VOLUME XIV, ISSUE 1 WINTER 2020

Articles

American University
Washington
College of Law

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American University
Health Law & Policy Brief
Volume 14 • Issue 1 • Winter 2020

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2019-2020

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Letter from the Editors

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On behalf of the Editorial Board and Staff, we proudly present Volume 14, Issue 1 of the *Health Law & Policy Brief* (HLPB). HLPB is an online publication run entirely by law students at American University Washington College of Law (WCL). Since its formation in 2007, HLPB has published articles on a wide variety of topics in the areas of health law, food and drug law, and emerging health technologies. Such topics include health care privacy and data security, health care fraud and abuse, medical malpractice, bioethics and regulation of human subjects research, global health law, and others.

HLPB also maintains a blog on emerging health law issues that can be found on our website at www.healthlawpolicy.org. Furthermore, HLPB organizes an annual symposium on an emerging health law topic featuring distinguished speakers. The next symposium will take place in March 2020 and we are currently in the process of finalizing event details. More information will be available on our website and on our LinkedIn page at the end of January 2020.

We would like to thank the authors for their hard work and cooperation in writing, researching, and editing their work. We would also like to thank HLPB's article editors and staff members who worked diligently on this issue. Their efforts are greatly appreciated, and we are proud of their work.

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Sincerely,
Mika & Erin

Mika Sharpe
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* * *

Telemedicine: Benefits, Challenges, and Its Great Potential

*Samantha J. Achenbach**

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INTRODUCTION

Advancements in technology have changed how we do things in more ways than most of us could have ever imagined. For example, technology has allowed specialties within the practice of medicine to reach locations that were previously without access to those specialties, thus, also reaching a wider range of patients in need.[1] Through the use of telemedicine, doctors in all areas of medicine are able to treat patients regardless of the patient's geographical location.[2] Additionally, telemedicine gives patients more freedom to decide when and how to see their physicians, and allows them to avoid traveling great distances to do so.[3] This helps patients take control and make better informed choices regarding their health.

While the terms "telemedicine" and "telehealth" are often used interchangeably, telemedicine is defined as the remote delivery of healthcare services and clinical information using telecommunications technology, and includes a wide variety of clinical services through Internet, wireless, satellite, and telephone media.[4] Telehealth, on the other hand, is used to describe diagnosis and management, education, and other fields of health care.[5] It is important to note that each state tends to have its own definitions of telehealth and telemedicine.[6] For the purpose of this paper, I will be using the term telemedicine.

To support the advancement of telemedicine, rural and urban areas must work together and continually share information in order to educate physicians, clarify laws for attorneys, and strengthen the overall healthcare delivery system. This article takes a brief look at the history of telemedicine in both rural and urban areas and explores the challenges that come with each.[7] It explains how telemedicine affects the physician-patient relationship and the issues surrounding the traditional definition of standard of care in the medical field.[8] Further, it explains the benefits of cross-over licensing that would allow physicians to practice across state lines.[9] It concludes with a review of potential ways to improve telemedicine in both rural and urban areas, including increasing access to affordable broadband and implementing interstate licensure.[10]

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[1] *The Ultimate Telemedicine Guide: What is Telemedicine?*, eVisit (May 25, 2018), https://evisit.com/resources/what-is-telemedicine/#2 [hereinafter *The Ultimate Telemedicine Guide*].

[2] *Id*.

[3] *Id*.

[4] *Id.*

[5] *About Telehealth*, Ctr. for Connected Health Pol'y, https://www.cchpca.org/about/about-telehealth (last visited Nov. 8. 2019) [hereinafter *About Telehealth*].

[6] *Id.*

[7] *Infra* Part I.

[8] *Infra* Part III.

[9] *Infra* Part III.C.

[10] *Infra* Part IV.

I. Background

The first electronic medical record transfer occurred in the 1940's with the transmission of radiology images between two towns that were twenty-four miles apart.[11] This subsequently became a widespread practice, and in 1959 the University of Nebraska began using video communication in the medical field.[12] In the late 1960's, closed-circuit television and point-to-point leased lines were first used for communication, and this practice was considered telemedicine.[13] Further, the National Aeronautics and Space Administration (NASA) was closely involved with the development of early telemedicine systems.[14] NASA needed a way to monitor the astronauts while they were in space, which led to the development of the Integrated Medical and Behavioral Laboratories and Measurement Systems (IMBLMS) program in 1964.[15] This new technology allowed NASA to monitor astronauts during missions, and aided in emergencies when it was impossible for them to quickly return to earth.[16] The data conveyed back to the base helped in guiding medical treatment by the non-physician astronauts on the spacecraft.[17]

In 1967, the city of Boston set up a medical station at Logan International Airport that connected to Massachusetts General Hospital which treated patients with a "two-way microwave audio/video link."[18] Subsequently, in 1971, telemedicine was tested in Alaska through satellite communication.[19] Next, in a 1977 clinical trial, critical care patients with limited access to specialists were effectively treated through telemedicine.[20] In another study, from 1999 to 2001, two Intensive Care Units (ICU) of a large tertiary care hospital used telemedicine to supplement patient treatment.[21] The study showed improvements in "clinical outcomes" and "hospital financial performance" due to the supplemental use of telemedicine.[22]

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[11] *See* Kiley Aycock, *Just a Phone Call Away: Should Texas Require Insurance Providers to Cover Telehealth Services?*, 19 Tex. Tech Admin. L.J. 347, 347 (2018) (discussing the first electronic medical record transfer); *see also* Vanessa Daves, *The History of Telemedicine*, Iris Telehealth (Feb. 2, 2017), https://iristelehealth.com/blog/the-history-of-telemedicine (discussing the development of telemedicine).

[12] Daves, *supra* note 11.

[13] *Id.;* CJ Rhoads, Telehealth in Rural Hospitals: Lessons Learned from Pennsylvania 77 (2016).

[14] Annalise DeJesus and M. Kamran Athar, *Commentary: Tele-ICU Development and Application*, 12 JHN J. 24, 24 (2017) (explaining that the Integrated Medical and Behavioral Laboratories and Measurement Systems allowed for better monitoring of astronauts during critical times).

[15] *Id.*

[16] *Id.*

[17] *Id.*

[18] Daves, *supra* note 11.

[19] *Id.*

[20] *Id.*

[21] DeJesus and Athar, *supra* note 14, at 25.

[22] *Id.*

Through telemedicine, a patient can interact with a provider over his smartphone, and hospitals that lack certain specialists can facilitate specialist-patient visits through the use of "telemedicine robots."[23] Roughly one thousand hospitals in the United States use such technology to expand access to specialists;[24] the "robots" show a physician's face on a screen, allow the patient and physician to interact with each other, and give patients access to specialists in areas such as neurology, cardiology, neonatology, pediatrics, and even mental health.[25] Furthermore, CVS Pharmacy collaborates with three leading telemedicine technology providers, American Well, Doctor on Demand, and Teledoc, to implement telemedicine services within their CVS Minute Clinics nationwide.[26]

While advancements in technology have allowed for the recent expansion of telemedicine, its uses, benefits, and pitfalls differ among states. Laws governing and defining telemedicine vary and are not enforced uniformly.[27] Additionally, telemedicine may be used differently in a rural location than in an urban setting.[28] Exploring and learning from such differences will help strengthen the implementation and continued growth of telemedicine throughout the country and ultimately help to improve patient care overall.

A. Telemedicine in Rural Areas

Generally, people in rural areas tend to have more restricted access to healthcare resources compared to those living in urban areas.[29] For patients living in rural areas, telemedicine offers an opportunity to access healthcare services and other resources that would otherwise be unavailable to them.[30] Since rural patients would likely need

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[23] Terence Chea, *Medical Specialists Are Increasingly 'Beamed' Into Remote Hospitals*, Bus. Insider (Nov. 18, 2013, 5:28 AM), https://www.businessinsider.com/robots-let-doctors-beam-into-remote-hospitals-2013-11.

[24] *Id.*

[25] *Id.*

[26] Laura E.A. Wibberley, *Telemedicine in Illinois: Untangling the Complex Legal Threads*, 50 J. Marshall L. Rev. 885, 891 (2017); *see also CVS Health to Partner with Direct-to-Consumer Telehealth Providers to Increase Access to Physician Care*, CVS Health (Aug. 26, 2015), https://cvshealth.com/newsroom/press-releases/cvs-health-partner-direct-consumer-telehealth-providers-increase-access (explaining that CVS is collaborating with American Well, Doctor on Demand, and Teladoc to connect telehealth providers, retail pharmacy, and retail clinic providers to improve patient care).

[27] *About Telehealth*, *supra* note 5; *see e.g.*, *State Telehealth Laws and Reimbursement Policies*, Ctr. For Connected Health Pol'y, https://www.cchpca.org/telehealth-policy/state-telehealth-laws-and-reimbursement-policies-report?utm_source=Telehealth+Enthusiasts&utm_campaign=a64963125e-EMAIL_CAMPAIGN_2019_05_29_05_05&utm_medium=email&utm_term=0_ae00b0e89a-a64963125e-353236391 (discussing telehealth-related regulations for all fifty states and noting that telehealth policy varies from state-to-state). For example, some form of reimbursement is provided in all fifty states and Washington D.C. for live video telemedicine visits. *Id.* Further, there are only fourteen states that provide reimbursement for "store-and-forward" telemedicine visits, which allow for secure transmission of medical information. *Id.*; Wibberley, *supra* note 26, at 887 n.14.

[28] *The Ultimate Telemedicine Guide, supra* note 1.

[29] Candi Helseth, *Telemedicine Reaches Beyond Clinic Walls,* Rural Health Info. Hub (Aug. 17, 2011), https://www.ruralhealthinfo.org/rural-monitor/telemedicine-reaches-beyond-clinic-walls.

[30] *Id.*

to travel great distances to get adequate medical care, they are more likely to forego regular check-ups and instead wait until their condition worsens to seek medical care.[31] Furthermore, telemedicine can connect physicians in rural areas with specialists in urban areas by facilitating concurrent examinations and consultations, which may increase the rural physicians' medical knowledge.[32]

Since 2010, a lack of medical personnel in rural areas has led to closures of over eighty hospitals across the country, and many more continue to struggle.[33] For example, Idaho, Wyoming, and Montana each currently have less than two thousand specialists in total, and fewer than eleven specialists per ten thousand people, which makes it difficult for patients to receive specialized treatment.[34] Consequently, many patients living in these states need to travel great distances to receive specialized treatment, which adds costs that patients living in urban areas do not incur.[35]

This article argues that priority should be placed on the use of telemedicine to preserve rural hospitals and to improve access to quality healthcare to patients in such areas.[36] This next section will discuss the different ways in which states have implemented telemedicine and the various difficulties involved in the effort to deliver quality healthcare to rural areas.

i. Maine

Telemedicine functions differently in various rural areas across the country as each area learns how telemedicine can benefit its residents specifically.[37] Maine uses telemedicine networks, the majority of which are managed by Maine Telemedicine Services and include over thirty community health centers along with home care services.[38] Additionally, Maine utilizes a boat as a telemedicine clinic to reach patients living on islands off the coast of Maine.[39] Patients use the boat for both primary care treatment and specialist appointments.[40] Maine Telemedicine Services benefits patients by providing them with quality healthcare and ensuring that physicians are properly trained to

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[31] Dominique LeVert, *Telemedicine: Revamping Quality Healthcare in Rural America*, 19 Annals Health L. Advance Directive 215, 216 (2010).

[32] *Id.*

[33] Michael W. King, *Telemedicine: Game Changer, or Costly Gimmick*, 95 Denv. L. Rev. 289, 316 (2018).

[34] *Id*. at 318.

[35] *See id.* at 318–19 (noting that without the expansion of telemedicine, some must travel long distances for "many key aspects of their health care needs").

