units that, as a result of a disaster or emergency, need to relocate inpatients from the excluded distinct part psychiatric unit to an acute care bed and unit. The hospital should continue to bill for inpatient psychiatric services under the Inpatient Psychiatric Facility Prospective Payment System for such patients and annotate the medical record to indicate the patient is a psychiatric inpatient being cared for in an acute care bed because of capacity or other exigent circumstances related to COVID-19. This waiver may be utilized where the hospital's acute care beds are appropriate for psychiatric patients and the staff and environment are conducive to safe care. For psychiatric patients, this includes assessment of the acute care bed and unit location to ensure those patients at risk of harm to self and others are safely cared for.	Approved by CMS 3/30/20	Blanket Waiver	https://www.cms.gov/files/document/covid19-emergency-declaration-health-care-providers-fact-sheet.pdf	Acute Care Hospitals
Care for Excluded Inpatient Rehabilitation Unit Patients in the Acute Care Unit of a Hospital	CMS is waiving requirements to allow acute care hospitals with excluded distinct part inpatient Rehabilitation units that, as a result of a disaster or emergency, need to relocate inpatients from the excluded distinct part rehabilitation unit to an acute care bed and unit. The hospital should continue to bill for inpatient rehabilitation services under the inpatient rehabilitation facility prospective payment system for such patients and annotate the medical record to indicate the patient is a rehabilitation inpatient being cared for in an acute care bed because of capacity or other exigent circumstances related to the disaster or emergency. This waiver may be utilized where the hospital's acute care beds are appropriate for providing care to rehabilitation patients and such patients continue to receive intensive rehabilitation services. CMS is waiving requirements to allow IRFs to exclude patients from the hospital's or unit's inpatient population for purposes of calculating the applicable thresholds associated with the requirements to receive payment as an IRF (commonly referred to as the "60 percent rule") if an IRF admits a patient solely to respond to the emergency and the patient's medical record properly identifies the patient as such. In addition, during the applicable waiver time period, we would also apply the exception to facilities not yet classified as IRFs, but that are attempting to obtain classification as an IRF.	Approved by CMS 3/30/20	Blanket Waiver	https://www.cms.gov/files/document/covid19-emergency-declaration-health-care-providers-fact-sheet.pdf	Acute Care Hospitals
Supporting Care for Patients in Long-Term Care Acute Hospitals	Allows a long-term care hospital to exclude patient stays where an LTCH admits or discharges patients in order to meet the demands of the emergency from the 25-day average length of stay requirement which allows these facilities to be paid as LTCHs.	Approved by CMS 3/30/20	Blanket Waiver	https://www.cms.gov/files/document/covid19-emergency-declaration-health-care-providers-fact-sheet.pdf	Long-Term Acute Hospitals (LTCH)
Home Health Agencies	Provides relief to Home Health Agencies on the timeframes related to OASIS Transmission. Allows Medicare Administrative Contractors to extend the auto-cancellation date of Requests for Anticipated Payment during emergencies.	Approved by CMS 3/30/20	Blanket Waiver	https://www.cms.gov/files/document/covid19-emergency-declaration-health-care-providers-fact-sheet.pdf	Home Health Agencies

Federal Waivers

Category	Waiver Request	Status	Waiver Type	Approval Link	Applies To:
Provider Locations	Temporarily waive requirements that out-of-state providers be licensed in the state where they are providing services when they are licensed in another state. This applies to Medicare and Medicaid.	Approved by CMS 3/30/20	Blanket Waiver	https://www.cms.gov/files/document/covid19-emergency-declaration-health-care-providers-fact-sheet.pdf	Medicare and Medicaid Providers
Provider Enrollment	<p>Provider Enrollment:</p> <ul style="list-style-type: none"> • Establish a toll-free hotline for non-certified Part B suppliers, physicians and nonphysician practitioners to enroll and receive temporary Medicare billing privileges • Waive the following screening requirements: <ul style="list-style-type: none"> o Application Fee - 42 C.F.R 424.514 o Criminal background checks associated with FCBC - 42 C.F.R 424.518 o Site visits - 42 C.F.R 424.517 • Postpone all revalidation actions • Allow licensed providers to render services outside of their state of enrollment • Expedite any pending or new applications from providers 	Approved by CMS 3/30/20	Blanket Waiver	https://www.cms.gov/files/document/covid19-emergency-declaration-health-care-providers-fact-sheet.pdf	Medicare Providers
Medicare Appeals (FFS, MA & Part D)	<p>Medicare appeals in Fee for Service, Medicare Advantage and Part D:</p> <ul style="list-style-type: none"> o Extension to file an appeal o Waive timeliness for requests for additional information to adjudicate the appeal; o Processing the appeal even with incomplete Appointment of Representation forms but communicating only to the beneficiary; o Process requests for appeal that don't meet the required elements using information that is available. o Utilizing all flexibilities available in the appeal process as if good cause requirements are satisfied. 	Approved by CMS 3/30/20	Blanket Waiver	https://www.cms.gov/files/document/covid19-emergency-declaration-health-care-providers-fact-sheet.pdf	Medicare and Medicaid Providers
Telehealth	<p>CMS has recently relaxed the standards regarding telehealth. Many of the originating site requirements have been temporarily waived. Nothing has been mentioned regarding the distant site requirement for RHCs. A copy of the CMS verbiage regarding distant site requirements is below. We are requesting the distant site requirement for RHCs be waived until the federal disaster declaration has expired.</p> <p>"Payment for Telehealth Services RHCs can serve as a telehealth services originating site if the RHC is in a qualifying area. An originating site is where an eligible Medicare beneficiary is located during the telehealth service. RHCs that serve as an originating site for telehealth services are paid an originating site facility fee. Charges for the originating site facility fee may be included on a claim. RHCs are not authorized to serve as a distant site for telehealth consultations. A distant site is where the practitioner is located during the time of the telehealth service.</p>	Pending - Likely requires legislation			Rural Health Clinics
Quality Reporting	CMS announced it is granting exceptions from reporting requirements and extensions for clinicians and providers participating in Medicare quality reporting programs with respect to upcoming measure reporting and data submission for those programs. For those programs with data submission deadlines in April and May 2020, submission of those data will be optional, based on the facility's choice to report. In addition, no data reflecting services provided Jan. 1, 2020 through June 30, 2020 will be used in CMS's calculations for the Medicare quality reporting and value-based purchasing programs. This is being done to reduce the data collection and reporting burden on providers responding to the COVID-19 pandemic.	Approved by CMS 3/22/20	Blanket Waiver	https://www.cms.gov/newsroom/press-releases/cms-announces-relief-clinicians-providers-hospitals-and-facilities-participating-quality-reporting	Medicare and Medicaid Providers
Schedule II-V Controlled Substances	DEA-registered practitioners in all areas of the U.S. may issue prescriptions for all schedule II-V controlled substances to patients for whom they have not conducted an in-person medical evaluation.	Approved by DEA 3/16/20	Blanket Waiver	https://deadiversion.usdoj.gov/coronavirus.html	Physicians and Prescribers

Federal Waivers

Category	Waiver Request	Status	Waiver Type	Approval Link	Applies To:
Medicare Advantage	Under 42 CFR Section 422.100(m) during a disaster, Medicare Advantage plans must cover out-of-network visits; waive gatekeeper referrals; provide in-network cost sharing to patients who visit out-of-network facilities; and make these changes effective immediately (rather than after 30 days).	CMS 3/10/20 Memo to Medicare Advantage Plans Informing them of their Obligations	Blanket Waiver	https://www.cms.gov/files/document/hpms-memo-covid-information-plans.pdf	Medicare Advantage
Surveys	<p>CMS has provided a focused COVID-19 infection control survey for both acute care facilities and nursing homes. In addition, CMS is prioritizing surveys by authorizing modification of timetables and deadlines for the performance of certain required activities, delaying revisit surveys and generally exercising enforcement discretion for three weeks. During this three-week timeframe, only the following types of surveys will be prioritized and conducted: complaint/facility-reported incident surveys; Targeted Infection Control Surveys ; and Voluntary self-assessments (based on the focused COVID-19 infection control survey). Initial certification surveys will continue to be authorized in accordance within current guidance and prioritization.</p> <p>During the prioritization period, the following surveys will not be authorized: standard surveys for long term care facilities, hospitals, home health agencies, intermediate care facilities for individuals with intellectual disabilities and hospices. Further, for Clinical Laboratory Improvement Amendments CMS intends to prioritize immediate jeopardy situations over recertification surveys, and generally intend to use enforcement discretion, unless immediate jeopardy situations arise.</p>	Approved 3/20/20 by CMS through letter to State Survey Agency Directors.	CMS Letter to State Survey Agency Directors	https://www.cms.gov/files/document/qso-20-20-allpdf.pdf	Long term care facilities, hospitals, home health agencies, intermediate care facilities for individuals with intellectual disabilities and hospices
DME	Signature Requirements: CMS is waiving signature and proof of delivery requirements for Part B drugs and Durable Medical Equipment when a signature cannot be obtained because of the inability to collect signatures. Suppliers should document in the medical record the appropriate date of delivery and that a signature was not able to be obtained because of COVID-19.	Approved 3/30/20	Blanket Waiver	https://www.cms.gov/files/document/covid-hospitals.pdf	Medicare Part B Drugs and DME
Verbal Orders	<p>CMS is waiving the requirements of §482.23, §482.24 and §485.635(d)(3) to allow for additional flexibilities related to verbal orders where read-back verification is still required but authentication may occur later than 48 hours. This will allow for more efficient treatment of patients in a surge situation. Specifically, the following requirements are waived:</p> <ul style="list-style-type: none"> o §482.23(c)(3)(i)- If verbal orders are used for the use of drugs and biologicals (except immunizations), they are to be used infrequently; o §482.24(c)(2) - All orders, including verbal orders, must be dated, timed, and authenticated promptly by the ordering practitioner or by another practitioner who is responsible for the care of the patient; o §482.24(c)(3)- Hospitals may use pre-printed and electronic standing orders, order sets, and protocols for patient orders. This would include all subparts at §482.24(c)(3). o §485.635(d)(3)- Although the regulation requires medication administration be based on a written, signed order, this does not preclude the CAH from using verbal orders. A practitioner responsible for the care of the patient must authenticate the order in writing as soon as possible after the fact. 	Approved by CMS 3/26/20.	Texas and Blanket.	https://dnnsymkuj.blob.core.windows.net/portals/0/Issues/Emergency%20Readiness/TX-Texas_Hospital_Association-Waiver_Approval_Letter-3-26-2020.pdf?sr=b&si=DNNFileManagerPolicy&sig=y7SkK%2FGDStAjFDi8W7DE0fbZ2xo2fIM%2BlokV5atpNok%3D	Physicians and practitioners.

Federal Waivers

Category	Waiver Request	Status	Waiver Type	Approval Link	Applies To:
Reporting Requirements	CMS is waiving the requirements at 42 C.F.R. §482.13(g) (1)(i)-(ii) which require hospitals to report patients in an intensive care unit whose death is caused by their disease process but who required soft wrist restraints to prevent pulling tubes/IVs may be reported later than close of business next business day, provided any death where the restraint may have contributed is continued to be reported within standard time limits. Due to current hospital surge, we are waiving this requirement to ensure hospitals are focusing on increased care demands and patient care.	Approved by CMS 3/26/20.	Texas and Blanket.	https://dnnsymkuj.blob.core.windows.net/portals/0/Issues/Emergency%20Readiness/TX-Texas_Hospital_Association-Waiver_Approval_Letter-3-26-2020.pdf?sr=b&si=DNNFileManagerPolicy&sig=y7SkK%2FGDStAjFDi8W7DE0fbZ2xo2fIM%2BlokVSatpNOK%3D	Hospitals
Patient Rights	42 C.F.R. §482.13. CMS is waiving requirements under this section only for hospitals which are considered to be impacted by a widespread outbreak of COVID-19. Hospitals that are located in a State which has widespread confirmed cases (i.e., 6-50 or more confirmed cases), as updated under the CDC States Reporting Cases of COVID-19 to CDC at https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html would not be required to meet the following requirements: <ul style="list-style-type: none"> o 42 C.F.R. §482.13(d)(2) with respect to timeframes in providing a copy of a medical record. o 42 C.F.R. §482.13(h) related to Patient visitation, including the requirement to have written policies and procedures on visitation of patients who are in COVID-19 isolation and quarantine processes. o 42 C.F.R. §482.13(e)(C)(1)(ii) regarding seclusion. 	Approved by CMS 3/26/20.	Texas and Blanket.	https://dnnsymkuj.blob.core.windows.net/portals/0/Issues/Emergency%20Readiness/TX-Texas_Hospital_Association-Waiver_Approval_Letter-3-26-2020.pdf?sr=b&si=DNNFileManagerPolicy&sig=y7SkK%2FGDStAjFDi8W7DE0fbZ2xo2fIM%2BlokVSatpNOK%3D	Hospitals
Sterile Compounding	42 C.F.R. §482.25(b)(1) and §485.635(a)(3). CMS is waiving these requirements in order to allow used face masks to be removed and retained in the compounding area to be re-donned and reused during the same work shift in the compounding area only. This will conserve scarce face mask supplies which will help with the impending shortage of medications. While USP797 also outlines this, CMS will not be reviewing the use and storage of facemasks under these requirements.	Approved by CMS 3/26/20.	Texas and Blanket.	https://dnnsymkuj.blob.core.windows.net/portals/0/Issues/Emergency%20Readiness/TX-Texas_Hospital_Association-Waiver_Approval_Letter-3-26-2020.pdf?sr=b&si=DNNFileManagerPolicy&sig=y7SkK%2FGDStAjFDi8W7DE0fbZ2xo2fIM%2BlokVSatpNOK%3D	Health care providers.
Medical Records Timing	Medical Records: CMS is waiving 42 CFR §482.24(a) through (c), which cover the subjects of the organization and staffing of the medical records department, requirements for the form and content of the medical record, and record retention requirements. CMS is waiving requirements under 42 CFR §482.24(c)(4)(viii) and §485.638(a)(4)(iii) related to medical records to allow flexibility in completion of medical records within 30 days following discharge and for CAHs that all medical records must be promptly completed. This flexibility will allow clinicians to focus on the patient care at the bedside during the pandemic. (There was a narrower waiver here approved on 3/26/20, which was expanded).	Approved by CMS 3/26/20 and expanded on 3/30/20.	Texas and Blanket.	https://www.cms.gov/files/document/covid-hospitals.pdf https://dnnsymkuj.blob.core.windows.net/portals/0/Issues/Emergency%20Readiness/TX-Texas_Hospital_Association-Waiver_Approval_Letter-3-26-2020.pdf?sr=b&si=DNNFileManagerPolicy&sig=y7SkK%2FGDStAjFDi8W7DE0fbZ2xo2fIM%2BlokVSatpNOK%3D	Hospitals and Critical Access Hospitals

Federal Waivers

Category	Waiver Request	Status	Waiver Type	Approval Link	Applies To:
Flexibility in Patient Self Determination Act Requirements (Advance Directives)	CMS is waiving the requirements at section 1902(a)(58) and 1902(w)(1)(A) for Medicaid, 1852(i) (for Medicare Advantage); and 1866(f) and 42 CFR 489.102 for Medicare, which require hospitals and CAHs to provide information about its advance directive policies to patients. We are waiving this requirement to allow for staff to more efficiently deliver care to a larger number of patients. This would not apply to the requirements at §482.13(a) for hospitals and at §485.608(a) for CAHs to receive information about the presence of a policy regarding the facility's recognition of advanced directives.	Approved by CMS 3/26/20.	Texas and Blanket.	https://dnnsymkuj.blob.core.windows.net/portals/0/Issues/Emergency%20Readiness/TX-Texas_Hospital_Association-Waiver_Approval_Letter-3-26-2020.pdf?sr=b&si=DNNFileManagerPolicy&sig=y7SkK%2FGDStAjFDi8W7DE0fbZ2xo2fIM%2BloKVSatpNOK%3D https://www.cms.gov/files/document/covid-hospitals.pdf	Hospitals and Critical Access Hospitals
Physical Environment	CMS is waiving certain requirements under the Medicare conditions at 42 C.F.R. §482.41 and §485.623 to allow for flexibilities during hospital, psychiatric hospital, and CAH surges. CMS will permit non-hospital buildings/space to be used for patient care and quarantine sites, provided that the location is approved by the State (ensuring safety and comfort for patients and staff are sufficiently addressed). This allows for increased capacity and promotes appropriate cohorting of COVID-19 patients.	Approved by CMS 3/26/20.	Texas and Blanket.	https://dnnsymkuj.blob.core.windows.net/portals/0/Issues/Emergency%20Readiness/TX-Texas_Hospital_Association-Waiver_Approval_Letter-3-26-2020.pdf?sr=b&si=DNNFileManagerPolicy&sig=y7SkK%2FGDStAjFDi8W7DE0fbZ2xo2fIM%2BloKVSatpNOK%3D	Hospitals, Psychiatric Hospitals and Critical Access Hospitals
Staffing Data Submission	CMS is waiving 42 CFR 483.70(q) to provide relief to long term care facilities on the requirements for submitting staffing data through the Payroll-Based Journal system.	Approved by CMS 3/26/20.	Texas and Blanket.	https://dnnsymkuj.blob.core.windows.net/portals/0/Issues/Emergency%20Readiness/TX-Texas_Hospital_Association-Waiver_Approval_Letter-3-26-2020.pdf?sr=b&si=DNNFileManagerPolicy&sig=y7SkK%2FGDStAjFDi8W7DE0fbZ2xo2fIM%2BloKVSatpNOK%3D	Skilled Nursing Facilities
Waive Pre-Admission Screening and Annual Resident Review	CMS is waiving the following requirements related to PASARR for nursing home residents who may also have a mental illness or intellectual disability (42 CFR §483.106(b)(4)). <ul style="list-style-type: none"> o Level I screens are not required for residents when they are being transferred between NFs (inter-facility transfers) and staff cannot enter nursing facilities due to quarantine. If the NF is not certain whether a Level I evaluation had been conducted at the resident's transferring/evacuating facility, a Level I can be conducted by the admitting facility during the first few days of admission as part of intake. If there is not enough information to complete a Level I evaluation, the NF must document this in the resident's case files. Level II evaluations and determinations are also not required preadmission when residents are being transferred between NFs. Residents who are transferred will receive a post admission review which must be completed as resources become available.	Approved by CMS 3/26/20.	Texas and Blanket.	https://dnnsymkuj.blob.core.windows.net/portals/0/Issues/Emergency%20Readiness/TX-Texas_Hospital_Association-Waiver_Approval_Letter-3-26-2020.pdf?sr=b&si=DNNFileManagerPolicy&sig=y7SkK%2FGDStAjFDi8W7DE0fbZ2xo2fIM%2BloKVSatpNOK%3D	Skilled Nursing Facilities

Federal Waivers

Category	Waiver Request	Status	Waiver Type	Approval Link	Applies To:
Physical Environment	Provided that the State has approved the location as one that sufficiently addresses safety and comfort for patients and staff, CMS is waiving requirements under §483.90 to allow for a non-SNF buildings to be temporarily certified as and available for use by a SNF in the event there are needs for isolation processes for COVID-19 positive residents which may not be feasible in the existing SNF structure to ensure care and services during treatment for COVID-19 is available while protecting other vulnerable adults. CMS believes this will also provide another measure that will free up inpatient care beds at hospitals for the most acute patients while providing beds for those still in need of care. CMS will revise processes, as necessary, to facilitate certification and surveys of these sites under this waiver. Waiver of certain conditions of participation and certification requirements for opening a NF if the state determines there is a need to quickly stand up a temporary COVID-19 isolation and treatment location.	Approved by CMS 3/26/20.	Texas and Blanket.	https://dnnsymkuj.blob.core.windows.net/portals/0/Issues/Emergency%20Readiness/TX-Texas_Hospital_Association-Waiver_Approval_Letter-3-26-2020.pdf?sr=b&si=DNNFileManagerPolicy&sig=y7SkK%2FGDStAjFDi8W7DE0fbZ2xo2fIM%2BlokVSatpNOK%3D	Skilled Nursing Facilities
Resident Groups	CMS is waiving the requirements at §483.10(f)(5) which allow for residents to have the right to participate in-person in resident groups. This waiver would only permit the facility to restrict having in-person meetings during the national emergency given the recommendations of social distancing and limiting gatherings of more than ten people. Refraining from in-person gatherings will help prevent the spread of COVID-19.	Approved by CMS 3/26/20.	Texas and Blanket.	https://dnnsymkuj.blob.core.windows.net/portals/0/Issues/Emergency%20Readiness/TX-Texas_Hospital_Association-Waiver_Approval_Letter-3-26-2020.pdf?sr=b&si=DNNFileManagerPolicy&sig=y7SkK%2FGDStAjFDi8W7DE0fbZ2xo2fIM%2BlokVSatpNOK%3D	Skilled Nursing Facilities
Training and Certification of Nurse Aids	CMS is waiving the requirements at §483.35(d) which requires that a SNF and NF may not employ anyone for longer than 4 months unless they met the training and certification requirements under §483.35(d). CMS is waiving these requirements to assist in potential staffing shortages seen with the COVID-19 pandemic.	Approved by CMS 3/26/20.	Texas and Blanket.	https://dnnsymkuj.blob.core.windows.net/portals/0/Issues/Emergency%20Readiness/TX-Texas_Hospital_Association-Waiver_Approval_Letter-3-26-2020.pdf?sr=b&si=DNNFileManagerPolicy&sig=y7SkK%2FGDStAjFDi8W7DE0fbZ2xo2fIM%2BlokVSatpNOK%3D	Skilled Nursing Facilities
Reporting	Provides relief to Home Health Agencies on the timeframes related to OASIS Transmission. (Approved on 3/13/2020- Clarified) This waiver includes: <ul style="list-style-type: none"> o Extension of the 5-day completion requirement for the comprehensive assessment o Waives the 30-day OASIS submission requirement 	Approved by CMS 3/26/20.	Texas and Blanket.	https://dnnsymkuj.blob.core.windows.net/portals/0/Issues/Emergency%20Readiness/TX-Texas_Hospital_Association-Waiver_Approval_Letter-3-26-2020.pdf?sr=b&si=DNNFileManagerPolicy&sig=y7SkK%2FGDStAjFDi8W7DE0fbZ2xo2fIM%2BlokVSatpNOK%3D	Home Health Agencies