[36] *Id.* at 319.

[37] Roger A. Rosenblatt & L Gary Hart, *Physicians and rural America,* 173 W. J. of Med. 348, 351 (2000).

[38] Michael A. Edwards, & Arvind C. Patel, *Telemedicine in the State of Maine: A Model for Growth Driven by Rural Needs*, 9 Telemedicine J. & E-Health 25, 25, 26 (2003) (discussing Maine's two interlinked telemedicine networks, which consist of rural health clinics, mental health agencies, Indian health centers, and other social service and state agencies).

[39] Helseth, *supra* note 30.

[40] *Id.*

provide such care.[41] Specifically, Maine Telemedicine Services provides "telemedicine demonstrations for providers, training of local site coordinators, protocol development, scheduling, quality assurance, and continued medical education planning."[42]

ii. Texas

In 2009, twenty-five counties in Texas were entirely without physicians, and the areas with the lowest ratio of providers were West Texas, South Texas, and the Panhandle.[43] Accordingly, patients often depend on Texas Emergency Medical Service (EMS) to transport them to the nearest hospital; however, in some cases it could take up to ninety minutes to reach the nearest hospital, just to find out that the facility is not equipped to treat the patient's condition.[44] To address such issues, Texas University Health Sciences Center, the Commission on State Emergency Communications, and swyMed have partnered to implement telemedicine to facilitate a connection between EMS providers and trauma centers which allows trauma surgeons to virtually assess patients in ambulances and direct treatment.[45] This helps ensure that patients are transported to the correct facility and that treatment may begin immediately upon their arrival.[46] In general, the implementation of telemedicine has brought Texas tremendous benefits, some of which include improved access to specialists, increased patient satisfaction, improved clinical outcomes, reduction in emergency room utilization, and financial relief.[47]

iii. North Carolina

North Carolina has two telemedicine programs and a telepsychiatry program, each with its own procedures.[48] The East Carolina University Telemedicine Center opened in 1992, and operates in three areas: clinical transactions, education, and provider consultations.[49] Within these areas, the Center provides distance-learning for physicians, consultations for those interested in practicing telemedicine, and scheduled, urgent, and emergent services which include patient assessments, diagnoses, and follow-ups.[50] Additional treatment areas include dermatology, cardiology, pediatrics, psychiatry, and rehabilitation medicine.[51]

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41 *Id.*

42 Edwards & Patel, *supra* note 38, at 37.

43 Aycock, *supra* note 11, at 350.

44 *Id.* at 351. *See also Professional Emergency Care*, Tex. Emergency Med. Serv., https://mytexasems.org (explaining that EMS provides skilled "pre-hospital care and professional emergency medical transportation").

45 Aycock, *supra* note 11, at 351.

46 *Id.*

47 *Id.* at 350.

48 Jennifer M. Little, *Into the Future: The Statutory Implications of North Carolina's Telepsychiatry Program*, 93 N.C. L. Rev. 863, 864, 872 (2015).

49 *Id.* at 873.

50 *Id.*

51 *Id.*

In 2010, the North Carolina Telepsychiatry Program was established with the primary objective of "mak[ing] psychiatric assessments readily available for all patients presenting to the emergency department with behavioral health-related issues."[52] Over a secure network, a consultant physician can make a diagnosis and treatment recommendation to the physician treating the patient, thus granting access to mental health care to those to whom such treatment would otherwise be unavailable.[53] The success of the aforementioned telemedicine programs resulted in the creation of the North Carolina Statewide Telepsychiatry Program, which has continued to grow since its origination in 2014.[54]

iv. North Dakota

Rural communities of North Dakota, and nationwide, face challenges stemming from the lack of available mental health treatment providers.[55] The University of North Dakota is attempting to address this issue through its residency training program in psychiatry that uses telemedicine to extend psychiatric services to rural areas.[56] The residents in the program are mainly stationed in Fargo, North Dakota, and use telemedicine to reach and serve rural areas of the state.[57] The program teaches them how to utilize technology to reach out to healthcare facilities in rural areas which lack psychiatric treatment services on-site.[58] In addition to having weekly visits with patients using telemedicine technology, the residents make monthly trips to the rural communities to connect with patients face-to-face.[59]

v. South Dakota

A facility in South Dakota works entirely by webcam and contains no inpatient beds.[60] Since its opening, the admissions to outside area hospitals have decreased by eighteen percent.[61] Additionally, South Dakota's regional health system, Avera Health, has implemented a program which aims to increase the use of telemedicine for emergency department patients with sepsis.[62] Through this program, a board-certified emergency

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[52] *Id.* at 874.

[53] *Id.*

[54] *Id.*

[55] *See* Jan Orvik, *Telepsychiatry – Making the Connection*, UND Today (Mar. 22, 2018), http://blogs.und.edu/und-today/2018/05/telepsychiatry-making-the-connection (explaining the desperate need of psychiatrists to help combat addition and psychiatric problems in North Dakota and stating that many towns in the state do not have psychiatric services on site).

[56] *Id.*

[57] *Id.*

[58] *Id.*

[59] *Id.*

[60] Rhoads, *supra* note 13, at 87.

[61] *Id.*

[62] Nicholas M. Mohr et al., *Improving Access to High Quality Sepsis Care in a South Dakota Emergency Telemedicine Network,* Rural Telehealth Res. Ctr. 2 (Aug. 2017), https://ruraltelehealth.org/briefs/2017-8-23_Access%20to%20Sepsis%20Care%20Emergency%20Telemedicine.pdf.

physician and an emergency department nurse can be connected twenty-four hours per day to assist patient treatment.[63] While the implementation of the program increased sepsis consultation rates, the rates remained fairly low overall.[64] Additionally, the project also helped shed light on other potential issues that contribute to the difficulty of treating sepsis in rural areas.[65] For example, the project revealed that the availability of screening laboratory tests, such as serum lactate measurement, is limited in rural areas, which affects how sepsis patients' risk levels are assessed.[66]

Since the program is still in the early stages of implementation, its effectiveness in treating sepsis patients in rural areas will have to be determined through continued evaluation.[67] The information that has been obtained thus far provides helpful insight into where improvement can be made with regard to how emergency physicians assess, diagnose, and treat patients with sepsis in rural hospitals. Future focus will be on "measuring the effect of telemedicine in influencing the process of care and clinical outcomes in rural patients with severe sepsis and septic shock," as well as "the impact of telemedicine utilization on clinical outcomes of sepsis treatment and on barriers to more widespread telemedicine adoption."[68]

vi. Wyoming

Wyoming has implemented video conferencing technology, Converged Management Application ("CMA"), which allows physicians to connect in a secure, HIPAA-compliant method and exchange information with ease.[69] Cardiologists, mental health specialists, and nursing homes across the state utilize CMA.[70] Specifically, the utilization of CMA in mental health areas has allowed providers in remote communities to share information more efficiently.[71]

Further, the Wyoming Department of Health awarded a contract to Ptolemy Data Systems, a data storage and managed services provider involved in connecting healthcare providers, to expand and reinforce its support of telemedicine services for "all state-funded healthcare facilities and public health offices."[72] Aside from CMA, the state implemented another program to utilize telemedicine through the state's Prison Health Services.[73] The process allows inmates to receive mental health treatment without requiring physicians to travel potentially very long distances to different prisons across

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[63] *Id.*

[64] *Id.*

[65] *Id.*

[66] *Id.*

[67] *Id.*

[68] *Id.*

[69] Jeff Rowe, *3 Ways Telemedicine is Helping Wyoming*, Healthcare IT News (May 9, 2013), https://www.healthcareitnews.com/news/3-ways-telemedicine-helping-wyoming.

[70] *Id.*

[71] *Id.*

[72] *Id.*

[73] *Id.*

the state.[74] According to Wyoming state officials, about 440 telemedicine appointments with prisoners take place every year.[75]

In addition to CMA and the Prison Health Services programs, Wyoming has also developed a Telepsychiatry Project.[76] The goal of the project is to bring medical and psychiatric care to isolated communities throughout the state.[77]

vii. Idaho

Idaho's largest health system, St. Luke's Health System, has opened a "virtual hospital" to provide access to top specialists and emergency providers to patients in rural areas.[78] The virtual hospital, called "St. Luke's Virtual Care," joins a number of other facilities that have consolidated telemedicine services into one platform, sometimes called a "hospital without beds."[79] Provided services include telestroke, telemedicine programs for behavioral health, telepharmacy services, and newborn critical care.[80] While this system is not intended to replace a patient's primary physician, it can help identify and treat healthcare problems before they become emergencies.[81]

Further, Idaho has also attempted to use telemedicine to provide safe abortion access to citizens in need, but this process has come with difficulties.[82] In 2017, Idaho's Senate voted to amend HB-250, the state telemedicine legislation which prohibited physicians from prescribing abortion-inducing drugs via telemedicine.[83] This amendment came after Idaho settled a case with Planned Parenthood over the state's Telehealth Access Act, as well as other legislation that was passed in 2015.[84] A group led by Planned Parenthood oversees the use of telemedicine to improve safe access to abortion services

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[74] Michael Ollove, *State Prisons Turn to Telemedicine to Improve Health and Save Money*, PEW (Jan. 21, 2016), https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2016/01/21/state-prisons-turn-to-telemedicine-to-improve.

[75] *Id.*

[76] Rowe, *supra* note 69.

[77] *Id.*

[78] Eric Wicklund, *New Telemedicine Center to Extend Connected Health Across Idaho*, mHealth Intelligence, (Aug. 28, 2018), https://mhealthintelligence.com/news/new-telemedicine-center-to-extend-connected-health-across-idaho; *About St. Luke's*, St. Luke's Online, https://www.stlukesonline.org/about-st-lukes.

[79] Wicklund, *supra* note 78.

[80] *Id.*; Bart M. Demaerschalk et al., *American Telemedicine Association: Telestroke Guidelines*, 23 Telemedicine J. & E-Health 376, 378 (2017) (explaining that "telestroke" refers to the use of interactive videoconferencing technology for the treatment of acute stroke patients).

[81] *Id*.

[82] Eric Wicklund, *Idaho Revises Anti-Abortion Telemedicine Legislation*, mHealth Intelligence (Mar. 22, 2015), https://mhealthintelligence.com/news/idaho-revises-anti-abortion-telemedicine-legislation.

[83] *Id.*; H.R. 250, 64th Leg., 1st Reg. Sess. (Idaho 2017).

[84] Telehealth Access Act, Idaho Code Ann. §§ 54–701–713 (West 2016) (clarifying how telemedicine in Idaho would be used and regulated); Wicklund, *supra* note 82.

in underserved parts of the country, especially where intimidation is used against those seeking an abortion.[85]

viii. Alaska

In 2016, the Governor of Alaska signed two bills that expanded the use of telemedicine throughout Alaska; the first, Senate Bill 74 (SB74), removed the requirement that the provider must be in-state to render treatment, while the second, House Bill 234 (HB234), required Alaska insurance plans to cover mental health treatment received remotely.[86] Additionally, the bills allow the use of telemedicine for speech pathology, counseling, family therapy, social work, and occupational therapy.[87] However, communities need to have secure Internet access for residents to receive the full benefits of telemedicine.[88] To achieve this, Alaska's major telecommunications companies have partnered with health-related nonprofits to expand broadband access to rural communities and provide telemedicine connections that are high-speed and secure.[89]

ix. Illinois

Through telemedicine, Illinois medical providers can consult with patients and licensed clinical staff simultaneously through two-way video, use "store and forward" functions to collect patient data and send to another physician for evaluation, and utilize "remote patient monitoring" for a patient located off-site.[90] The "store and forward" and "remote patient monitoring" functions each allow on-site physicians to collect patient information, such as laboratory values and heartbeat rhythm, which that physician can forward to an off-site colleague for consultation and concurrent patient treatment.[91] Additionally, some Illinois facilities offer "robot" services, which allow for the instant transmission of data to a specialist physician who can assess and treat potential stroke patients.[92]

Illinois also offers physician education and telemedicine training programs.[93] One such program is the Extension of Community Healthcare Outcomes ("ECHO") program, launched by the University of Chicago, which enables medical specialists to provide medical guidance and training to rural primary care physicians through live videoconferences.[94] As of 2014, more than 250 medical providers have been trained

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[85] Wicklund, *supra* note 82.

[86] Julie Stricker, *Telehealth Expands in Alaska*, Alaska Bus. J. 28, 28–29 (2016).

[87] *Id*. at 29.

[88] *See id*. (stating that state's "major telecommunications companies have been expanding broadband access across the state").

[89] *Id*.

[90] *See* Wibberley *supra* note 26, at 890–91 (discussing current telemedicine practices that medical professionals in Illinois may provide treatment through).

[91] *Id*.

[92] *Id*. at 890.

[93] *Id*. at 891.

[94] *Id*. "ECHO" stands for Extension for Community Healthcare Outcomes, and the project was first created by Sanjeev Arora, MD, a specialist at the University of New Mexico Health Sciences Center. *Project Echo*, Robert Wood Johnson Found., https://www.rwjf.org/en/how-we-work/grants-explorer/featured-programs/project-echo.html [hereinafter *Project Echo*]. The project was designed

through ECHO in a variety of areas, including the treatment of hepatitis C and resistant hypertension.[95] Training programs like ECHO ensure that physicians in rural areas stay informed of advancements in telemedicine and remain connected with their colleagues in urban areas.[96]

x. Georgia

In Georgia, where about fifty-two percent of physicians located in five areas throughout the state serve roughly thirty-eight percent of the state's population, telemedicine can be used to bridge the gap in healthcare.[97] A new federal grant will allow Augusta University to maintain a two-way teleconnection with emergency departments at Miller County Hospital, Crisp Regional Hospital, Emanuel Medical Center, Washington County Regional Medical Center, and Wills Memorial Hospital.[98] Additionally, ConnectWell is a program that combines telemedicine and remote monitoring practices by allowing diabetic patients in rural Central and South Georgia to monitor their diabetes from home and interact with their doctors using a tablet that is provided to them.[99]

Currently, Georgia offers telemedicine services in the areas of "maternal fetal medicine, HIV services and counseling, infectious disease care, psychiatry, pediatric emergency and critical care, hospital intensive care, acute stroke care, and general neurology."[100] Since 2009, the pediatric organization Children's Healthcare of Atlanta has used telemedicine to treat over seven thousand patients and supply over six thousand patients with eyeglasses.[101] However, while telemedicine has allowed Georgia to provide healthcare services to many of its rural citizens, the state's Public Health Commissioner recognizes that there are challenges associated with the continued growth of telemedicine, which include obtaining insurer reimbursement and increasing broadband capacity.[102]

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to facilitate collaboration between physicians in rural and urban areas using teleconferencing technology. *Id.* The Project is now operational in 46 states across the United States, and in 34 countries globally. *Id.*

95 Wibberley *supra* note 26, at 891.

96 *Project Echo*, *supra* note 94.

97 *See* Adelyn B. Boleman, Comment, *Georgia's Telemedicine Laws and Regulations: Protecting against Health Care Access*, 68 Mercer L. Rev. 489, 489 (2017) (explaining that advancements in technology could bridge such a gap where physicians are willing to utilize non-traditional means to treat patients and patients "simply [want] access to physicians").

98 Andy Miller, *Telemedicine Spreading in Georgia but There's Still Much Room to Grow*, Ga. Health News (Jan. 30, 2018), http://www.georgiahealthnews.com/2018/01/telemedicine-spreading-georgia-room-grow (discussing a new federal grant that is part of an effort to grow telemedicine in Georgia).

99 Linda S. Morris, *Program Will Allow Rural Diabetic Patients to Manage Disease by Internet*, Telegraph (Jan. 22, 2018), https://www.macon.com/news/business/article195952859.html.

100 Miller, *supra* note 98.

101 *Id*.

102 *Id.*

xi. Nebraska

In 2016, a group of approximately 450 primary care physicians and specialists affiliated with the Midwest Independent Physicians Practice Association began to use telemedicine to consult with their patients.[103] The participating physicians have access to a web-based program that allows for the secure exchange of information between the physician and the patient.[104] This prevents rural patients from needing to travel long distances to facilities located in more metropolitan areas of the state.[105] The goal of the program is to enable patients to obtain quality medical care despite the physician shortage.[106]

Like many states with large rural geographical areas, one-third of counties in Nebraska have no mental health care providers, and approximately eighty-eight out of its ninety-three counties are experiencing a shortage of such providers.[107] A 2018 study concluded that the use of telemedicine for mental health treatment is scarce; specifically, the study found that some mental health providers did not offer telemedicine services, some providers lacked training, and some are reluctant to offer telehealth services without the patient explicitly asking for the service.[108] Telemedicine advocates have expressed that their colleagues were hesitant to adopt the technology, that they lacked the necessary support staff to successfully implement the technology, and that some feared losing their patients to telemental health.[109] Nevertheless, Nebraska has pushed forward with telemedicine programs, and patients are adapting to the technology; nearly all who used telemedicine for mental health services chose to continue treatment.[110]

xii. Washington

Roughly 1.2 million residents of Washington state live in areas with a shortage of local access to primary care.[111] This shortage is estimated to worsen over the next ten to fifteen years, and it is estimated that the state will eventually face a shortage of up to four thousand physicians and twenty-four thousand registered nurses.[112] While outpatient clinics throughout Washington possess telemedicine capabilities, the medical provider

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103 Rick Ruggles, *Telemedicine Service Expanding in Nebraska to Spare Rural Patients Long Trips*, Omaha World Herald (May 17, 2016), https://www.omaha.com/livewellnebraska/health/telemedicine-service-expanding-in-nebraska-to-spare-rural-patients-long/article_ae38d6c9-6414-53cc-aaf3-9468f34edb53.html.

104 *Id.*

105 *Id.*

106 *Id.* (explaining that the program is meant to be used by patients who live inconveniently far away from the specialists they need to see in person).

107 Riley Johnson, *Is Telehealth the Answer to Nebraska's Mental Health Care Shortage?*, Lincoln J. Star (July 3, 2018), https://journalstar.com/news/local/is-telehealth-the-answer-to-nebraska-s-mental-health-care/article_35a5e37e-e1bd-51ee-9ac6-b3ceb6bca4b3.html.

108 *Id.* (describing a University of Michigan survey that found only half of 42 responding Nebraska mental health care providers use telehealth).

109 *Id.*

110 *Id.*

111 Roger Stark, *The Benefits of Telemedicine in Washington State*, Wash. Pol'y Ctr., 1 (2017), https://www.washingtonpolicy.org/library/doclib/Stark-Telemedicine-in-WA-11.20.2017.pdf.

112 *Id.* at 2.

shortage will likely be worse in rural areas.[113] Nevertheless, Washington has taken steps to combat this issue; in May of 2017 the state signed on to the Interstate Medical Licensure Compact, which provides an expedited process for out-of-state doctors to treat patients throughout Washington.[114]

Medicine Telehealth, the University of Washington School of Medicine's system which encompasses fourteen programs in over twenty specialties across five states, is evidence of the state's commitment to servicing rural and underserved patients.[115] This program gives patients access to nationally and internationally recognized physicians through reliable and secure communication systems.[116] The university's telehealth technologies span from teleconferencing to the storage and forwarding of health data.[117]

B. Telemedicine in Urban Areas

Urban areas have the advantage of ongoing telemedicine advancements, educational opportunities, and developments in technology that may not reach more rural areas as quickly. For example, at Thomas Jefferson University Hospital in Philadelphia, there is a one-year Telehealth Leadership Fellowship that gives fellows the opportunity to graduate as both a telehealth researcher and a program leader.[118] The program gives graduates a solid background in telehealth marketing, finance, health informatics,[119] and in legal and ethical concerns surrounding these practices.[120] During the 2016–2017 academic year, about eighty-four medical schools in the United States offered telemedicine as either an elective or a required course.[121]

Another benefit of providing telemedicine in urban areas stems from the abundance of physicians practicing in such areas. Students from urban areas are overrepresented in medical schools; thus, these students are more likely to choose to live and practice medicine in the urban areas that they are familiar with.[122] The tendency of physicians to

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113 *Id.*

114 *Id.*

115 *Consultations*, Univ. of Wash. Med., https://www.uwmedicine.org/provider-resource/consultations (last visited Nov. 8, 2018).

116 *Id.*

117 *Id.*

118 *Telehealth Leadership Fellowship*, T. Jefferson U., https://www.jefferson.edu/university/jmc/departments/emergency_medicine/education/fellowships/telehealth_leadership.html (last visited Nov. 8, 2019) (explaining that the program allows fellows to develop the research, knowledge, and skills necessary to contribute to telehealth, as well as the leadership skills needed to successfully implement telehealth solutions).

119 *See* Tiffany C. Veinot et al., *Health Informatics and Health Equity: Improving Our Reach and Impact*, 26 J. Am. Med. Info. Ass'n. 689, 689 (2019) (describing health informatics studies as "the use of information technology to improve human health").

120 *Telehealth Leadership Fellowship, supra* note 118.

121 Robin Warshaw, *From Bedside to Webside: Future Doctors Learn How to Practice Remotely*, Am. Ass'n Med. Coll. (Apr. 24, 2018), https://www.aamc.org/news-insights/bedside-webside-future-doctors-learn-how-practice-remotely.

122 Daniel McCarthy, *The Virtual Health Economy: Telemedicine and the Supply of Primary Care Physicians in Rural America*, 21 Am. J.L. & Med. 111, 120 (1995).

remain in urban areas is also reflective of the difference in income levels between rural and urban areas.[123] As technology and telemedicine continue to advance, doctors can remain in urban areas which have medical universities, greater earning potential, and more prestige, while retaining the ability to practice in underserved rural communities from afar.[124]

II. CHALLENGES ASSOCIATED WITH TELEMEDICINE

A. Challenges in Rural Areas

While telemedicine offers significant benefits to patients living in rural areas, such areas still face challenges. For example, Montana received a Network Planning Grant from the Health Resources and Services Administration (HRSA) in 2011 to begin offering primary care telemedicine services;[125] however, by April of 2015 the program was non-operational due to a staffing shortage.[126] While most physicians do not consider access to telemedicine when deciding where to practice medicine, the idea of being isolated in a rural area deters many from choosing to practice in such locations.[127] Montana may serve as an example to other states by highlighting the importance of adequate preparation before implementing a telemedicine program. To ensure success in implementation, states should properly educate providers, evaluate the cost of the program, and determine the patient volume.[128]

A lack of access to affordable broadband at adequate connection speeds is another roadblock to providing telemedicine in rural areas.[129] Many rural communities lack the resources to offer fiber optics at all, which frustrates providers and makes the quality of telehealth treatment lower than in urban areas.[130] In 2017, Microsoft introduced a plan to make broadband connections more accessible to larger rural healthcare providers and to lower costs, which would allow providers to reinvest additional funds in patient care.[131] Additionally, facilities are encouraging better connectivity in these areas by adopting telemedicine programs.[132]

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123 Lindsey T. Goehring, *H.R. 2068: Expansion of Quality or Quantity in Telemedicine in the Rural Trenches of America?*, 11 N.C. J.L. & Tech. 99, 104 (2009).

124 *Id.*

125 Chris Hopkins, *Montana Health Network Primary Care Telemedicine*, Rural Health Info. Hub. (Oct. 5, 2012), https://www.ruralhealthinfo.org/project-examples/706.

126 *Id*.