Federal Waivers

Category	Waiver Request	Status	Waiver Type	Approval Link	Applies To:
Home Health	Home health agencies can perform initial assessments and determine patients' homebound status remotely or by record review. This will allow patients to be cared for in the best environment while supporting infection control and reducing impact on acute care and long-term care facilities. This will allow for maximizing coverage by already scarce physician and advanced practice clinicians and allow those clinicians to focus on caring for patients with the greatest acuity.	Approved by CMS 3/26/20.	Texas and Blanket.	https://dnnsymkuj.blob.core.windows.net/portals/0/Issues/Emergency%20Readiness/TX-Texas_Hospital_Association-Waiver_Approval_Letter-3-26-2020.pdf?sr=b&si=DNNFileManagerPolicy&sig=y7SkK%2FGDStAjFDi8W7DE0fbZ2xo2fIM%2BlokVSatpNOK%3D	Home Health Agencies
Hospice Volunteers	Waive requirement for hospices to use volunteers. CMS is waiving the requirement that hospices are required to use volunteers (including at least 5% of patient care hours). It is anticipated that hospice volunteer availability and use will be reduced related to COVID-19 surge and anticipated quarantine. (42 CFR §418.78(e))	Approved by CMS 3/26/20.	Texas and Blanket.	https://dnnsymkuj.blob.core.windows.net/portals/0/Issues/Emergency%20Readiness/TX-Texas_Hospital_Association-Waiver_Approval_Letter-3-26-2020.pdf?sr=b&si=DNNFileManagerPolicy&sig=y7SkK%2FGDStAjFDi8W7DE0fbZ2xo2fIM%2BlokVSatpNOK%3D	Hospice.
Comprehensive Assessments	CMS is waiving certain requirements for Hospice (§418.54) related to update of the comprehensive assessments of patients. This waiver applies the timeframes for updates to the comprehensive assessment (§418.54(d)). Hospices must continue to complete the required assessments and updates, however, the timeframes for updating the assessment may be extended from 15 to 21 days.	Approved by CMS 3/26/20.	Texas and Blanket.	https://dnnsymkuj.blob.core.windows.net/portals/0/Issues/Emergency%20Readiness/TX-Texas_Hospital_Association-Waiver_Approval_Letter-3-26-2020.pdf?sr=b&si=DNNFileManagerPolicy&sig=y7SkK%2FGDStAjFDi8W7DE0fbZ2xo2fIM%2BlokVSatpNOK%3D	Hospice.
Waive Non-Core Services	CMS is waiving the requirement for hospices to provide certain non-core hospice services during the national emergency, including the requirements at §418.72 for physical therapy, occupational therapy, and speech-language pathology.	Approved by CMS 3/26/20.	Texas and Blanket.	https://dnnsymkuj.blob.core.windows.net/portals/0/Issues/Emergency%20Readiness/TX-Texas_Hospital_Association-Waiver_Approval_Letter-3-26-2020.pdf?sr=b&si=DNNFileManagerPolicy&sig=y7SkK%2FGDStAjFDi8W7DE0fbZ2xo2fIM%2BlokVSatpNOK%3D	Hospice.

Federal Waivers

Category	Waiver Request	Status	Waiver Type	Approval Link	Applies To:
Waived Onsite Visits for Home Health Agencies and Hospice & Aide Supervision	CMS is waiving the requirements at 42 CFR 418.76 (h) and 484.80(h), which require a nurse to conduct an onsite visit every two weeks. This would include waiving the requirements for a nurse or other professional to conduct an onsite visit every two weeks to evaluate if aides are providing care consistent with the care plan as this may not be physically possible for a period of time. This waiver is also temporarily suspending 2-week aide supervision requirement at 42 CFR §484.80(h)(1) by a registered nurse for home health agencies, but virtual supervision is encouraged during the period of the waiver.	Approved by CMS 3/26/20.	Texas and Blanket.	https://dnnsymkuj.blob.core.windows.net/portals/0/Issues/Emergency%20Readiness/TX-Texas_Hospital_Association-Waiver_Approval_Letter-3-26-2020.pdf?sr=b&si=DNNFileManagerPolicy&sig=y7SkK%2FGDStAjFDi8W7DE0fbZ2xo2fIM%2BlokVSatpNOK%3D	Home Health and Hospice.
HIPAA and Disclosures to Law Enforcement, Paramedics, Other First Responders and Public Health Authorities	The Office for Civil Rights released guidance regarding a covered entities ability to share identifying information of an individual infected with, or exposed to, COVID-19. The guidance indicates that covered entities may disclose PHI of such individuals with law enforcement, paramedics, other first responders, and public health authorities without HIPAA authorization, in certain circumstances.	Guidance issued on 3/26/20.	Blanket Waiver	https://www.hhs.gov/sites/default/files/covid-19-hipaa-and-first-responders-508.pdf	HIPAA Covered Entities
Medicare Payment	On March 28, CMS announced it will provide accelerated or advance payments during the COVID-19 emergency to any Medicare provider that submits a request to the appropriate Medicare Administrative Contractor and meets the required qualifications. Qualified providers/suppliers must request a specific amount to be paid using an "Accelerated or Advance Payment Request" form, which is not yet available from Novitas' web page. Read AHA's summary and CMS' fact sheet.	Approved 3/28/20	Blanket Waiver	https://www.cms.gov/files/document/Accelerated-and-Advanced-Payments-Fact-Sheet.pdf https://www.cms.gov/files/document/covid-hospitals.pdf	Medicare Providers

Federal Waivers

Category	Waiver Request	Status	Waiver Type	Approval Link	Applies To:
Liability Protection	<p>The Coronavirus Aid, Relief, and Economic Security Act (CARES Act, H.R. 748) has a provision limiting liability for certain volunteer healthcare professionals: SECTION 3215: LIMITATION ON LIABILITY FOR VOLUNTEER HEALTH CARE PROFESSIONALS DURING COVID-19 EMERGENCY RESPONSE</p> <ul style="list-style-type: none"> o Limits liability for health care volunteers under Federal and State law for “any harm caused by an act or omission of the professional in the provision of health care services during a public health emergency” for the duration of the COVID-19 emergency. This applies if: <ul style="list-style-type: none"> (1) the professional is providing health care services in response to such public health emergency, as a volunteer; and (2) the act or omission occurs— <ul style="list-style-type: none"> (A) in the course of providing health care services; (B) in the health care professional’s capacity as a volunteer; (C) in the course of providing health care services that— <ul style="list-style-type: none"> (i) are within the scope of the license, registration, or certification of the volunteer, as defined by the State of licensure, registration, or certification; and (ii) do not exceed the scope of license, registration, or certification of a substantially similar health professional in the State in which such act or omission occurs; and (D) in a good faith belief that the individual being treated is in need of health care services. o This section ensures liability protections for health-care volunteers during the COVID-19 public health emergency by preempting “the laws of a State or any political subdivision of a State to the extent that such laws are inconsistent with this section, unless such laws provide greater protection from liability.” o For additional information on exceptions and definitions, see Section 3215. 	Passed.	Federal Law	https://www.congress.gov/bill/116th-congress/house-bill/748/text?q=%7B%22search%22%3A%5B%22hr+748%22%5D%7D&r=1&s=1	Health care volunteers.
Medicaid Coverage	<p>Extend pre-existing authorizations for which a beneficiary has previously received prior authorization through the end of the public health emergency: If prior authorization processes are outlined in Texas state plan for particular benefits, CMS is using the flexibilities afforded under section 1135(b)(1)(C) of the Act that allow for waiver or modification of pre-approval requirements to permit services approved to be provided on or after March 1, 2020, to continue to be provided without a requirement for a new or renewed prior authorization, through the termination of the public health emergency, including any extensions (up to the last day of the emergency period under section 1135 (e) of the Act), for beneficiaries with a permanent residence in the geographic area of the public health emergency declared by the Secretary.</p>	Approved by CMS 3/30/20	Texas	https://www.medicaid.gov/state-resource-center/disaster-response-toolkit/federal-disaster-resources/?entry=54093	Medicaid beneficiaries.

Federal Waivers

Category	Waiver Request	Status	Waiver Type	Approval Link	Applies To:
Medicaid Flexibilities	<p>Suspend Pre-Admission Screening and Annual Resident Review Level I and Level II Assessments for 30 days:</p> <p>Section 1919(e)(7) of the Act allows Level I and Level II assessments to be waived for 30 days. All new admissions can be treated like exempted hospital discharges. After 30 days, new admissions with mental illness (MI) or intellectual disability (ID) should receive a Resident Review as soon as resources become available.</p> <p>Additionally, please note that per 42 C.F.R. §483.106(b)(4), new preadmission Level I and Level II screens are not required for residents who are being transferred between nursing facilities. If the NF is not certain whether a Level I had been conducted at the resident's evacuating facility, a Level I can be conducted by the admitting facility during the first few days of admission as part of intake and transfers with positive Level I screens would require a Resident Review.</p> <p>The 7-9-day timeframe for Level II completion is an annual average for all preadmission screens, not individual assessments, and only applies to the preadmission screens (42 C.F.R. §483.112(c)). There is not a set timeframe for when a Resident Review must be completed, but it should be conducted as resources become available.</p>	Approved by CMS 3/30/20	Texas	https://www.medicaid.gov/state-resource-center/disaster-response-toolkit/federal-disaster-resources/?entry=54093	Medicaid-certified nursing facilities
Medicaid Flexibilities	<p>State Fair Hearing Requests and Appeal Timelines: Texas requested flexibility to temporarily delay scheduling of Medicaid fair hearings and issuing fair hearings decisions during the emergency period. CMS approves a waiver under section 1135 that allows enrollees to have more than 90 days, up to an additional 120 days for an eligibility or fee for service appeal to request a fair hearing. The timeframes in 42 C.F.R. §431.221(d) provides that states can choose a reasonable timeframe for individuals to request a fair hearing not to exceed 90 days for eligibility or fee-for-service issues.</p>	Approved by CMS 3/30/20	Texas	https://www.medicaid.gov/state-resource-center/disaster-response-toolkit/federal-disaster-resources/?entry=54093	Medicaid enrollees
Medicaid Provider Enrollment	<p>Texas currently has the authority to rely upon provider screening that is performed by other State Medicaid Agencies and/or Medicare. As a result, Texas is authorized to provisionally, temporarily enroll providers who are enrolled with another SMA or Medicare for the duration of the public health emergency.</p> <p>Under current CMS policy, as explained in the Medicaid Provider Enrollment Compendium at page 42, Texas may reimburse otherwise payable claims from out-of-state providers not enrolled in Texas Medicaid program if the following criteria are met:</p> <p>The item or service is furnished by an institutional provider, individual practitioner, or</p>	Approved by CMS 3/30/30	Texas	https://www.medicaid.gov/state-resource-center/disaster-response-toolkit/federal-disaster-resources/?entry=54093	Medicaid providers