127 McCarthy, *supra* note 122, at 127.

128 *Id.*

129 Maren Niemeier, *Telehealth Use in Rural Healthcare*, Rural Health Info. Hub, https://www.ruralhealthinfo.org/topics/telehealth (last reviewed Mar. 26, 2019).

130 Juliet Van Wagenen, *Rural Connectivity Stands as One of Telehealth's Last Hurdles*, HealthTech (Jan. 16, 2018), https://healthtechmagazine.net/article/2018/01/rural-connectivity-stands-one-telehealths-last-hurdles.

131 *A Rural Broadband Strategy: Connecting Rural America to New Opportunities,* Microsoft 40 (July 10, 2017), https://selectra.co.uk/sites/default/files/pdf/Rural-Broadband-Strategy-Microsoft-Whitepaper-FINAL-7-10-17.pdf

132 *Id.*

B. Crossover Issues in Rural and Urban Areas

i. Protection of Patient Medical Information

Some challenges apply to the implementation of telemedicine in both rural and urban areas; one major concern is the potential for unauthorized access to patients' medical information.[133] With the continued use of, and reliance on, electronic data collection and storage and frequent distant data transfer, the risk of exposing patient medical information is substantial.[134]

Several federal and state laws protect patient health data. For example, the Food and Drug Administration (FDA) protects patient information through the Food, Drug, and Cosmetic Act of 1938 and the Medical Device Amendments of 1976.[135] Videoconferencing systems, including those integrated into a telemedicine unit, are subject to the Food, Drug, and Cosmetic Act of 1938, the purpose of which is to ensure device efficacy and patient safety.[136] Further, in 2013, the FDA issued a broad regulatory guidance for mobile medical devices that are used for monitoring patients and data transfer.[137] However, recent data breaches, such as that of Experian,[138] have shown that even with regulatory protection patient medical information may still be at risk.[139]

Additionally, new healthcare related cell phone applications, such as those that help manage medical conditions, schedule doctors' appointments, and see counselors, store large amounts of patient data.[140] While the Health Insurance Portability and Accountability Act (HIPAA) contains privacy and security provisions designed to protect patient health information, many of these mobile health applications may not be subject to HIPAA.[141] The Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH) expanded the protections that HIPAA offers by extending some HIPAA privacy and security requirements to "certain Business Associates that create, receive, maintain or transmit identifiable health information while performing a service

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133 Joseph L. Hall & Deven McGraw, *For Telehealth to Succeed, Privacy and Security Risks Must Be Identified and Addressed,* 33 Health Aff. 216, 217 (2014).

134 Kimberly Lovett Rockwell, *The Promise of Telemedicine Current Landscape and Future Decisions*, Mich. B.J., 38, 39 (Feb. 2017), https://www.michbar.org/file/barjournal/article/documents/pdf4article3059.pdf.

135 *Id.*

136 Ashley Geraghty, *Are Telemedicine Units a Medical Device?*, AAMI, https://www.aami-bit.org/doi/pdf/10.2345/i0899-8205-40-6-479.1.

137 *See* U.S. Food & Drug Admin., *Policy for Device Software Functions and Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff* (2013).

138 *Experian Data Breach Settlement*, FTC (Sept. 2019), https://www.ftc.gov/enforcement/cases-proceedings/refunds/equifax-data-breach-settlement.

139 Berkeley Lovelace Jr., *FDA Issues Warning on Medical Devices That Are Vulnerable to Takeover From Hackers*, CNBC (Oct. 1, 2019), https://www.cnbc.com/2019/10/01/fda-issues-warning-on-medical-devices-that-are-vulnerable-to-cyberattacks.html.

140 Angus Chen, *How Your Health Data Lead a Not-So-Secret Life Online,* NPR (July 30, 2016), https://www.npr.org/sections/health-shots/2016/07/30/487778779/how-your-health-data-lead-a-not-so-secret-life-online.

141 Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104–191, 110 Stat. 1936 (1996); *Id.*

or function on behalf of a covered entity."[142] However, because third-party developers that make the majority of mobile health applications available to consumers are not considered Business Associates performing a function on behalf of a "covered entity," the HIPAA protections do not apply.[143]

ii. Physician Licensing Requirements

Another major issue that applies to the use of telemedicine in both rural and urban locations regards licensure.[144] State laws require that physicians are licensed in the state in which they practice medicine, but physicians utilizing telemedicine practice across state lines, which presents a problem.[145] Many states have amended their medical practice laws and enacted regulation to address licensing requirements for the practice of telemedicine, but many of these laws are quite vague.[146] While some suggest that a national licensure system would eliminate this problem, such a system would impose additional requirements that physicians practicing across state lines may be unable to meet.[147] For example, many states define telemedicine differently and have different rules pertaining to when a provider needs to physically see a patient before utilizing telemedicine.[148] Other states require patients to interact with off-site health care professionals while services are being provided, some require in-person follow-up visits after treatment via telemedicine, a few require the presence of a telepresenter[149] during treatment, and so on.[150] Physicians practicing across state lines must also be aware of each state's particular laws regarding the prescribing of controlled and non-controlled substances.[151] Due to these issues, states should look to other states' laws in the same region when updating and implementing laws regarding the practice of medicine. Regional licensure would benefit physicians practicing telemedicine across state lines because they would be able to practice in multiple states.[152]

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142 Rockwell, *supra* note 134, at 39.

143 *See Examining Oversight of the Privacy & Security of Health Data Collected by Entities Not Regulated by HIPAA*, U.S. Dep't. of Health and Hum. Serv., https://www.healthit.gov/sites/default/files/non-covered_entities_report_june_17_2016.pdf [hereinafter HHS]; Chen, *supra* note 140.

144 Goehring, *supra* note 123, at 107.

145 *Providing Care Across State Lines*, Am. Acad. of Allergy, Asthma & Immunology, https://www.aaaai.org/practice-resources/running-your-practice/practice-management-resources/Telemedicine/state.

146 Roman J. Kupchynsky & Cherly S. Camin, *Legal Considerations of Telemedicine*, 64 Tex. B.J. 20, 22 (2001).

147 *Id.*; *See e.g.* Kip Poe, *Telemedicine Liability: Texas and Other States Delve into the Uncertainties of Health Care Delivery Via Advanced Communications Technology*, 20 Rev. of Litig. 682, 696–97 (2001) (describing a national licensure system implemented by Congress as being the most workable solution for healthcare providers).

148 Rockwell, *supra* note 134, at 40.

149 *Id.* (explaining that a telepresenter is a healthcare provider present at the patient's location during the telemedicine encounter).

150 *Id.*

151 *Id.*

152 Jennifer M. Little, *Into the Future: The Statutory Implications of North Carolina's Telepsychiatry Program*, 93 N.C. L. Rev. 863, 888 (2015).

III. STATE LAWS PERTAINING TO THE PRACTICE OF TELEMEDICINE

A. The Physician-Patient Relationship

Even though treatment via telemedicine does not occur face-to-face, this does not change the fact that certain interactions establish a physician-patient relationship.[153] One challenge with telemedicine is determining exactly when that relationship begins.[154] In general, a physician-patient relationship has been established when there has been two-way communication, the physician has agreed to treat the patient, and the patient has agreed to accept treatment from the physician.[155]

Most states have implemented laws that determine when the physician-patient relationship has been established for the purposes of treatment rendered via telemedicine.[156] For example, in New York, a physician-patient relationship can be established by a mere telephone call that initiates treatment.[157] Similarly, Arkansas law allows for the establishment of a physician-patient relationship via audio-video interaction.[158] Conversely, Georgia and Texas each require an in-person follow-up after the telemedicine visit, even though the telemedicine encounter itself establishes the physician-patient relationship.[159]

It is important for states with more rural areas to allow the establishment of physician-patient relationships through the use of telemedicine because patients in those areas often need to travel several hours to get to a physician or a hospital. Some states, including Idaho, Nebraska, North Carolina, North Dakota, West Virginia, and Wyoming, allow for a physician-patient relationship to be established via a two-way video conference.[160] It is likely that the number of states that allow for a physician-patient relationship to be established this way will grow as the use of telemedicine becomes more routine.

B. Standard of Care

Standard of care is defined as "the standard of conduct to which one must conform… [and] is that of a reasonable [physician] under like circumstances."[161] In medical

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153 Lynette Herscha, *Is There a Doctor in the House? Licensing and Malpractice Issues Involved in Telemedicine,* 2 B.U. J. Sci. & Tech. L. 8, 35 (1996).

154 *Id.* at 34.

155 *Id.*

156 *50-State Survey: Establishment of a Patient-Physician Relationship Via Telemedicine,* AMA (2018), https://www.ama-assn.org/system/files/2018-10/ama-chart-telemedicine-patient-physician-relationship.pdf (compilation of state laws related to the establishing a definition of the patient-physician relationship in telemedicine) [hereinafter *50-State Survey*].

157 Erin Grunzke, *Long-Distance Doctors: The Crossroads of Telemedicine Licensure in Illinois,* 89 Ill. B.J. 362, 363 (2001).

158 Latoya Thomas & Gary Capistrant, *State Telemedicine Gaps Analysis: Physician Practice Standards & Licensure*, Am. Telemedicine Ass'n. 2 (2017).

159 Rockwell, *supra* note 134, at 38.

160 Thomas & Capistrant, *supra* note 158, at 25, 40, 46, 47, 61, 63.

161 Peter Moffett and Gregory Moore, *The Standard of Care: Legal History and Definitions: the Bad and Good News,* 12 West J. Emergency Med. 109 (2011).

malpractice cases, the standard of care is generally established through the use of expert testimony.[162] However, the standard of care to which telehealth physicians should be held is not clearly defined by many states.[163] While some states view telemedicine as a tool used to practice medicine, rather than as its own form of medicine, the standard of care should be the same regardless of whether the patient is seen via telemedicine or in person.[164]

In 2017, Texas passed legislation recognizing that since telemedicine services are comparable to those provided in a physician's office, the standard of care should be as well.[165] While this addressed the question of which standard of care should be applied to telemedicine services, Texas also requires the use of a patient site presenter.[166] Therefore, while the physician-patient relationship may be established through a telemedicine interaction, it must occur at an established medical site and in the presence of a patient site presenter.[167]

While patient site presenters are not physicians, they usually have clinical experience.[168] The New College Institute's STAR Telehealth Program, which is supported by Virginia Telehealth Network, Mid-Atlantic Telehealth Resource Center, Broad Axe Care Coordination, and Totier Technologies, offers a program for students to become a Certified Telemedicine Clinical Presenter and Technology Professional.[169] The prerequisite to admission into the program is being certified to perform a basic patient exam, and the goal is to give graduates the skills necessary to correctly present patient information during virtual visits.[170] Many states, however, have not yet passed legislation stating whether they require a certified patient site presenter as opposed to another medical professional.[171]

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[162] Robert H. Aicher, *What Standard of Care?* 36 Aesthetic Surgery J. 376, 377 (2016).

[163] Alexis Slagle Gilroy, *Telemedicine, Mobile Health and the Standards of Care – A Look at State Specific Policies Altering Traditional Standards of Care Requirements as Applied to Telemedicine and Impacting the Utilization of Mobile Technologies,* Am. Ass'n. Advancement of Sci. 3 (2014).

[164] *Id.*

[165] Tex. Occ. Code Ann. § 111.004 (Vernon); Clay Wortham & Tesch West, *2017 Legislation Expands Telemedicine Opportunities in Texas and Ends Teladoc Dispute*, 20 J. Healthcare Compliance 59, 59 (2018).

[166] Wortham & West, *supra* note 165, at 60 (explaining that a patient site presenter is a person that facilitates the use of telemedicine equipment along with the encounter at the patient's bedside and is able to communicate with the physician).