Federal Waivers

Category	Waiver Request	Status	Waiver Type	Approval Link	Applies To:
	<p>pharmacy at an out-of-state/territory practice location— i.e., located outside the geographical boundaries of the reimbursing state/territory's Medicaid plan, The National Provider Identifier of the furnishing provider is represented on the claim, The furnishing provider is enrolled and in an "approved" status in Medicare or in another state/territory's Medicaid plan, The claim represents services furnished, and; The claim represents either: A single instance of care furnished over a 180-day period, or Multiple instances of care furnished to a single participant, over a 180-day period For claims for services provided to Medicaid participants enrolled with Texas Medicaid program, CMS will waive the fifth criterion listed above under section 1135(b)(1) of the Act. Therefore, for the duration of the public health emergency, Texas may reimburse out-of-state providers for multiple instances of care to multiple participants, so long as the other criteria listed above are met.</p> <p>If a certified provider is enrolled in Medicare or with a state Medicaid program other than Texas, Texas may provisionally, temporarily enroll the out-of-state provider for the duration of the public health emergency in order to accommodate participants who were displaced by the emergency.</p> <p>With respect to providers not already enrolled with another SMA or Medicare, CMS will waive the following screening requirements under 1135(b)(1) and (b)(2) of the Act, so the state may provisionally, temporarily enroll the providers for the duration of the public health emergency:</p> <p>Payment of the application fee - 42 C.F.R. §455.460 Criminal background checks associated with Fingerprint-based Criminal Background Checks - 42 C.F.R. §455.434 Site visits - 42 C.F.R. §455.432 In-state/territory licensure requirements - 42 C.F.R. §455.412 CMS is granting this waiver authority to allow Texas to enroll providers who are not currently enrolled with another SMA or Medicare so long as the state meets the following minimum requirements:</p> <p>Must collect minimum data requirements in order to file and process claims, including, but not limited to NPI. Must collect Social Security Number, Employer Identification Number, and Taxpayer</p>			https://www.medicaid.gov/sites/default/files/2019-12/mpec-7242018.pdf	

Federal Waivers

Category	Waiver Request	Status	Waiver Type	Approval Link	Applies To:
Medicare Provider Enrollment	<p>Provider Enrollment: CMS has established toll-free hotlines for all providers as well as the following flexibilities for provider enrollment:</p> <ul style="list-style-type: none"> • Waive certain screening requirements. • Postpone all revalidation actions. • Expedite any pending or new applications from providers. <p>Medicare appeals in Fee for Service, Medicare Advantage (MA) and Part D</p> <ul style="list-style-type: none"> • CMS is allowing Medicare Administrative Contractors (MACs) and Qualified Independent Contractor (QICs) in the FFS program 42 CFR 405.942 and 42 CFR 405.962 and MA and Part D plans, as well as the Part C and Part D Independent Review Entity (IREs), 42 CFR 562, 42 CFR 423.562, 42 CFR 422.582 and 42 CFR 423.582 to allow extensions to file an appeal; • CMS is allowing MACs and QICs in the FFS program 42 CFR 405.950 and 42 CFR 405.966 and the Part C and Part D IREs to waive requirements for timeliness for requests for additional information to adjudicate appeals; MA plans may extend the timeframe to adjudicate organization determinations and reconsiderations for medical items and services (but not Part B drugs) by up to 14 calendar days if: the enrollee requests the extension; the extension is justified and in the enrollee's interest due to the need for additional medical evidence from a noncontract provider that may change an MA organization's decision to deny an item or service; or, the extension is justified due to extraordinary, exigent, or other non-routine circumstances and is in the enrollee's interest 42 CFR § 422.568(b)(1)(i), § 422.572(b)(1) and § 422.590(f)(1); • CMS is allowing MACs and QICs in the FFS program 42 C.F.R 405.910 and MA and Part D plans, as well as the Part C and Part D IREs to process an appeal even with incomplete Appointment of Representation forms 42 CFR § 422.561, 42 CFR § 423.560. However, any communications will only be sent to the beneficiary; • CMS is allowing MACs and QICs in the FFS program 42 CFR 405.950 and 42 CFR 405.966 and MA and Part D plans, as well as the Part C and Part D IREs to process requests for appeal that don't meet the required elements using information that is available 42 CFR § 422.562, 42 CFR § 423.562. • CMS is allowing MACs and QICs in the FFS program 42 CFR 405.950 and 42 CFR 405.966 and MA and Part D plans, as well as the Part C and Part D IREs, 42 CFR 422.562, 42 CFR 423.562 to utilize all flexibilities available in the appeal process as if good cause requirements are satisfied. 	Approved 3/30/20	Blanket Waiver	https://www.cms.gov/files/document/covid-hospitals.pdf	Medicare Fee For Service, Medicare Advantage and Medicare Part D
Quality Reporting	<p>Quality assessment and performance improvement program. CMS is waiving 482.21(a)-(d) and (f), and 485.641(a), (b), and (d), which provide details on the scope of the program, the incorporation, and setting priorities for the program's performance improvement activities, and integrated QAPI programs (for hospitals that are a part of a hospital system). These flexibilities, which apply to both hospitals and CAHs, should be implemented so long as they are not inconsistent with a state's emergency preparedness or pandemic plan. We expect any improvements to the plan to focus on the Public Health Emergency. While this waiver decreases burden associated with the development of a hospital or CAH QAPI program, the requirement that hospitals and CAHs maintain an effective, ongoing, hospital-wide, datadriven quality assessment and performance improvement program will remain.</p>	Approved 3/30/20	Blanket Waiver	https://www.cms.gov/files/document/covid-hospitals.pdf	Hospitals and Critical Access Hospitals

Federal Waivers

Category	Waiver Request	Status	Waiver Type	Approval Link	Applies To:
Medicaid Flexibilities	<p>The State of Texas requested a waiver of public notice requirements applicable to the state plan amendment (SPA) submission process. Public notice for SPAs is required under 42 C.F.R §447.205 for changes in statewide methods and standards for setting Medicaid payment rates, 42 C.F.R. §447.57 for changes to premiums and cost sharing, and 42 C.F.R. §440.386 for changes to ABPs. These requirements help to ensure that the affected public has reasonable opportunity to comment on these SPAs.</p> <p>CMS recognizes that during this public health emergency, Texas must act expeditiously to protect and serve the general public. Therefore, under section 1135(b)(1)(C) of the Act, CMS is approving the state's request to waive these notice requirements applicable to SPA submissions. This approval applies only with respect to SPAs that provide or increase beneficiary access to items and services related to COVID-19 (such as cost sharing waivers, payment rate increases, or amendments to ABPs to add services or providers) and that would not restrict or limit payment or services or otherwise burden beneficiaries and providers, and that are temporary, with a specified sunset date that is not later than the last day of the declared COVID-19 emergency (or any extension thereof). Even though CMS is approving this waiver, we encourage the state to make all relevant information available to the public so they are aware of the changes.</p>	Approved by CMS 3/30/30	Texas	https://www.medicaid.gov/state-resource-center/disaster-response-toolkit/federal-disaster-resources/?entry=54093	Texas Medicaid
Alternate Care Settings	<p>Under an additional initiative, CMS is relaxing certain conditions of participation (CoPs) for hospital operations to maximize hospitals ability to focus on patient care. The same initiative will also allow currently enrolled ambulatory surgical centers, to temporarily enroll as hospitals and to provide hospital services to help address the urgent need to increase hospital capacity to take care of patients. Other interested entities, such as freestanding emergency departments, could pursue enrolling as an ASC and then pursue converting their enrollment to hospital during the PHE. ASCs that wish to enroll to receive temporary billing privileges as a hospital should call the COVID-19 Provider Enrollment Hotline to reach the contractor that serves their jurisdiction, and then will complete and sign an attestation form specific to the COVID-19 PHE.</p>	Approved by CMS 3/30/20	Blanket Waiver	https://www.cms.gov/files/document/covid-hospitals.pdf https://www.cms.gov/files/document/provider-enrollment-relief-faqs-covid-19.pdf	Ambulatory Surgical Centers
Medicaid Flexibilities	<p>Utilization review: CMS is waiving these requirements at 42 CFR §482.1(a)(3) and 42 C.F.R §482.30, that requires that hospitals participating in Medicare and Medicaid to have a utilization review plan that meets specified requirements. CMS is waiving the entire Utilization Review CoP at §482.30, which requires that a hospital must have a utilization review plan with a UR committee that provides for review of services furnished to Medicare and Medicaid beneficiaries to evaluate the medical necessity of the admission, duration of stay, and services provided. These flexibilities should be implemented so long as they are not inconsistent with a State or pandemic/emergency plan. Removing these administrative requirements will allow hospitals to focus more resources on providing direct patient care.</p>	Approved 3/30/20	Blanket Waiver	https://www.cms.gov/files/document/covid-hospitals.pdf	Hospitals
Alternate Care Settings	<p>CAH Status and location: CMS is waiving the requirement at 485.610(b) that the CAH be located in a rural area or an area being treated as rural, allowing the CAHs flexibility in the establishment of surge site locations. Waiving the requirement at 485.610(e) regarding off-campus and co-location requirements allows the CAH flexibility in establishing off-site locations. In an effort to facilitate the establishment of CAHs without walls, these waivers will remove restrictions on CAHs regarding their rural location and their location relative to other hospitals and CAHs. These flexibilities should be implemented so long as it is not inconsistent with State or emergency or pandemic plan.</p>	Approved 3/30/20	Blanket Waiver	https://www.cms.gov/files/document/covid-hospitals.pdf	Critical Access Hospitals

Federal Waivers

Category	Waiver Request	Status	Waiver Type	Approval Link	Applies To:
Telemedicine	Telemedicine: CMS is waiving the provisions related to telemedicine for hospitals and CAHs at 42 CFR 482.12(a)(8-9) and 42 CFR 485.616(c), making it easier for telemedicine services to be furnished to the hospital's patients through an agreement with an off-site hospital. This allows for increased access to necessary care for hospital and CAH patients, including access to specialty care	Approved by CMS 3/30/20	Blanket Waiver	https://www.cms.gov/files/document/covid-hospitals.pdf	Hospitals
Staffing	Nursing services: CMS is waiving the provision at 42 CFR 482.23(b)(4), 42 CFR 482.23(b)(7), and 485.635(d)(4), which requires the nursing staff to develop and keep current a nursing care plan for each patient, and the provision that requires the hospital to have policies and procedures in place establishing which outpatient departments are not required under to have a registered nurse present. These waivers allow nurses increased time to meeting the clinical care needs of each patient and allows for the provision of nursing care to an increased number of patients. In addition, we expect that hospitals will need relief for the provision of inpatient services and as a result, the requirement to establish nursing-related policies and procedures for outpatient departments is likely unnecessary. These flexibilities apply to both hospitals and CAHs, and should be implemented so long as they are not inconsistent with a State or pandemic/emergency plan.	Approved by CMS 3/30/20	Blanket Waiver	https://www.cms.gov/files/document/covid-hospitals.pdf	Nursing
Food and Dietetic Services	Food and dietetic service: CMS is waiving the requirement at 42 CFR 482.28(b)(3) to have a current therapeutic diet manual approved by the dietician and medical staff readily available to all medical, nursing, and food service personnel. Such manuals would not need to be maintained at surge capacity sites. These flexibilities should be implemented so long as they are not inconsistent with a State or pandemic/emergency plan. Removing these administrative requirements will allow hospitals to focus more resources on providing direct patient care.	Approved 3/30/20	Blanket Waiver	https://www.cms.gov/files/document/covid-hospitals.pdf	Food Services
Alternate Care Settings	Emergency preparedness policies and procedures: CMS is waiving 482.15(b) and 485.625(b), which requires the hospital and CAH to develop and implement emergency preparedness policies and procedures, and 482.15(c)(1)-(5) and 485.625(c)(1)-(5) which requires that the emergency preparedness communication plans for hospitals and CAHs to contain specified elements with respect to the surge site. The requirement under the communication plan requires hospitals and CAHs to have specific contact information for staff, entities providing services under arrangement, patients' physicians, other hospitals and CAHs, and volunteers. This would not be an expectation for the temporary expansion site. This waiver removes the burden on facilities to establish these policies and procedures for their surge facilities or surge sites.	Approved 3/30/20	Blanket Waiver	https://www.cms.gov/files/document/covid-hospitals.pdf	Off-campus emergency departments
Alternate Care Settings	Emergency preparedness policies and procedures: CMS is waiving 482.15(b) and 485.625(b), which requires the hospital and CAH to develop and implement emergency preparedness policies and procedures, and 482.15(c)(1)-(5) and 485.625(c)(1)-(5) which requires that the emergency preparedness communication plans for hospitals and CAHs to contain specified elements with respect to the surge site. The requirement under the communication plan requires hospitals and CAHs to have specific contact information for staff, entities providing services under arrangement, patients' physicians, other hospitals and CAHs, and volunteers. This would not be an expectation for the temporary expansion site. This waiver removes the burden on facilities to establish these policies and procedures for their surge facilities or surge sites.	Approved 3/30/20	Blanket Waiver	https://www.cms.gov/files/document/covid-hospitals.pdf	Temporary Expansion Sites

Federal Waivers

Category	Waiver Request	Status	Waiver Type	Approval Link	Applies To:
Cost Reports	Cost Reporting: CMS is delaying the filing deadline of certain cost report due dates due to the COVID-19 outbreak. We are currently authorizing delay for the following fiscal year end (FYE) dates. CMS will delay the filing deadline of FYE 10/31/2019 cost reports due by March 31, 2020 and FYE 11/30/2019 cost reports due by April 30, 2020. The extended cost report due dates for these October and November FYEs will be June 30, 2020. CMS will also delay the filing deadline of the FYE 12/31/2019 cost reports due by May 31, 2020. The extended cost report due date for FYE 12/31/2019 will be July 31, 2020	Approved 3/30/20	Blanket Waiver	https://www.cms.gov/files/document/covid-hospitals.pdf	Hospitals
Staffing	Physician services: CMS is waiving 482.12(c), which requires that Medicare patients be under the care of a physician. This allows hospitals to use other practitioners, such as physician's assistant and nurse practitioners to the fullest extent possible. This waiver should be implemented so long as they are not inconsistent with a state's emergency preparedness or pandemic plan.	Approved 3/30/20	Blanket Waiver	https://www.cms.gov/files/document/covid-hospitals.pdf	Physician Services
Staffing	Anesthesia services. CMS is waiving the requirements at 42 CFR 482.52(a)(5), 42 CFR 485.639(c)(2), and 42 CFR 416.42 (b)(2) that a certified registered nurse anesthetist (CRNA) is under the supervision of a physician. CRNA supervision will be at the discretion of the hospital or Ambulatory Surgical Center (ASC), and state law. This waiver applies to hospitals, CAHs, and ASCs. These waivers will allow CRNAs to function to the fullest extent of their licensure, and should be implemented so long as they are not inconsistent with a State or pandemic/emergency plan.	Approved 3/30/20	Blanket Waiver	https://www.cms.gov/files/document/covid-hospitals.pdf	CRNAs
Staffing	Respiratory care services: We are waiving the requirement at 42 CFR 482.57(b)(1) that hospitals designate in writing the personnel qualified to perform specific respiratory care procedures and the amount of supervision required for personnel to carry out specific procedures. These flexibilities should be implemented so long as they are not inconsistent with a State or pandemic/emergency plan. Not being required to designate these professionals in writing will allow qualified professionals to operate to the fullest extent of their licensure and training in providing patient care for respiratory illnesses.	Approved 3/30/20	Blanket Waiver	https://www.cms.gov/files/document/covid-hospitals.pdf	Respiratory Care Services
Staffing	CAH Personnel qualifications: CMS is waiving the minimum personnel qualifications for clinical nurse specialist, nurse practitioners, and physician assistants described at 42 CFR 485.604 (a)(2), 42 CFR 485.604 (b)(1-3), and 42 C.F.R 485.604 (c)(1-3). Clinical Nurse Specialists, Nurse Practitioners, and Physician Assistants will still have to meet state requirements for licensure and scope of practice, but not additional Federal requirements that may exceed State requirements. This will give States and facilities more flexibility in using clinicians in these roles to meet increased demand. These flexibilities should be implemented so long as they are not inconsistent with a State or pandemic/emergency plan.	Approved 3/30/20	Blanket Waiver	https://www.cms.gov/files/document/covid-hospitals.pdf	Critical Access Hospitals
Staffing	CAH staff licensure: CMS is deferring to staff licensure, certification, or registration to State law by waiving the requirement at 42 CFR 485.608(d) that staff of the CAH be licensed, certified, or registered in accordance with applicable Federal, State, and local laws and regulations. The CAH and its staff must still be in compliance with applicable Federal, State and Local laws and regulations, and all patient care must be furnished in compliance with State and local laws and regulations. This waiver would defer all licensure, certification, and registration requirements for CAH staff to the state, which would add flexibility where Federal requirements are more stringent. These flexibilities should be implemented so long as they are not inconsistent with a State or pandemic/emergency plan.	Approved 3/30/20	Blanket Waiver	https://www.cms.gov/files/document/covid-hospitals.pdf	Critical Access Hospitals

Federal Waivers

Category	Waiver Request	Status	Waiver Type	Approval Link	Applies To:
Stark Law	<p>CMS Issued Blanket Waivers of Sanctions under the Physician Self-Referral Law Yesterday CMS also issued a long-awaited waiver of elements of the Physician Self-Referral Law, known as the Stark Law. In the waiver, CMS lists 18 arrangements and provides examples of permissible conduct that would normally be prohibited under the Physician Self-Referral Law. Examples include a hospital paying physicians above their contracted rate to care for COVID-19 patients in a challenging environment, a hospital renting office space from independent physicians below fair market value to accommodate a patient surge, a hospital providing meals, comfort items and childcare to physicians working long hours, and many others. The blanket waivers apply only to financial relationships and referrals that are related to the COVID-19 outbreak. Parties who use these waivers must keep records and make them available to HHS upon request.</p>	Granted 3/30/20	Blanket Waiver	https://www.cms.gov/files/document/covid-19-blanket-waivers-section-1877g.pdf	Physicians and Hospitals
Physicians and Clinicians	<p>CMS has permitted physicians to provide more Medicare services through telehealth (including emergency services), permitted other clinicians to expand telehealth use, eased physician supervision requirements and relaxed certain reporting requirements.</p>	Approved by CMS 3/30/20	Blanket Waiver	https://www.cms.gov/files/document/covid-19-physicians-and-practitioners.pdf	Physicians and Clinical Staff
Medicare Flexibilities	<p>Beneficiary Notice Delivery Guidance in light of COVID-19: If you are treating a patient with suspected or confirmed COVID-19, CMS encourages the provider community to be diligent and safe while issuing the following beneficiary notices to beneficiaries receiving institutional care:</p> <p>Important Message from Medicare (IM)_CMS-10065 Detailed Notices of Discharge (DND)_CMS-10066 Notice of Medicare Non-Coverage (NOMNC)_CMS-10123 Detailed Explanation of Non-Coverage (DENC)_CMS-10124 Medicare Outpatient Observation Notice (MOON)_CMS-10611 Advance Beneficiary Notice of Non-Coverage (ABN)_CMS-R-131 Skilled Nursing Advance Beneficiary Notice of Non-Coverage (SNFABN)_CMS-10055 Hospital Issued Notices of Non-Coverage (HINN)</p> <p>In light of concerns related to COVID-19, current notice delivery instructions provide flexibilities for delivering notices to beneficiaries in isolation. These procedures include:</p> <p>Hard copies of notices may be dropped off with a beneficiary by any hospital worker able to enter a room safely. A contact phone number should be provided for a beneficiary to ask questions about the notice, if the individual delivering the notice is unable to do so. If a hard copy of the notice cannot be dropped off, notices to beneficiaries may also delivered via email, if a beneficiary has access in the isolation room. The notices should be annotated with the circumstances of the delivery, including the person delivering the notice, and when and to where the email was sent.</p> <p>Notice delivery may be made via telephone or secure email to beneficiary representatives who are offsite. The notices should be annotated with the circumstances of the delivery, including the person delivering the notice via telephone, and the time of the call, or when and to where the email was sent.</p>	3/26/20 Medicare Learning Network Flexibility	Blanket Waiver	https://www.cms.gov/outreach-and-education/outreachffsprovpartprogprovider-partnership-email-archive/2020-03-26-mlnc-se	Medicare Providers

Federal Waivers

Category	Waiver Request	Status	Waiver Type	Approval Link	Applies To:
Physical Environment	Waive CMS Conditions of Participation for Treating Psychiatric Patients. CMS has cumbersome conditions of participation on psychiatric patients that are burdensome on hospitals during this time of crisis. Texas hospitals seek waivers on many of the CMS Conditions of Participation for treating psychiatric patients. For example, hospitals may not have the resources to be able to provide on one-on-one caregivers for certain patients, and need some relaxation for the intensive requirements. This would require flexibility under the interpretive guidance of 42 C.F.R. 482.13(c)(2) (relating to 1:1 monitoring with continuous visual observation); a waiver of portions of 42 C.F.R. 482.61 (special medical requirements for psychiatric hospitals); and a waiver or flexibility under 42 C.F.R. 482.62 (staffing).	Requested 4/3/20			
FDA	FDA Request: Provide Waivers to Modify Medical Devices. Many medical devices are in short supply or not available. Hospitals need to be able to do improvise and create or modify medical devices that are regulated by the FDA to the best of our ability to treat patients. This includes potentially creating certain supplies from 3D printing. The FDA has given written guidance, but it is not sufficient. Hospitals need additional guidance on what is and what is not permitted.	Requested 4/3/20			
Reporting	Suspend all Government Audits and CMS Contractor Reviews. While Texas hospitals have been told Novitas (the Medicare Administrative Contractor in our region) that they have suspended their Target, Probe, and Educate (TPE) reviews and the Recovery Audit Contractors (RAC) have suspended their audits (effective today March 27, 2020), we request that the TPE and RAC suspension be retroactive to any requests starting on or after March 1, 2020. We would also request that any scheduled federal audits or inquiries from the Office of Inspector General be suspended.	Requested 4/3/20			
HIPAA	HIPAA: Suspend provisions of 45 CFR 164.402, 45 CFR 164.404, 45 CFR 164.408, 45 CFR 164.414, and any related provisions in the Final Rule (78 FR 5565) that require a covered entity to investigate or report a breach. Under these provisions, a covered entity may take a reasonable time to investigate potential breaches, and collect and develop information required in a notice (if a breach did occur). Such investigation and notice should occur within a reasonable time of discovery, which is considered the day a covered entity knew or should have known about a potential breach – statute limits “reasonable time” to 60 days. During this declared emergency, covered entities do not have the time and resources to investigate all potential breaches within the 60-day timeframe. Suspension of these requirements during the declared disaster, and for a period of 30 days after will allow hospitals to concentrate on treating infected individuals.	Requested 4/3/20			
Patient Rights	HIPAA: Suspend CMS Administrative Requirements Related to Unnecessary Patient Contact. Hospitals are subject to all CMS/OCR routine paperwork requirements such as Notice of Privacy Practices, Advanced Directives, and Advanced Beneficiary Notices. There has been some relaxation of the requirements under Secretary Azar’s 1135 waiver, but it does not go far enough. For example, certain documentation requirements for HIPAA were waived, but only for 72 hours during a hospital disaster protocol. Hospitals still have to obtain a patient’s written confirmation that he/she received a Notice of Privacy Practices.	Requested 4/3/20			
Patient Rights	Other Paperwork: For advance beneficiary notices of noncoverage, some of the requirements have been relaxed, but we still must hand deliver documents or somehow provide the physical documents to patients, increasing our staff’s interactions with potentially infectious patients. Additional flexibility, such as the ability to provide these forms electronically, would be welcomed.	Requested 4/3/20			