[167] *Id.*

[168] *See The Role of Telepresenter,* NW. Regional Telehealth Resource Ctr. (Sept. 26, 2013), https://www.nrtrc.org/education-article-19 (stating that a telepresenter is generally a nurse who is trained to use the technology).

[169] *Star Telehealth at New College Institute*, New Coll. Inst., https://www.newcollegeinstitute.org/programs/southside-telehealth-training-academy-and-resource-center-(star), (last visited Nov. 8, 2019).

[170] *Id.*

[171] *50-State Survey, supra* note 156.

Unlike Texas, Illinois law is unsettled as to the appropriate standard of care that should apply when a patient is treated using telemedicine.[172] Current law broadly allows for independent physician judgment within the bounds of established procedures and for physician discretion under certain circumstances, such as during an emergency situation.[173]

Although Illinois law is vague regarding the applicable standard of care when using telemedicine, the state enacted a law applicable to occupational therapists which states that the standard should be the same regardless of whether the patient is seen face-to-face or via telemedicine, which is a standard that many states have implemented for telemedicine in general.[174] For example, Colorado,[175] New Hampshire,[176] and South Carolina[177] have laws requiring that the standard of care for telemedicine be the same as the standard for in-person visits.[178] Conversely, other states do not follow such standards, and instead have laws specific to telemedicine; for example, the standard of care for telemedicine services in Hawaii is that of "non-in-person consultation," recognizing that a physician may be limited in performing a proper exam when it is conducted through telemedicine.[179]

Regardless of where a physician is providing telemedicine services, it is important that he knows what the standard of care is for that specific area to ensure that he is meeting or exceeding that standard. While it remains to be seen how states choose to implement laws regarding the standard of care for telemedicine, laws will likely differ among states and could include more complex definitions than the traditional standard of care.

C. Cross-Over Licensing for Physicians Practicing Across State Lines

Some states have attempted to facilitate physician practice of telemedicine across state lines by implementing cross-over licensing, which makes it easier for physicians to become licensed in that state.[180] However, many states still have strict licensing requirements which may negatively affect the utilization of telemedicine since obtaining multiple licenses can be impractical.[181] For example, Michigan law states that private payers and Michigan Medicaid "need not reimburse telemedicine services not furnished by a Michigan-licensed provider."[182] Such strict laws may contribute to the physician

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172 Wibberley, *supra* note 26, at 908.

173 *Id.* at 909.

174 Colo. Rev. Stat. § 10-16-123 (2017); Wibberley, *supra* note 26, at 910.

175 § 10-16-123.

176 N.H. Rev. Stat. Ann. § 329:1-d (LexisNexis 2019).

177 S.C. Code Ann. § 40–47–37(A) (2016).

178 Wibberley, *supra* note 26, at 910–11.

179 *Id.* at 912.

180 *Telemedicine Policies*, Fed'n. State Med. Bd. (Oct. 30, 2019), http://www.fsmb.org/siteassets/advocacy/key-issues/telemedicine_policies_by_state.pdf.

181 Goehring, *supra* note 124, at 107.

182 Rockwell, *supra* note 134, at 41.

shortage since out-of-state physicians cannot treat patients using telemedicine unless they undergo the possibly rigorous licensing process for that state.[183]

One solution to the licensing problem is special telemedicine licensing certificates.[184] Nine states currently issue such certificates, which allow a physician to practice telemedicine in his state if he meets certain requirements.[185] Additionally, some states, including New York, Maryland, and Virginia, have reciprocity statutes that allow a physician licensed in bordering states to practice within their state without needing to obtain a separate license.[186] Finally, multiple states have adopted a version of the Federation of State Medical Board's Interstate Medical Licensure Compact ("IMLC"), which allows physicians to become licensed through an expedited process.[187]

The IMLC makes it easier for physicians to become licensed in multiple states and thus establish jurisdiction at their patients' locations.[188] The program aims to reduce barriers to multistate licensure and to enable "licensure portability and telemedicine while expanding access to health care by physicians, particularly in underserved areas of the nation."[189] The fact that the director of the Wyoming State Board of Medicine originally proposed the exploration of an interstate compact evidences the importance of its implementation in states with large rural areas.[190] In June of 2017, Maine became the twenty-second state to join the IMLC,[191] and in 2018 Guam became the first U.S. territory to join.[192] For Guam, this is an opportunity to ensure that its residents can obtain "quality health care, regardless of geographical challenges."[193] Since it joined the IMLC, more than 750 medical licenses have been issued in Guam.[194]

Interstate licensing could be exactly what rural areas need to help ensure that, despite physician shortages, patients get adequate treatment via telemedicine services. It appears that the Federation of State Medical Boards ("FSMB") considered both patient protection

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183 *Id.*

184 *Id.*

185 *Id.*

186 *Id.*

187 *Id.*

188 *The IMLC*, Interstate Med. Licensure Compact, (Oct. 30, 2019), https://imlcc.org; Katie Dvorak, *Interstate Medical Licensure Compact Ready for Consideration by States*, Fierce Healthcare (Sept. 5, 2014), https://www.fiercehealthcare.com/it/interstate-medical-licensure-compact-ready-for-consideration-by-states.

189 Dvorak, *supra* note 188.

190 *Id.*

191 *Id.* (noting that Alabama, Arizona, Colorado, Idaho, Illinois, Iowa, Kansas, Maine, Maryland, Minnesota, Mississippi, Montana, Nebraska, Nevada, New Hampshire, Pennsylvania, South Dakota, Tennessee, Utah, Vermont, Washington, West Virginia, Wisconsin, Wyoming, Guam and the District of Columbia have joined the Compact).

192 *Guam Joins Interstate Medical Licensure Compact*, Fed'n. State Med. Bds. (Feb. 27, 2018), http://www.fsmb.org/siteassets/advocacy/news-releases/2018/guam-joins-interstate-medical-licensure-compact.pdf.

193 *Id.*

194 *Id.*

and patient needs in rural areas of the country when creating the IMLC.[195] In mid-2017, after Maine joined the IMLC, the president and CEO of FSMB, Dr. Chaudhry, stated, "[a]t a time when our nation's physician shortage is disproportionately impacting rural communities, it is critical that states like Maine are able to attract eligible physicians from across state lines to treat patients in need."[196]

The IMLC shows no plans of slowing down, and approximately eighty percent of physicians in the United States meet its criteria for licensure.[197] Since April 2017, approximately 3,426 medical licenses have been issued and roughly 497 licenses have been renewed through the IMLC.[198] This may be a step towards helping lessen physician shortage in rural areas; however, the actual impact of this initiative and whether it has increased access to quality healthcare in rural communities will continue to be assessed.

D. Overall Growth of Telemedicine

Telemedicine technology has improved dramatically from when it was first introduced, and it has reached patients that would otherwise have been unable to obtain adequate medical care. In 1959, the Nebraska Psychiatric Institute used a microwave link for telepsychiatry consultations with a mental hospital that was 112 miles away.[199] The same year, teleradiology was introduced in Montreal, Quebec, which allowed for the transmission of telefluoroscopic exams over coaxial cable.[200] Today, radiologists can manipulate imaging in ways that were previously impossible, which gives them the ability to reach a more accurate diagnosis and make better clinical recommendations.[201]

In 1999, the term "telestroke" was first introduced with the goal of reducing complication rates associated with the administration of intravenous tissue-type plasminogen activator (tPA).[202] A tPA injection is considered "the gold standard" treatment for ischemic stroke, as it dissolves the clot that caused the stroke and thus helps restore blood flow.[203] While some rural hospitals previously had to transfer ischemic stroke patients to hospitals

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195 *Maine Joins Interstate Medical Licensure Compact*, Fed'n. State Med. Bds. (June 28, 2017), http://www.fsmb.org/siteassets/advocacy/news-releases/2017/maine-joins-interstate-medical-licensure-compact.pdf.

196 *Id.*

197 *Interstate Medical Licensure Compact Commission Issues 3,000th License*, Fed'n. State Med. Bds (Nov. 8, 2018), https://www.fsmb.org/advocacy/news-releases/interstate-medical-licensure-compact-commission-issues-3000th-license.

198 *Id.*

199 Douglas A. Perednia & Ace Allen, *Telemedicine Technology and Clinical Applications*, 273 JAMA 483, 483 (1995).

200 *Id.; See Fluoroscopy*, FDA, https://www.fda.gov/radiation-emitting-products/medical-x-ray-imaging/fluoroscopy (explaining that fluoroscopy is a type of medical imaging).

201 Rashid L. Bashshur et al., *The Empirical Foundations of Teleradiology and Related Applications: A Review of the Evidence*, 11 Telemedicine J. and E-Health 686, 868 (2016).

202 Lawrence R. Wechsler et al., *Telemedicine Quality and Outcomes: A Scientific Statement for Healthcare Professionals from the American Heart Association/American Stroke Association,* 48 J. Am. Heart Ass'n., e3, e4 (2016).

203 *Stroke*, Mayo Clinic, https://www.mayoclinic.org/diseases-conditions/stroke/diagnosis-treatment/drc-20350119.

hundreds of miles away for treatment, telestroke allows such hospitals to treat patients with the use of intravenous tPA on-site.[204] As the practice has evolved, it has helped to bridge the gap in care in areas without stroke centers and neurologists, or with limited neurological expertise.[205] As telestroke advances, it has the potential to help areas with and without available neurological expertise by providing increased speed and quality aids to improve treatment outcomes of stroke patients.[206]

Telemedicine has virtually revived home visits, which were almost a thing of the past.[207] Thomas Jefferson University Hospital in Philadelphia has emergency medicine physicians available twenty-four hours a day, seven days a week, to see patients via JeffConnect, an on-demand video service.[208] Patients can communicate with emergency medicine physicians, schedule video visits, and even schedule remote second visits using their cell phone, tablet, or computer.[209] JeffConnect also offers virtual rounds, which allows patients to meet their care team, and Jefferson Health Neuroscience Network, which connects patients and doctors in regional hospitals with specialists that have neuroscience expertise. [210]

In addition to improving overall patient care and providing access to specialists in isolated areas that would not otherwise have such access, telemedicine has also been introduced into the correctional system.[211] Incarcerated individuals have health issues that must be treated, diagnosed, and managed.[212] In *Estelle v. Gamble*,[213] the Supreme Court held that all prisoners have the right to adequate medical care.[214] Telemedicine has "remove[d] the requirement for multiple guards and special transport equipment for moving prisoners to conventional healthcare settings," and "reduce[d] poor public acceptance of shackled prisoners in the waiting area with non-prisoner patients."[215]

Telemedicine has expanded in ways that were unthinkable at the time it was first implemented; for example, teaching hospitals are beginning to incorporate telemedicine

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204 *Id.*

205 *See generally* Wechsler, *supra* note 202, at e3 (stating that telestroke is one of "the most successful applications of telemedicine, bringing the experience of stroke experts to hospitals lacking appropriate stroke expertise.").

206 *Id*.

207 *See generally Telehealth and Its Impact on Facilities Management*, Healthcare Tech Outlook (Sept. 3, 2019), https://www.healthcaretechoutlook.com/news/telehealth-and-its-impact-on-facilities-management-nid-1457.html (stating that "home calls are now starting to revive virtually–thanks to increased use of telehealth").

208 *Faster, Easier Way to See a Doctor- by Video!,* Jefferson U. Hosp.: JeffConnect https://hospitals.jefferson.edu/jeffconnect.html (last visited Nov. 8, 2019).

209 *Id.*

210 *Id.*

211 Jeremy D. Young and Melissa E. Badowski, *Telehealth: Increasing Access to High Quality Care by Expanding the Role of Technology in Correction Medicine*, 6(2) J. Clin. Med. 20, 23 (2017); Ollove, *supra* note 74.

212 *Id.* at 22.

213 429 U.S. 97 (1976).

214 *Id.* at 103.