Federal Waivers

Category	Waiver Request	Status	Waiver Type	Approval Link	Applies To:
Staffing	Physician supervision of NPs in RHCs and FQHCs. CMS has relaxed 42 C.F.R. 491.8(b) (1) ("The physician performs the following: Except for services furnished by a clinical psychologist in an FQHC, which State law permits to be provided without physician supervision, provides medical direction for the clinic's or center's health care activities and consultation for, and medical supervision of, the health care staff."). CMS has modified the requirement that physicians must provide medical direction for the clinic's or center's health care activities and consultation for, and medical supervision of, the health care staff, only with respect to medical supervision of nurse practitioners, and only to the extent permitted by state law. The physician, either in person or through telehealth and other remote communications, continues to be responsible for providing medical direction for the clinic or center's health care activities and consultation for the health care staff, and medical supervision of the remaining health care staff. This allows RHCs and FQHCs to use nurse practitioners to the fullest extent possible and allows physicians to direct their time to more critical tasks.	Granted 4/9/20	Blanket Waiver	https://www.cms.gov/newsroom/press-releases/trump-administration-acts-ensure-us-healthcare-facilities-can-maximize-frontline-workforces-confront	Physicians, Nurse Practitioners, Occupational Therapists and Nurses
Enforcement	OIG is committed to protecting patients by ensuring that healthcare providers have the regulatory flexibility necessary to adequately respond to COVID-19 concerns. Ordinarily, routine reductions or waivers of costs owed by Federal health care program beneficiaries, including cost sharing amounts such as coinsurance and deductibles, potentially implicate the Federal antikickback statute, the civil monetary penalty and exclusion laws related to kickbacks, and the civil monetary penalty law prohibition on inducements to beneficiaries. Nonetheless, recognizing the unique circumstances resulting from the COVID-19 outbreak, OIG will not subject physicians and other practitioners to OIG administrative sanctions for arrangements that satisfy both of the following conditions: 1. A physician or other practitioner reduces or waives cost-sharing obligations (i.e., coinsurance and deductibles) that a beneficiary may owe for telehealth services furnished consistent with the then-applicable coverage and payment rules. 2. The telehealth services are furnished during the time period subject to the COVID-19 Declaration.	Issued 3/17/20	Blanket Waiver	https://oig.hhs.gov/fraud/docs/alertsandbulletins/2020/policy-telehealth-2020.pdf	Telehealth Providers
Enforcement	CMS consulted with the HHS Office of Inspector General (OIG) and HHS OIG advised that should an Medicare Advantage Organization choose to voluntarily waive or reduce enrollee cost-sharing, as approved by CMS herein, such waivers or reductions would satisfy the safe harbor to the Federal anti-kickback statute set forth at 42 CFR 1001.952 (l).	Issued 3/10/20	Blanket Waiver	https://www.cms.gov/files/document/hpms-memo-covid-information-plans.pdf	Medicare Advantage Plans and Part D Sponsors
Fact Sheet	On April 9, 2020, CMS issued a new fact sheet detailing all of the blanket waivers it has granted in response to COVID-19.	Issued 4/9/20	Blanket Waiver	https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf	All Medicare and Medicaid Providers
Medicare and Medicaid Flexibilities	On April 30, the Centers for Medicare & Medicaid Services announced new waivers and rule changes to increase hospital capacity and expand COVID-19 diagnostic testing for Medicare and Medicaid beneficiaries. Under the new waivers and rule changes, certain hospitals can increase bed capacity without reducing applicable ancillary payments for indirect medical education, teaching status or rural health clinics. In addition, CMS is relaxing admission standards for inpatient rehabilitation facilities, allowing certain off-campus provider-based hospital outpatient departments to be paid under the Outpatient Prospective Payment System, permitting hospitals to bill as the originating site for telehealth services furnished by hospital-based practitioners to Medicare patients	Issued 4/30/20	Blanket Waiver	https://www.cms.gov/newsroom/press-releases/trump-administration-issues-second-round-sweeping-changes-support-us-healthcare-system-during-covid	All Medicare and Medicaid Providers

Federal Waivers

Category	Waiver Request	Status	Waiver Type	Approval Link	Applies To:
	<p>registered as hospital outpatients, including when the patient is located at home, broadening telehealth service payment to include behavioral health and providing other additional flexibilities related to telehealth, payment and capacity. To expand COVID-19 testing, Medicare will no longer require a written order from the treating physician or practitioner for COVID-19 tests and any health care professional authorized by state law may order COVID-19 tests. CMS will also provide payment to hospitals and practitioners to assess Medicare beneficiaries and collect laboratory samples for COVID-19 when that is the only service the patient receives. Medicare and Medicaid will also cover certain serology tests.</p>			https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf	
Alternate Care Settings	<p>Expanded ability for hospitals to offer long-term care services (“Swing-Beds”) for patients who do not require acute care but do meet the skilled nursing facility (SNF) level of care criteria as set forth at 42 CFR 409.31. CMS has waived the requirements at 42 CFR 482.58 to allow hospitals to establish SNF swing beds payable under the SNF prospective payment system to provide additional options for hospitals with patients who no longer require acute care but are unable to find placement in a SNF. In order to qualify for this waiver, hospitals must:</p> <ul style="list-style-type: none"> • Not use SNF swing beds for acute level care. • Comply with all other hospital conditions of participation and those SNF provisions set out at 42 CFR 482.58(b) to the extent not waived. • Be consistent with the state’s emergency preparedness or pandemic plan. <p>Hospitals must call the CMS Medicare Administrative Contractor (MAC) enrollment hotline to add swing bed services. The hospital must attest to CMS that:</p> <ul style="list-style-type: none"> • They have made a good faith effort to exhaust all other options; • There are no skilled nursing facilities within the hospital’s catchment area that under normal circumstances would have accepted SNF transfers, but are currently not willing to accept or able to take patients because of the COVID-19 public health emergency; • The hospital meets all waiver eligibility requirements; and • They have a plan to discharge patients as soon as practicable, when a SNF bed becomes available, or when the public health emergency ends, whichever is earlier. <p>This waiver applies to all Medicare enrolled hospitals, except psychiatric and long term care hospitals that need to provide post-hospital SNF level swing-bed services for non-acute care patients in hospitals, so long as the waiver is not inconsistent with the state’s emergency preparedness or pandemic plan. The hospital shall not bill for SNF PPS payment using swing beds when patients require acute level care or continued acute care at any time while this waiver is in effect. This waiver is permissible for swing bed admissions during the COVID-19 PHE with an understanding that the hospital must have a plan to discharge swing bed patients as soon as practicable, when a SNF bed becomes available, or when the PHE ends, whichever is earlier.</p>	Approved 5/11/20 (See page 7 of Approval Link)	Blanket Waiver, but requires notification to MAC	https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf	Medicare enrolled hospitals, except psychiatric and long term care hospitals
Alternate Care Settings	<p>CMS is waiving certain eligibility requirements at 42 CFR § 412.92(a) for hospitals classified as sole community hospitals prior to the public health emergency. Specifically, CMS is waiving the distance requirements and market share requirements in order to provide for increased capacity due to COVID-19. MACs will resume their standard practice for evaluation of all eligibility requirements after the conclusion of the public health emergency period.</p>	Approved 5/11/20 (See page 10 of Approval Link)	Blanket Waiver	https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf	Sole Community Hospitals

Federal Waivers

Category	Waiver Request	Status	Waiver Type	Approval Link	Applies To:
Alternate Care Settings	For hospitals classified as Medicare-Dependent Hospitals prior to the public health emergency, CMS is waiving the eligibility requirement at 42 CFR § 412.108(a)(1)(ii) that the hospital has 100 or fewer beds during the cost reporting period, and the eligibility requirement at 42 CFR § 412.108(a)(1)(iv)(C) that at least 60 percent of the hospital's inpatient days or discharges were attributable to individuals entitled to Medicare Part A benefits during the specified hospital cost reporting periods.	Approved 5/11/20 (See page 10 of Approval Link)	Blanket Waiver	https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf	Medicare-Dependent Hospitals
Physical Environment	CMS is waiving elements of the Life Safety Code related to fire drills, hand sanitizer dispensers and restrictions preventing the use of temporary walls.	Approved 5/11/20 (See page 26 of Approval Link)	Blanket Waiver	https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf	Hospitals, Critical Access Hospitals and Hospices
Commercial Insurance	A group health plan and a health insurance issuer offering group or individual health insurance coverage (including a grandfathered health plan (as defined in section 1251(e) of the Patient Protection and Affordable Care Act)) shall provide coverage, and shall not impose any cost sharing (including deductibles, copayments, and coinsurance) requirements or prior authorization or other medical management requirements, for the following items and services furnished during any portion of the emergency period defined in paragraph (1)(B) of section 1135(g) of the Social Security Act (42 U.S.C. 1320b-5(g)) beginning on or after the date of the enactment of this Act: (1) In vitro diagnostic products (as defined in section 809.3(a) of title 21, Code of Federal Regulations) for the detection of SARS-CoV-2 or the diagnosis of the virus that causes COVID-19 that are approved, cleared, or authorized under section 510(k), 513, 515 or 564 of the Federal Food, Drug, and Cosmetic Act, and the administration of such in vitro diagnostic products. (2) Items and services furnished to an individual during health care provider office visits (which term in this paragraph includes in-person visits and telehealth visits), urgent care center visits, and emergency room visits that result in an order for or administration of an in vitro diagnostic product described in paragraph (1), but only to the extent such items and services relate to the furnishing or administration of such product or to the evaluation of such individual for purposes of determining the need of such individual for such product.	Effective March 18, 2020	Families First Coronavirus Response Act	https://www.congress.gov/116/plaws/publ127/PLAW-116publ127.pdf	Commercial Insurance

CAUSE NO: 048329996-21

**ERIN JONES, Individually and as
Legal Representative and
Next Friend of Jason Jones**

Plaintiff,

v.

**TEXAS HEALTH HUGULEY, INC.,
d/b/a TEXAS HEALTH HUGULEY
HOSPITAL FT. WORTH SOUTH;
DR. JASON A. SIEDEN;
JOHN DOES #1-5; JANE ROES #1-5;**

Defendants.