215 Young & Badowski, *supra* note 211, at 23.

into their curriculum.[216] To keep advancing telemedicine and give patients in rural areas better access to medicine, and to keep physicians interested and up to date, it is important that telemedicine becomes a regular part of healthcare education.[217] It is also important to ensure that all physicians, regardless of their experience level, are dedicated to helping telemedicine evolve in their facilities and to becoming comfortable with the technology.[218]

IV. IMPROVING ACCESS TO TELEMEDICINE IN RURAL AND URBAN AREAS

One significant challenge to advancing access to telemedicine is a lack of in-depth research regarding its implementation in rural areas. This may be because many telemedicine programs are fairly new but may also be due to issues such as a lack of follow-up on the programs' progress, ineffective implementation, or a lack of follow-through to ensure success. Whatever the issues may be, it is important to utilize this information to improve telemedicine in all areas.

Improving access to affordable broadband and ensuring that enough physicians are available would help improve access to telemedicine in rural areas.[219] As discussed above, interstate licensure would benefit rural areas since physicians would be able to become licensed in multiple states more easily, and thus be able to utilize telemedicine across state lines.[220] However, even if the problem of physician shortage is ameliorated with interstate licensure, patients will still be unable to access health services via telemedicine if they cannot obtain affordable broadband and a smartphone, tablet, or computer.[221]

It is worth exploring further how Georgia was able to afford to give tablets to their diabetic patients living in rural communities to interact with their doctors from home, and to determine if this could be implemented in other states.[222] This could potentially solve the issue faced by patients living in rural areas who are unable to afford the smartphone, tablet, laptop, or desktop computer required to access telemedicine services. However, this would solve only half of a two-pronged problem for citizens living in rural areas; even if patients were given tablets free of charge, they would still need Internet access to connect with the telemedicine provider.[223]

Alaska may serve as a model for others with regard to finding solutions to implement affordable broadband.[224] In addition to Alaska's major telecommunications companies

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216 Elizabeth Veringa, *Training Clinicians with Telehealth*, Health Recovery Solutions (June 19, 2019) https://www.healthrecoverysolutions.com/blog/teaching_telehealth.

217 *Id*.

218 *Id*.

219 *See supra* notes 129–132 and accompanying text.

220 Dvorak, *supra* note 188.

221 Gianluca Montanari Vergallo et al., *The Doctor-Patient Relationship in Telemedicine and Mobile Health*, 4 Senses Sci. 1, 2, 5 (2017).

222 Miller, *supra* note 98.

223 Niemeier, *supra* note 129.

224 Stricker, *supra* note 86.

partnering with health-related nonprofits to bring access to high-speed, secure telemedicine options, one such company, General Communication Inc. (GCI), has expanded broadband capacity to many rural villages throughout the state via its TERRA project.[225] The project helped build a terrestrial microwave system in Alaska's Northwest Arctic region that provides rural Alaskans with faster and more reliable internet access.[226] In addition, communities are provided access to Connect MD Medical Network Solution, which has been implemented across Alaska for more than a decade.[227] Also, in late 2016, the state implemented Doctor on Demand, an application that allows patients to connect directly to board-certified physicians.[228] However, while the application is free and Alaskans pay a flat fee per visit, Doctor on Demand does not partner with any insurance companies that operate in Alaska, which creates a barrier for some patients.[229]

As new technology becomes available, telemedicine will continue to expand. However, to ensure that telemedicine is properly implemented in facilities throughout the country, physicians must be on board.[230] Many physicians are resistant to change their preferred method of practice, and telemedicine often does not fit into that practice; one potential solution to this problem is to begin to utilize telemedicine technology as part of a standard curriculum in medical schools and during residencies, so that physicians can become accustomed to its use early on in their careers.[231]

CONCLUSION

There is much that we have learned from the implementation of telemedicine thus far, and even more that we have yet to learn as it continues to evolve and create more innovative ways to treat patients. While new treatments and technological advancements will likely reach urban areas first, it is important that rural areas are not left behind.

Many difficulties and challenges that arise from the implementation of telemedicine occur in both urban and rural areas.[232] Thus, those areas need to work together to determine the best approach to overcome challenges. This could mean sharing information with physicians in rural communities regarding new technology for treatment of certain diseases, new radiologic innovations, and even introducing additional telemedicine education to ensure physicians in rural areas are kept up to date on new advancements. Further, ensuring that physicians in both urban and rural areas are comfortable with using telemedicine technology will create more telemedicine opportunities in rural areas.[233]

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225 *Project Summary*, STG Inc., https://stgincorporated.com/project/gci-terra.

226 *Id.*; Stricker, *supra* note 86, at 20.

227 Stricker, *supra* note 86, at 20.

228 *Id.* at 29.

229 *Id.* at 30.

230 Patrick Y.K. Chau and Paul Jen-Hwa Hu, *Investigating Healthcare Professionals' Decisions to Accept Telemedicine Technology: An empirical Test of Competing Theories*, 39 Info. & Mgm't 297, 298 (2002).

231 Veringa, *supra* note 216.

232 *Supra* Part II.B.

233 Veringa, *supra* note 216.

Additionally, physicians' voices and those of other healthcare providers using telemedicine services play an important role as use of telemedicine continues to grow. Further, the physicians using telemedicine technology in rural communities could have important insight and ideas on how to improve use and reach more patients in rural areas throughout their states.

Attorneys practicing in health law and other related areas also need to be aware of changes that arise as telemedicine advances. The more widespread the use of telemedicine becomes the more likely states are to implement laws pertaining to treatment via telemedicine. Similarly, to provide adequate representation, attorneys need to remain up-to-date on state laws regarding when a physician-patient relationship is formed when telemedicine is the mode of treatment, and of any adjustments made to the standard of care with regard to treatment rendered via telemedicine.

Telemedicine will continue to grow and improve in areas where it has already been implemented and is likely to expand into areas that have not yet reaped its benefits. It is important that all physicians, regardless of experience, are committed to this growth and improvement. Implementing telemedicine into the medical curriculum and offering extensive continuing education courses involving telemedicine, especially in rural communities, will improve the use and function of telemedicine in both urban and rural areas, and will also help improve overall patient care and treatment.

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Buprenorphine Medication-Assisted Treatment: The Role of Informed Consent

*John Tyler Stocking**

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INTRODUCTION

In *Washington v. Glucksberg*,[1] the Supreme Court recognized that a "good physician is not just a mechanic of the human body whose services have no bearing on a person's moral choices, but one who does more than treat symptoms, one who ministers to the patient."[2] The doctor-patient relationship is a highly personal one where doctors, by virtue of their relationship with a patient and knowledge of his medical condition, can best advise the patient.[3] This relationship has traditionally been treated as a sacrosanct relationship with fiduciary duties.[4] The duties imposed on doctors involve fully informing the patient about treatment options and maintaining the established standard of care.[5] Traditional legal principles, such as medical malpractice and informed consent, help ensure that doctors deliver the best possible care.[6]

It is especially important to protect the doctor-patient relationship when dealing with a life-threatening condition such as Opioid Use Disorder ("OUD").[7] Unfortunately, the most effective treatment for OUD, the use of buprenorphine, is currently also one of the most restricted treatments in the field of medicine.[8] The treatment of OUD is the only area of medicine in which a doctor's ability to prescribe a certain drug is limited by the number of patients that the doctor treats.[9] This restriction is especially egregious since buprenorphine is a potentially lifesaving medication during a nationwide epidemic.[10]

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[1] 521 U.S. 702 (1997).

[2] *Id.* at 779 (Souter, J., concurring) (citing Roe v. Wade, 410 U.S. 113, 153 (1973)).

[3] Desimini v. Bristol Hosp., Inc., 927 A.2d 1004, 1007 (Conn. Super. Ct. 2007) (citing Sherwood v. Danbury Hospital, 896 A.2d 777 (Conn. 2006)); Vitanza v. Upjohn Co., 778 A.2d 829 (Conn. 2001)).

[4] Wohlgemuth v. Meyer, 293 P.2d 816, 820 (Cal. Dist. Ct. App. 1956).

[5] Paden v. Rudd, 669 S.E.2d 548, 550 (Ga. Ct. App. 2008).

[6] For an explanation of the progression of medical malpractice standards see Peter Moffett & Gregory Moore, *The Standard of Care: Legal History and Definitions: The Bad and Good News*, 12 West. J. Emergency Med. 109, 109–112 (2011). Even with the current "minimally competent physician" standard, described by Moffet and Moore, malpractice still serves as a measuring stick for maintaining a certain quality of care. *Id.* at 110–12; *See also* Michael C. Barnes & Daniel C. McClughen, *Warm Handoffs: The Duty of and Legal Issues Surrounding Emergency Departments in Reducing the Risk of Subsequent Drug Overdoses*, 48 U. Mem. L. Rev. 1099, 1130–42 (2018) (explaining potential medical malpractice liability for hospitals who release patients without a warm handoff policy).

[7] *See generally* Joshua W. Elder et. al., *Optimal Implementation of Prescription Drug Monitoring Programs in the Emergency Department*, 19 West. J. Emergency Med. 387, 387 (2018) (describing OUD as the "most significant modern-day, public health crisis").

[8] *See infra* notes 51–58 and accompanying text.

[9] *30–100 Patient Limit*, Nat'l Alliance of Advoc. for Buprenorphine Treatment, https://www.naabt.org/30_patient_limit.cfm [hereinafter *30–100 Patient Limit*].

[10] *See generally Methadone and Buprenorphine: Opioid Agonist Substitution Tapers*, Providers Clinical Support Sys., (Dec. 6, 2017), https://pcssnow.org/resource/methadone-buprenorphine-opioid-agonist-substitution-tapers (describing how blocking withdrawal symptoms and reducing cravings reduces the risk of relapse).

Another threat to the doctor-patient relationship is unfair business practices. Market leading businesses, which range from addiction recovery centers to behavioral healthcare hospitals, present outdated abstinence treatment methods as superior to medication-assisted treatment.[11] Twelve-step abstinence-based treatment programs reject the use of buprenorphine; therefore, these businesses do not provide the necessary institutional support required for the growth of buprenorphine-medication assisted treatment ("B-MAT").[12] However, outcome-based research clearly shows that medication-assisted treatment ("MAT") with medicines like buprenorphine is dramatically superior to abstinence.[13] Alex Azar, Secretary of the U.S. Department of Health and Human Services (HHS), has stated that not offering MAT is like "trying to treat an infection without antibiotics."[14]

One of the most prominent threats to the doctor-OUD patient relationship is patient discrimination; doctors often see OUD patients as "moral failures" rather than people affected by a chronic condition.[15] Further, Congress continues to display bias by imposing limits on buprenorphine prescribing,[16] and, in the past, doctors were even disciplined for prescribing opiates for maintenance.[17] However, the focus of this Article is not to discuss whether a bias exists toward OUD patients; instead, it proposes that informed consent has the potential to serve as more than a 'checkbox' to avoid litigation, and genuinely enhance the doctor-OUD patient relationship. Regardless of the existing bias, OUD patients should have the right to self-determination.[18]

Given its life-and-death ramifications, OUD treatment provides a valuable case study of the benefits of informed consent on patient treatment.[19] According to a 2019 study, opioid deaths are expected to skyrocket by 2025, and researchers have identified the

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[11] *See e.g., infra* notes 99–101 and accompanying text.

[12] *See e.g.*, Katrine Jo Andersen & Cecilie Maria Kallestrup, *Rejected by A.A.: How the 12 Step Program and Its Decades-Old Philosophy are Exacerbating the Opioid Crisis*, New Republic (June 27, 2018), *https://newrepublic.com/article/149398/rejected-aa* (describing a Louisville, Kentucky native's experience feeling like a "fraud" in a 12-step program because he was also prescribed suboxone).