§
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§ **IN THE DISTRICT COURT OF**
§
§
§ **TARRANT COUNTY, TEXAS**
§
§
§ **323rd JUDICIAL DISTRICT**
§
§
§

FIRST AMENDED PRELIMINARY INJUNCTION MOTION

Plaintiff, by counsel, moves the Court to set Plaintiff’s Motion for Preliminary Injunction for a hearing at the earliest available date on the Court’s docket on Plaintiff’s previously Complaint for Emergency Medical Declaratory Judgment and Emergency Injunctive Relief, and in support states:

1. Plaintiff, Erin Jones, on behalf of Jason Jones, seeks an Order granting her immediate and emergency relief compelling Defendants’ and/or their agents to comply with Doctor Mary Talley Bowden, M.D.’s order and prescription to administer Ivermectin to her Husband, Jason.
2. Unless such conduct is enjoined and restrained by this Court, there is a substantial likelihood that such conduct, to wit: refusal to administer Ivermectin, will continue and Jason Jones will lose all chance to preserve his life.
3. The actions of the Defendants will result in immediate and irreparable harm to the Plaintiff, creating irreparable loss (death) and as more fully described in Plaintiff’s Complaint, which is incorporated herein by reference.

4. The harm to Plaintiff, if injunctive relief is not granted outweighs the harm to the Defendants if this motion is granted, as fully described in Plaintiff's Petition; Affidavit of Erin Jones, with Exhibits "A" through "P" which will be provided to the court reporter; the Affidavit of Ralph C. Lorigo with Exhibits "A" through "D"; and the Declaration of Pierre Kory, M.D. with Exhibits "A" through "H" all of which will be provided to the court reporter.

5. Plaintiff has no adequate remedy at law, and the interests of the public will not be disserved by granting Plaintiff's motion.

6. Injunctive relief is necessary to save Jason Jones' life and is appropriate because Plaintiff is likely to prevail on the merits of their claim.

WHEREFORE, Plaintiff respectfully asks the Court to grant the motion for preliminary injunctive relief and Order Defendants to comply with Doctor Mary Talley Bowden, M.D.'s order and prescription to administer Ivermectin to their mutual patient, Jason Jones.

Respectfully submitted,

Jerri Lynn Ward, J.D.

Jerri Lynn Ward
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College Station, TX 77840
(512) 302-1103
Email: jward@garloward.com

/s/ Ralph C. Lorigo

Ralph C. Lorigo
New York State Bar # 1563105
101 Slade Avenue
West Seneca NY 14224
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Email: rlorigo@lorigo.com

ATTORNEYS FOR PLAINTIFF

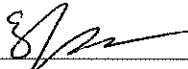
VERIFICATION

STATE OF TEXAS §
TARRANT COUNTY §

JT EJ Erin Jones

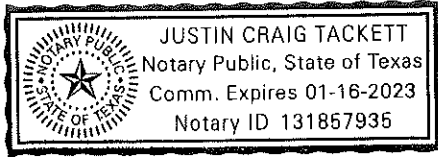
Before me, the undersigned notary, on this day personally appeared ~~{name of affiant}~~, the affiant, whose identity is known to me. After I administered an oath, affiant testified as follows:

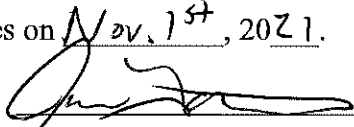
“My name is Erin Jones. I am capable of making this verification. I have read the First Amended Preliminary Motion.. The facts stated in it are within my personal knowledge and are true and correct.”



~~{Name of affiant}~~ EJ JT
Erin Jones

Sworn to and subscribed before me by Erin Jones on Nov. 1st, 2021.





Notary Public in and for
the State of Texas
My commission expires: 1-16-23

CERTIFICATE OF SERVICE

I hereby certify that on the 1st day November 2021, I electronically served the foregoing First Amended Preliminary Injunction Motion through the E-filing system to the following participant:

Mr. Joshua D. Ross
Cantey Hanger L.L.P.
600 W. 6th St. Ste. 300
Fort Worth, Texas 76102

Hand Filed w/
Court on
10/26/2021
@ 7:55 a.m.
(P)

CAUSE NO. 323 · 117290 21

ERIN JONES, INDIVIDUALLY AND AS
LEGAL REPRESENTATIVE AND
NEXT FRIEND OF JASON JONES
v.

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§
§
§

_____ JUDICIAL DISTRICT

TEXAS HEALTH HUGULEY HOSPITAL, FT.
WORTH, SOUTH
DR. JASON A. SIEDEN
JOHN DOES #1-5, JANE ROES #1-5
DEFENDANTS.

§
§

TARRANT COUNTY, TEXAS

THOMAS A. WILDER
DISTRICT CLERK

2021 OCT 26 PM 12:14

FILED
TARRANT COUNTY

ORDER GRANTING PLAINTIFF'S APPLICATION FOR TEMPORARY RESTRAINING ORDER

ON THIS DAY came on to be considered the Application for Temporary Restraining Order and Injunction (the "Application") filed by ("Plaintiff") on an *ex parte* and emergency basis. After considering the Application, which is verified, including the Exhibit A attached thereto, and the argument of counsel, the Court has resolved to render this Order. It is therefore

FOUND that there is some evidence to support each of the following findings of fact: (1) Dr. Jason A. Sieden, Texas Health Huguley Hospital, Ft. Worth South and its doctors, nurses, and other medical professionals, John Does #1-5 (collectively, the "Does") and Jane Roes #1-5 (collectively, the "Roes") (collectively, "Defendants") have refused to treat Plaintiff Jason Jones with the drug known as Ivermectin; (2) Plaintiff was admitted as a patient to Texas Health Huguley Hospital, Ft. Worth South, owned and operated by Texas Health Resources and AdventHealth., Jason Jones was diagnosed with COVID-19; (3) Dr Sieden and the Does and Roes are the medical professionals that have rendered and continue to render medical treatment to Plaintiff while he has been hospitalized at Texas Huguley Hospital, Ft. Worth South;

(4) Plaintiff has not responded well to his current medical treatment and his condition has deteriorated substantially to the point where Plaintiff is at medically substantial risk of death; (5)

Plaintiff has been prescribed Ivermectin, and a true and correct copy of this

prescription is attached hereto as Exhibit 1; (6) notwithstanding, Defendants have refused to treat Plaintiff with the drug commonly known as Ivermectin because, upon information and belief, Ivermectin has not yet received official approval of regulatory agencies for the treatment of COVID-19; (7) Defendants have declined to do so because, upon information and belief, Defendants are concerned with their potential liability for treatment of Plaintiff with Ivermectin for COVID-19 in the absence of official approval of regulatory agencies for the treatment of COVID-19; (8) considering his deteriorating condition, Plaintiff desires for Defendants to treat him with Ivermectin, notwithstanding the current absence of official approval of regulatory agencies for the treatment of COVID-19; (9) Plaintiff, Erin Jones, as legal representative and next Friend of Jason Jones, stipulates that she shall release Defendants, and any and all other persons, from any and all liability for any damages and injuries, up to and including death, that may be proximately caused by the administration of his treatment with Ivermectin in accordance with his prescription that is attached hereto as Exhibit A (1) ;it clearly appears from the specific facts shown in the Application, which is verified, that immediate and irreparable injury will result to Plaintiff before notice can be served and a hearing had thereon; (11) the injury sought to be avoided includes death, which is irreparable by definition; and (12) the Application is being granted without notice to Defendants because death could potentially result if the granting of the Application is delayed to allow notice to Defendants. It is further

ORDERED that the Application is **GRANTED**. It is further

ORDERED that, for a period of 14 days from the signing of this Order, under penalty of contempt, Defendants, along with their agents, servants, employees, and attorneys, and all persons in active concert or participation with any of the foregoing who receive actual notice of the injunction by personal service or otherwise, are compelled to immediately administer Jason

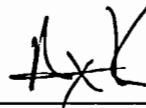
Jones Ivermectin in accordance with the prescription attached hereto as Exhibit A as part of his medical treatment. It is further

¢ 25⁰⁰ (AW)

ORDERED that Plaintiff shall post a bond in the amount of \$1.00, which Plaintiff can pay at the time Plaintiff files the petition for this cause and/or the application with the Clerk of the Court and/or other instrument through the Texas e-File system. It is further

ORDERED that a hearing on a temporary injunction for this temporary restraining order shall be held at 4 o'clock p.m. on the 6th day of November, 2021, in the courtroom for the 323rd Judicial District Court in Tarrant County, Texas, unless notice is given before this date and time that this matter will be heard elsewhere.

RENDERED and SIGNED at 7 54 o'clock am on this 25th day of October, 2021.

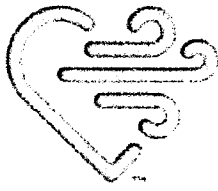


The Hon. Alex Kim, Judge Presiding

APPROVED AS TO FORM & SUBSTANCE

Jerri Lynn Ward, J.D.

Attorney for Plaintiffs



BreatheMD
OPTIMAL AIRWAY HEALTH.

Prescription Form

Date: 10/22/21. Patient: Jason Jones DOB 12/4/1972

Ivermectin 3mg. Give 21 tablets per NGT qD, Dispense 210 tablets, Refill:2

Calcitriol 0.25mcg per NGT QD, Dispense: #30, Refill:2

Melatonin 12mg per NGT QHS, Dispense: #30, Refill:2

Fluvoxamine 50mg per NGT BID, Dispense #60, Refill:2

Cyproheptadine 8mg per NGT TID, Dispense #90, Refill2

Zinc 100mg per NGT QD, Dispense #30, Refill: 2

Famotidine 80mg per NGT BID, Dispense #60, Refill 2

Avorstatin 80mg per NGT QD, Dispense #30, Refill 2

Flutamide 250mg per NGT TID, Dispense #90, Refill 2

Spironolactone 100mg per NGT BID, Dispense #60, Refill 2

Finasteride 10mg per NGT QD, Dispense #30, Refill 2

Nitazoxanide 500mg per NGT BID, Dispense #60, Refill 2

IV Infusions Recommended:

- Methylprednisolone 80mg IV bolus then 40mg IV BID
- Vitamin C 25mg IV BID x 3 days
- Thiamine 200mg IV BID
- Therapeutic Plasma Exchange

Prescriber: 3600 Kirby Dr. Suite F
Mary Talley Bowden, MD Houston, TX 77098
Tx license: K9770 713-492-2340
NPI: 1699858282

713-206-8988 (ccu)

EXHIBIT 16

CAUSE NO. 342-329996-21

ERIN JONES, INDIVIDUALLY AND AS
LEGAL REPRESENTATIVE AND
NEXT FRIEND OF JASON JONES

Plaintiff,

v.

TEXAS HEALTH HUGULEY HOSPITAL,
FT. WORTH SOUTH, DR. JASON SEIDEN
JOHN DOES #1-5, JANE ROES #1-5

Defendants.

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IN THE DISTRICT COURT

OF TARRANT COUNTY, TEXAS

342ND JUDICIAL DISTRICT

DEFENDANTS’ NOTICE OF ACCELERATED INTERLOCUTORY APPEAL

Notice is hereby given that Defendants, Appellants, Texas Health Huguley, Inc. d/b/a Texas Health Huguley Hospital Fort Worth South (“Huguley Hospital”), incorrectly named in the style as Texas Health Huguley Hospital, Ft. Worth South, Jason Seiden, M.D., John Does #1-5, and Jane Roes #1-5, Defendants in the above-styled and numbered Cause, desire to appeal the 348th District Court’s November 8, 2021 Order granting Plaintiff’s Temporary Injunction, attached as Exhibit “A.”