[13] *See* Alex M. Azar, *Plenary Address to National Governors Association* (Feb. 24, 2018) (transcript available at https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/plenary-addres-to-national-governors-association.html) (stating that MAT can "reduce[] future chances of a fatal overdose by more than 50 percent").

[14] *Id.*

[15] *See* Robert Heimer et. al., *Prevalent Misconceptions About Opioid Use Disorders in the United States Produce Failed Policy and Public Health Responses*, 69 Clinical Infectious Diseases 546, 548 (2018) (discussing the misconception of addicts as moral failures).

[16] *See infra* notes 52–57 and accompanying text.

[17] *See* Webb v. United States, 249 U.S. 96, 99 (1919) (holding that a physician cannot prescribe opiates to a person suffering from addiction).

[18] *See* Jenny Lindberg et. al., *Temporising and respect for patient self-determination*, 45 J. Med. Ethics 161, 161 (2019) (explaining that self-determination, in the doctor-patient relationship context, means that it is the patient who should decide which treatment option to pursue).

[19] Qiushi Chen et. al., *Prevention of Prescription Opioid Misuse and Projected Overdose Deaths in the United States*, Jama Network 1, 9 (2019), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2723405.

need for a "multipronged approach" that identifies those with OUD and improves their access to medications for treatment.[20] This Article proposes that an improved informed consent structure, tailored to the provider-OUD patient relationship, can play a role in narrowing the treatment gap by destigmatizing those with OUD, placing them in a decision-making position, and showing that understanding and accessing MAT does not have to be so difficult.[21]

While other Articles have discussed potential factors that may contribute to the limited utilization of MAT with buprenorphine, this Article will specifically analyze the unique legal factors involved. First, in Section I, this Article will review the history of drug regulation, and explain how legislation has adapted in response to the dramatic changes in opioid use that have taken place, particularly over the past two decades.[22] Next, in Section II, this Article will present a novel perspective on how fully informing patients of their available treatment options will create a dynamic shift away from unfair business practices that restrain the doctor-OUD patient relationship.[23] Next, Section III proposes a tailored list of best practices, specific to the OUD treatment setting, that doctors should implement when securing informed consent.[24] Finally, this Article suggests that the legal profession, legislators, and government agencies can play an important role in making lifesaving treatment more readily available.

I. BACKGROUND

A. History of Drug Regulation

The United States has a long history of drug regulation designed to prevent opioid abuse.[25] In the early 1900's, legislation involving opioids started to become progressively more restrictive.[26] Regulation began with ingredient disclosure (1906 Pure Food and Drug Act) and truthful labeling (1912 Sherley Amendment to the Pure Food and Drug Act) requirements for products containing opioids.[27] Next, opioid distribution itself was limited by the Harrison Narcotics Tax Act of 1914,[28] which allowed for the distribution of opiates by a physician only "in the course of his professional practice."[29] Because

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[20] *See id*. (stating that "under current conditions, the opioid overdose crisis is expected to worsen").

[21] *See* Maggie Ethridge, *Young People With Opioid Addiction Face Barriers To Treatment*, Fix (Feb. 1, 2019), https://www.thefix.com/young-people-opioid-addiction-face-barriers-treatment (explaining the tough road that all patients face in accessing treatment, and discussing Dr. Sharon Levy's belief that the idea that a person is "replacing one addiction with another" is outdated and that the "benefits of the medications outweigh any associated risks").

[22] *Infra* Part I.

[23] *Infra* Part II.

[24] *Infra* Part III.

[25] *Milestones of Drug Regulation in the United States*, U.S. Food & Drug Admin., https://www.fda.gov/media/109482/download [hereinafter *Milestones*].

[26] Pure Food and Drug Act of 1906, Pub. L. No. 59-384, 34 Stat. 768 (1906).

[27] *Id.*; Pure Food and Drug Act of 1906, Pub. L. No. 62-301, 37 Stat. 416, 417 (1912); *Milestones, supra* note 25.

[28] *See* Harrison Narcotics Tax Act, Pub. L. No. 63-223, 38 Stat. 785 (1914) (stating that prescribing opiates for addiction treatment is "so plain a perversion of meaning [of prescription]").

[29] *Id.*; Boyd v. United States, 271 U.S. 104, 105 (1926).

addiction was considered a moral failing and not a disease, doctors were not allowed to prescribe opiates for addiction treatment.[30] Twelve-step abstinence programs were established as a result of this emphasis on addiction as a moral failing and the resulting limitations on medical treatment.[31] Alcohol addiction was the first disorder addressed when Alcoholics Anonymous was formed (AA) in 1935.[32] Next, in 1953, Narcotics Anonymous (NA) was built on the same twelve-step principles.[33]

While the number of abstinence programs continued to increase, regulation of opioids also continued with the passage of the Controlled Substances Act (CSA),[34] which was passed as part of the Comprehensive Drug Abuse Prevention and Control Act of 1970.[35] The CSA created five controlled drug classifications (schedules I-V) and a "closed system" in which anyone authorized by the Drug Enforcement Agency (DEA) to handle controlled substances had to register.[36]

Finally, in 1974, physicians could once again use opioids to treat OUD patients.[37] Methadone, a long-acting opioid, proved effective in controlling withdrawal symptoms, and in 1972 the Food and Drug Administration (FDA) approved its use for the treatment of opioid addiction.[38] The Narcotic Addict Treatment Act of 1974 allowed federally licensed programs ("methadone clinics"), but not individual physicians, to dispense medication for "detoxification" or "maintenance" purposes.[39] During this period, researchers were also working on developing buprenorphine.[40] Buprenorphine was unique because it had a limited maximum or "ceiling" effect and a long half-life.[41] Such

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[30] Webb v. United States, 249 U.S. 96, 99–100 (1919).

[31] *See infra* notes 32–33 and accompanying text.

[32] *Over 80 Years of Growth*, Alcoholics Anonymous, https://www.aa.org/pages/enUS/aa-timeline; *see also Historical Data: The Birth of A.A. and Its Growth in the U.S./Canada*, Alcoholics Anonymous, https://www.aa.org/pages/en_US/historical-data-the-birth-of-aa-and-its-growth-in-the-uscanada (stating that "A.A. had its beginnings in 1935 at Akron, Ohio, as the outcome of a meeting between Bill W., a New York stockbroker, and Dr. Bob S., an Akron surgeon."). In 1939 the program "published its basic textbook, *Alcoholics Anonymous*. *Id*.

[33] *Information About NA*, Narcotics Anonymous, https://www.na.org/aboutus/?ID=PR-index.

[34] 21 U.S.C. § 812 *et seq.* (1970).

[35] Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1236 (1970).

[36] *See* 21 U.S.C. § 812; *Diversion Control Division, Resources,* U.S. Dept. Of Justice, https://www.deadiversion.usdoj.gov/21cfr/cfr/2108cfrt.htm (explaining the five schedules and process for registration).

[37] Narcotic Addict Treatment Act of 1974, Pub. L. No. 93-281, 88 Stat. 124 (1974).

[38] Rebecca L. Haffajee et al., *Policy Pathways to Address Provider Workforce Barriers to Buprenorphine Treatment*, 54 Am. J. Preventative Med. S230, S231 (2018).

[39] § 303, 88 Stat. at 124; *A History of Opiate Laws in the United States*, Nat'l All. of Advocates for Buprenorphine Treatment, http://www.naabt.org/laws.cfm (last visited Sept. 16, 2019).

[40] Nancy D. Campbell & Anne M. Lovell, *The History of the Development of Buprenorphine as an Addiction Therapeutic*, 1248 Annals N.Y. Acad. Sci. 124, 131–37 (2012).

[41] *Id.*; *see supra* note 10 (stating that buprenorphine's "ceiling effect" makes it safer than other opioids).

features made buprenorphine ideal for the treatment of withdrawal because it requires only a single daily dose and reduces the risks associated with methadone.[42]

Buprenorphine has proven to be effective. For example, in 1995, France (where primary care doctors are the primary prescribers of buprenorphine and may prescribe it without any special license or training) first allowed doctors to prescribe the drug for the treatment of OUD, and within four years the number of deaths caused by overdose declined by seventy-nine percent.[43] In the United States, the medical use of opioids significantly increased in the 1990's when doctors began to treat pain more aggressively.[44] In the mid-1990's, the American Pain Society proposed the recognition of pain monitoring as a "fifth vital sign," and in 2000, hospital systems such as the Veterans Health Administration (VA) began to recognize it as such.[45] Subsequently, in 2001, the Joint Commission[46] accepted such monitoring as one of its standards.[47] Along with an increase in opioid prescriptions, there was a parallel increase in the number of diagnoses of OUD.[48] By this time, the abstinence model was a prominent treatment for the growing number of OUD patients.[49]

The United States subsequently established stricter regulations concerning the use of buprenorphine for OUD treatment, and relaxation of these regulations has been slow.[50] For instance, the Drug Addiction Treatment Act of 2000 (DATA 2000) allowed

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[42] Methadone does not have a ceiling effect like buprenorphine does, so as the dose of methadone increases so do the risks of side effects such as impairment, respiratory depression, and even death. *See* Haffajee, *supra* note 38, at S232; *Buprenorphine*, Substance Abuse and Mental Health Servs. Admin., https://www.samhsa.gov/medication-assisted-treatment/treatment/buprenorphine (last visited Nov. 2, 2019).

[43] Marc Auriacombe et al., *French Field Experience with Buprenorphine*, 13 Am. J. Addictions. S17, S17, S19, S25 (2004).

[44] Andrew Rosenblum et al., *Opioids and the Treatment of Chronic Pain: Controversies, Current Status, and Future Directions*, 16 Experimental and Clinical Psychopharmacology 405, 406 (2008).

[45] *See Pain as the 5th Vital Sign Toolkit*, Dept. Of Veterans Aff., https://www.va.gov/PAINMANAGEMENT/docs/Pain_As_the_5th_Vital_Sign_Toolkit.pdf (stating that "the phrase 'pain as the 5th vital sign' was initially promoted by the American Pain Society to elevate awareness of pain treatment among healthcare professionals.").

[46] *See About the Joint Commission*, Joint Commission on Accreditation Of Healthcare Org., https://www.jointcommission.org/about_us/about_the_joint_commission_main.aspx [hereinafter Joint Commission]. The Joint Commission is an independent, not-for-profit organization that accredits and certifies over 22,000 health care organizations and programs throughout the United States for quality and meeting specific performance standards. *Id*.

[47] *See The Joint Commission's Pain Standards: Origins and Evolution* 1, 2, Joint Commission, https://www.jointcommission.org/assets/1/6/Pain_Std_History_Web_Version_05122017.pdf (explaining the Joint Commission's 2001 introduction of standards for organizations to provide better care to patients in pain).

[48] *See* Paige M. Smith, *Implementing Medicaid Health Homes to Provide Medication Assisted Treatment to Opioid Dependent Medicaid Beneficiaries*, 106 Ky. L. Rev. 112, 112 (2017) (describing overdoses and OUD as an "unanticipated consequence" increased prescribing).

[49] *See* Andersen, *supra* note 12 (describing detox wards, in which patients addicted to opioids stay while they experience withdrawal symptoms from quitting opioids "cold turkey").