Huguley Hospital appeals to the Second District Court of Appeals, Fort Worth, Texas.

Plaintiffs, Appellees, are Erin Jones, Individually, and as Legal Representative and Next Friend of Jason Jones.

Huguley Hospital has previously filed a petition for writ of mandamus in this case, which was withdrawn, but which was assigned Cause No. 02-21-00348-CV.

The appeal of this case is an accelerated appeal.

Respectfully submitted,

By: /s/ Joshua D. Ross

Joshua D. Ross

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CANTEY HANGER LLP

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Fort Worth, Texas 76102

(817) 877-2800 Telephone

(817) 877-2807 Facsimile

ATTORNEYS FOR DEFENDANTS

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was served on counsel for the Plaintiff on the 8th day of November, 2021 via e-service.

/s/ Joshua D. Ross

Joshua D. Ross

EXHIBIT A

CAUSE NO: 342-329996-21

ERIN JONES, Individually and as Legal Representative and Next Friend of Jason Jones	§	
	§	
	§	IN THE DISTRICT COURT OF
Plaintiff,	§	
v.	§	TARRANT COUNTY, TEXAS
	§	
TEXAS HEALTH HUGULEY, INC., d/b/a TEXAS HEALTH HUGULEY HOSPITAL FT. WORTH SOUTH; DR. JASON A. SIEDEN; JOHN DOES #1-5; JANE ROES #1-5;	§	
	§	342nd JUDICIAL DISTRICT
Defendants.	§	

TEMPORARY INJUNCTION ORDER & ORDER SETTING TRIAL

The Court having considered Plaintiffs’ Erin Jones, Individually and as Legal Representative and Next Friend of Jason Jones, Petition and Motion for Temporary Injunction, and upon reviewing all pleadings, affidavits, exhibits, arguments of the parties, the testimony of witnesses and hearing evidence from both parties, all Counsel of record being present, the Court hereby makes the following findings of fact and conclusions of law.

FINDINGS OF FACT

1. Plaintiff, Jason Jones, is a patient at Texas Health Huguley Hospital. The Petition seeks Emergency Medical Declaratory Judgment and Emergency Injunctive Relief against Defendants to administer the drug Ivermectin to Jason Jones.
2. Jason Jones was admitted to Defendant Hospital on September 28, 2021 and diagnosed with COVID-19.
3. On October 7, 2021, Jason Jones was sedated, intubated and placed on a ventilator.
4. Since October 7, 2021, Jason Jones has been on a ventilator in a medically induced coma,

continuing to decline.

5. Defendants have treated Jason Jones with their Covid-19 protocol and refuse to deviate from their protocol and administer an alternative medical treatment with the use of the drug ivermectin, despite the fact that their Covid-19 protocol has not improved his condition.

6. Dr. Mary Talley Bowden, M.D. has prescribed ivermectin for Jason Jones. Dr. Bowden is a Board-Certified Physician duly licensed to practice medicine under the laws of the State of Texas.

7. Dr. Bowden testified that she has successfully treated hundreds of covid patients with ivermectin and that Jason Jones would have a good chance of survival if treated with ivermectin. She further testified that ivermectin is safe and effective for covid patients, and that off-label use of approved FDA drugs, including ivermectin, is within the standard of care.

8. Plaintiff, Erin Jones, in her capacity as surrogate decision-maker, has consented to Dr. Bowden treating her husband, Jason Jones, with ivermectin.

9. Plaintiff, Erin Jones, testified that her husband, Jason Jones, requested to be treated with ivermectin prior to being placed on a ventilator.

10. Plaintiff, Erie Jones, testified that she is willing to execute an informed consent as well as a release and waiver, to the Defendant in regard to Jason Jones' treatment with ivermectin.

CONCLUSIONS OF LAW

1. Under Texas law, to determine whether the remedy of injunctive relief is warranted, Courts consider several factors.

2. There is sufficient evidence that Jason Jones' medical condition and health continues to decline as he has been on a ventilator, in a medically induced coma for 30 days, and imminent harm and irreparable injury in this matter will include death which by its nature is an irreparable loss.

3. Plaintiff has no adequate remedy at law, and Plaintiff has demonstrated a likelihood of success and a balance of equities favors the granting of injunctive relief in order to preserve the life of Jason Jones.

4. The Court takes judicial notice that the Centers for Medicare and Medicaid Services in 2020 waived requirements under 42 CFR §482.22(a)(1)-(4) for Texas Hospitals regarding the credentialing and privileging process due to covid-19. Further, the Centers for Medicare and Medicaid Services reaffirmed said waiver in May, 2021, allowing new physicians to be able to practice in a hospital before being credentialed and granted privileges. Pursuant to said waiver, no Federal or State would be violated by allowing Dr. Bowden to administer ivermectin to Jason Jones.

5. Furthermore, no Federal or State law would be violated as Medicaid and/or Medicare does not apply to Jason Jones. Jason Jones' private medical insurance is covering his hospitalization and medical costs, and no claim for reimbursement would be made to Texas or the Federal Government.

6. The Court takes judicial notice of the Texas Health and Safety Code, Chapter 489 "Access to Investigational Treatments for Patients with Terminal Illnesses". This law confirms the right of terminal patients to use an investigational drug, such as ivermectin.

7. Texas Health and Safety Code §489.052 further incorporates the doctrine of informed consent; in this case, Erin Jones, may provide informed consent on the patient's behalf.

8. Texas Health and Safety Code §489.054 and §489.151 further grants immunity to the hospital, physicians and providers "for any harm done to the patient resulting from the investigation drug".

9. The Court takes judicial notice of the Texas Health and Safety Code, Chapter 313 "Consent to Medical Treatment Act". §313.002 allows for a Surrogate decision-maker to

consent to medical treatment on behalf of an incapacitated person. §313.004(1) specifically states “the patient’s spouse” may consent to medical treatment on behalf of the patient; in this case, Erin Jones, may consent to medical treatment on behalf of her husband Jason Jones.

10. Further, the Texas Health and Safety Code §313.007 limits liability for hospitals, physicians and staff for the medical treatment consented to under this chapter.

11. The Court takes judicial notice of the Texas Civil Practice & Remedies Code, Chapter 74, §155 “Liability of Physicians, Health Care Providers, and First Responders during Pandemic”. Effective June 14, 2021, the Texas Legislature has conveyed immunity to the hospitals and physicians treating patients suffering from a pandemic disease.

12. Pursuant to Texas Civil Practice & Remedies Code, §74.155, Defendants hereunder are “not liable for an injury, or death arising from care, treatment, or failure to provide care or treatment relating to or impacted by a pandemic disease”.

Having found that Plaintiff met its burden for a Preliminary Injunction,

IT IS HEREBY:

ORDERED, that pending further order of this Court, the Defendants, their agents, and assigns, and any third parties acting on its behalf, upon receipt of this Order, shall grant Dr. Mary Talley Bowden, M.D. and/or her nurse working under her authority, temporary emergency privileges, which shall not be unreasonably delayed or denied, solely to administer Ivermectin to Jason Jones, pursuant to the order and the attached Prescription of Dr. Bowden; and it is further

ORDERED, that Dr. Bowden and/or her nurse working under her authority, is limited solely to the ivermectin portion of her prescription, which shall consist of crushing the ivermectin pills and flushing them into the feeding tube of Jason Jones; and it is further

ORDERED, that Dr. Bowden and/or her nurse working under her authority, is granted access in the ICU at Texas Health Huguley Hospital to Jason Jones for the sole purpose of

administering ivermectin to Jason Jones, and shall further provide notice to the Hospital of when she shall be administering the ivermectin to Jason Jones; and it is further

ORDERED, that Defendants, Texas Health Huguley, Inc., d/b/a Texas Health Huguley Hospital Ft. Worth South, and Dr. Jason A. Sieden, are not required to administer ivermectin to Jason Jones nor are they required to provide the medication for Dr. Bowden; and it is further

ORDERED, upon the completion of the administration of ivermectin to Jason Jones, Dr. Bowden and/or her nurse working under her authority, shall leave the hospital and that all other matters concerning Jason Jones will be under the control and authority of the Defendants; and it is further

ORDERED, that Dr. Bowden shall be available to consult with Jason Jones' hospital physicians regarding treatment of any adverse reaction to the ivermectin; and it is further

ORDERED, that in the event Jason Jones develops a serious adverse reaction to the ivermectin, the Hospital by and through their Physicians, can make the decision to discontinue the use of ivermectin;

At the hearing, Plaintiff agreed, on the record, to release Defendants, Defendants' employees, agents, officers, physicians, nurses, executors, assigns, or any third party acting on Defendants' behalf of any and all liability related to Mr. Jason Jones and the administration of ivermectin by Dr. Bowden:

Plaintiff's counsel drafted a proposed release, releasing Defendants, Defendants' employees, agents, officers, physicians, nurses, executors, assigns, or any third party acting on Defendants' behalf of any and all liability related to Mr. Jason Jones and the administration of ivermectin by Dr. Bowden. IT IS THEREFORE ORDERED that Plaintiff shall execute and deliver said release to Defendants prior to the administration of the ivermectin by Dr. Bowden.

ORDERED, that Plaintiff shall pay a cash bond in the amount of \$1.00 to the Clerk of the

Court by November 2, 2021, in connection with the above injunctive order; it is further

ORDERED, that all parties shall appear before the Honorable Kimberly L. Fitzpatrick on the 8 day of August, 2021 at 8:30 a.m. / ~~p.m.~~ for Trial and Hearing on a Permanent Injunction.

Signed on November 8, 2021.



Honorable Kimberly L. Fitzpatrick



BreatheMD
OPTIMAL AIRWAY HEALTH

Prescription Form

Date: 10/22/21. Patient: Jason Jones DOB 12/4/1972

Ivermectin 3mg. Give 21 tablets per NGT qD, Dispense 210 tablets, Refill:2

Calcitriol 0.25mcg per NGT QD, Dispense: #30, Refill:2

Melatonin 12mg per NGT QHS , Dispense: #30, Refill:2

Fluvoxamine 50mg per NGT BID, Dispense #60, Refill:2

Cyproheptadine 8mg per NGT TID, Dispense #90, Refill:2

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Avorstatin 80mg per NGT QD, Dispense #30, Refill 2

Flutamide 250mg per NGT TID, Dispense #90, Refill 2

Spirolactone 100mg per NGT BID, Dispense #60, Refill 2

Finasteride 10mg per NGT QD, Dispense #30, Refill 2

Nitazoxanide 500mg per NGT BID, Dispense #60, Refill 2

IV Infusions Recommended:

- Methylprednisolone 80mg IV bolus then 40mg IV BID
- Vitamin C 25mg IV BID x 3 days
- Thiamine 200mg IV BID
- Therapeutic Plasma Exchange

Prescriber: Mary Talley Bowden, MD
Tx license: K9770
NPI: 1699858282
3600 Kirby Dr. Suite F
Houston, TX 77098
713-492-2340

713-206-8988 (cell)