[50] *See generally infra* notes 51–58 and accompanying text.

physicians who met certain qualifications and conditions to treat OUD patients with schedule III, IV, and V medications.[51] Since buprenorphine is the only Schedule III-V medication approved by the FDA for the treatment of OUD, DATA 2000 exclusively applies to its use for the treatment of OUD.[52] Under DATA 2000, physicians were capped at a thirty patient limit, marking the first time that doctors were limited to a certain number of prescriptions they are allowed to prescribe.[53] The 2006 Office of National Drug Control Policy Reauthorization Act included legislation that advocated for the increase of patient limits from thirty to one hundred patients after one year of practice.[54] Ten years later, an HHS regulation allowed qualified physicians to increase their patient limit to 275 patients,[55] and the Comprehensive Addiction Recovery Act of 2016 ("CARA") allowed "qualified practitioners,"[56] including nurse practitioners and physician assistants, to treat up to thirty patients during their first year and one hundred patients after the first year.[57] Then, in 2018, the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act expanded the group of "qualifying other practitioner[s]" who could provide B-MAT to include "clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives" for a five year period in response to the epidemic.[58]

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[51] Drug Addiction Treatment Act of 2000, Pub. L. No. 106-310, §3502, 114 Stat. 123–25 (2000); *Drug Scheduling*, U.S. Drug Enforcement Admin., https://www.dea.gov/drug-scheduling [hereinafter *Drug Scheduling*] (explaining that the Drug Enforcement Administration classifies Schedule III drugs as having moderate to low potential for physical and psychological dependence, Schedule IV drugs as having a low potential for abuse and risk of dependence, and Schedule V drugs as having a lower potential for abuse than Schedule IV drugs and containing limited quantities of certain narcotics).

[52] *Drug Scheduling*, *supra* note 51; *30–100 Patient Limit, supra* note 9. Buprenorphine is a schedule III drug, while Methadone is a schedule II drug. Naltrexone is not scheduled. *Drug Scheduling*, *supra* note 51.

[53] *See 30–100 Patient Limit, supra* note 9 (stating that "no other medications have such restrictions, including prescription drugs people get addicted to and die from").

[54] Office of National Drug Control Policy Reauthorization Act, Pub. L. No. 109-469 (formerly H.R.6344), Title XI, § 1102 (2006).

[55] *Medication Assisted Treatment for Opioid Use Disorders,* 42 C.F.R. §8.610 2016.

[56] *See* Comprehensive Addiction and Recovery Act of 2016, Pub. L. No. 114-198, 130 Stat. 695, 720–23 (2016). As defined in the Comprehensive Addiction and Recovery Act ("CARA"), a qualifying physician must be licensed under state law and satisfy one or more of the following requirements: hold a subspecialty board certification in addiction psychiatry from the American Board of Medical Specialties, hold an addiction certification from the American Society of Addiction Medicine, or a subspecialty board certification in addiction medicine from the American Osteopathic Association; complete a minimum of eight hours of training in a specific location; must had participated as an investigator in a clinical trial leading to approval of a schedule III, IV, or V narcotic; have additional training that either the state licensing board or Secretary of Health and Human Services deems sufficient. *Id*. Further, a qualifying practitioner, which includes nurse practitioners and physician's assistants must hold licensure under state law to prescribe schedule III, IV, and V pain medications, complete a minimum 24 hours of training as outlined by the Act, and work with or under the supervision of a qualifying practitioner. *Id*.

[57] *Id.*

[58] Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, Pub. L. No. 115-271, 132 Stat. 3894 (2018); *Resources: Buprenorphine Waiver Management,* Am. Soc'y of Addiction Med., https://www.asam.org/resources/practice-

B. Statistics

Since the rates of opioid prescriptions began to increase in the 1990's, the number of overdoses and deaths from synthetic opioid use has also steadily increased.[59] Between 1999 and 2016, the number of deaths involving prescription opioids increased fivefold¾nearly 64,000 Americans overdosed in the latter year.[60] In 2019, opioid overdoses surpassed car accidents as a leading cause of preventable deaths.[61] According to data from the Substance Abuse and Mental Health Services Administration (SAMHSA), approximately 2.1 million Americans over the age of twelve are believed to have an opioid use disorder.[62]

From July 2016 to September 2017, opioid overdoses increased thirty percent in fifty-two areas across forty-five states, which led HHS to declare opioid addiction a public health emergency in 2017.[63] Additionally, the Centers for Disease Control and Prevention (CDC) estimates that nearly every eight minutes, an American dies of a drug overdose.[64] Further, opioid misuse has resulted in many life-threatening infections[65]

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resources/buprenorphine-waiver-management#bupauthority (last visited Nov. 2, 2019) [hereinafter ASAM]; *Buprenorphine Patient Limits: History and Overview* Nat'l Ass'n of State Alcohol and Drug Abuse Directors, https://nasadad.org/wp-content/uploads/2019/01/Buprenorphine-Patient-Limits-1.pdf (last visited Nov. 2, 2019).

[59] *See* Christopher Ingraham, *CDC Releases Grim New Opioid Overdose: 'We're Talking About More Than an Exponential Increase,'* Wash. Post, (Dec. 21, 2017), https://www.washingtonpost.com/news/wonk/wp/2017/12/21/cdc-releases-grim-new-opioid-overdose-figures-were-talking-about-more-than-an-exponential-increase/ (presenting statistics showing a 2016 surge in deaths from fentanyl and other synthetic opiates).

[60] *Opioid Overuse: Overview*, Ctr. for Disease Control and Prevention, https://www.cdc.gov/drugoverdose/data/prescribing/overview.html [hereinafter CDC].

[61] Tauren Dyson, *Opioid Overdoses Top Motor Vehicle Crashes as Cause of Preventable Death*, UPI: Health News, (Jan. 14, 2019), https://www.upi.com/Health_News/2019/01/14/Opioid-overdoses-top-motor-vehicle-crashes-as-cause-of-preventable-death/6631547474852/?st_rec=4591547584097.

[62] Rebecca Ahrnsbrak et al., *Key Substance Use and Mental Health Indicators in the United States: Results from the 2016 National Survey on Drug Use and Health*, Substance Abuse and Mental Health Services Admin. (Sept. 2017), https://www.samhsa.gov/data/sites/default/files/NSDUH-FFR1-2016/NSDUH-FFR1-2016.htm [hereinafter SAMHSA].

[63] *See Opioid Overdoses Treated in Emergency Departments: Identify Opportunities for Action*, CDC, https://www.cdc.gov/vitalsigns/opioid-overdoses/index.html (stating that this increase was even more drastic in some larger cities and in the Midwestern region of the country); *HHS Acting Secretary Declares Public Health Emergency to Address National Opioid Crisis,* Dep't of Health & Human Serv. (Oct. 26, 2017), https://www.hhs.gov/about/news/2017/10/26/hhs-acting-secretary-declares-public-health-emergency-address-national-opioid-crisis.html [hereinafter HHS].

[64] *Statement of Commissioner Rohit Chopra*, FTC, (July 11, 2019), https://www.ftc.gov/system/files/documents/public_statements/1534673/chopra_-_reckitt_statement_7-11-19.pdf. *See also National Kickoff Call: OPIS-S2 (Opioid Prevention in States-Surge Support) via the Cooperative Agreement for Emergency Response*, Ctr. for Disease Control: Nat'l Ctr. for Injury Prevention and Control (Sept.12, 2018), https://www.cdc.gov/cpr/readiness/00_docs/Opioid_Crisis_CoAg_National_Call_Slide_Deck_September_13_Final-a_Sept_18.pdf.

[65] *Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs: A Treatment Improvement Protocol (TIP 43)*, ASAM, 1, 163–64, https://www.asam.org/docs/advocacy/samhsa_tip43_matforopioidaddiction.pdf?sfvrsn=0 (last visited Nov. 2, 2019).

and over one thousand opioid-related emergency room visits per day.[66] Lastly, opioid misuse also carries an astronomical economic burden; the CDC estimates that its costs, including health care, lost productivity, addiction treatment, and criminal justice involvement, exceed $78.5 billion per year in the United States.[67]

The number of patients seeking treatment also continues to increase.[68] For example, the number of treatment facility admissions for opioid use increased fifty-eight percent between 2005 and 2015.[69] Unfortunately, the majority of those suffering from OUD are not receiving effective treatment.[70] According to a 2016 report by the Surgeon General, only ten percent of people with a drug use disorder received specialty treatment due to a lack of access to care.[71] Even when patients receive treatment, data suggests that less than half of treatment facilities offer opioid addiction medications.[72] SAMHSA data through 2015 showed that only 41.2 percent of more than 12,000 drug addiction treatment facilities in the United States provided at least one kind of medication for the treatment of opioid addiction.[73] Likewise, only 6.1 percent of treatment facilities offered all three medications approved by the FDA for OUD treatment (buprenorphine, methadone, and naltrexone).[74] This data suggests that the abstinence model continues to dominate OUD treatment.[75]

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66 *CSC Launches Campaign to Help States Fight Prescription Opioid Epidemic*, CDC (Sept. 25, 2017), https://www.cdc.gov/media/releases/2017/p0925-rx-awareness-campaigns.html.

67 Rita Milios, *Opioid Abuse: A Crisis and a Challenge,* Recovery.org: Am. Addiction Ctr. Resource (Oct.2, 2017), https://www.recovery.org/pro/articles/opioid-abuse-a-crisis-and-a-challenge/; *See also* Curtis Florence et al., *The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013*, 54 Med. Care. 899, 901–06 (2016).

68 *Treatment Episode Data Set (TEDS) 2005–2015*, SAMHSA, https://wwwdasis.samhsa.gov/dasis2/teds_pubs/2015_teds_rpt_natl.pdf (last visited Sept. 16, 2019) [hereinafter TEDS].

69 *Id.*; Dennis McCarty et al., *Treatment and Prevention of Opioid Use Disorder: Challenges and Opportunities*, 39 Annu. Rev. Pub. Health 525, 531 (2018).

70 *See e.g.*, *Executive Summary: Surgeon General's Report on Alcohol, Drugs, and Health,* Surgeon Gen., https://addiction.surgeongeneral.gov/executive-summary (last visited Sept. 16, 2019) (stating that "only about 10 percent of people with a substance use disorder receive any type of specialty treatment").

71 *Id.*

72 TEDS*, supra* note 68.

73 Austin Jones et al., *Where Multiple Modes of Medication-Assisted Treatment Are Available*, Health Aff. Blog (Jan. 9, 2018), https://www.healthaffairs.org/do/10.1377/hblog20180104.835958/full; *see* Ramin Mojtabai et al., *Medication Treatment for Opioid Use Disorders in Substance Use Treatment Facilities*, 38 Health Aff. 14, 17 (Jan. 2019), (stating that in 2016 only thirty-six percent of medical facilities offered any of the three medications approved by the FDA).

74 Mojtabai, *supra* note 73, at 17.

75 *See* Andersen, *supra* note 12 (describing a Louisville, Kentucky native's experience feeling like a "fraud" in a 12-step program because he was also prescribed suboxone).

C. Treatment Options

In response to the OUD epidemic, researchers have extensively evaluated the effectiveness of available treatment methods.[76] Through this research, OUD has come to be seen as a "chronic medical disease" rather than an ongoing series of moral failures.[77] There are currently three FDA approved medications for OUD: methadone, naltrexone, and buprenorphine.[78] Each has proven effective, but the three differ in safety, side effects, ease of use, and risk of diversion.[79] Additionally, the medications differ in who is authorized to prescribe or dispense them, and how difficult it is for patients to receive treatment with each medication.[80]

Naltrexone blocks the opioid receptors in the brain, but does not provide any relief for ongoing withdrawal symptoms.[81] Patients must abstain from opioids for at least one week before starting naltrexone.[82] Since naltrexone is not a controlled substance, it can be prescribed by any licensed physician.[83] However, if patients stop taking the drug and start reusing opioids, their risk of a life-threatening overdose increases.[84]

Methadone can only be dispensed through licensed opioid treatment programs ("OTP"), which are extensively regulated.[85] For safety reasons, patients must visit these treatment centers daily and take the medication under supervision.[86] This treatment regimen often

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[76] *Definition of Addiction,* Am. Soc'y of Addiction Med. (Aug. 15, 2011), https://www.asam.org/resources/definition-of-addiction.

[77] *Id.* For example, the American Society of Addiction Medicine (ASAM) states that addiction is "a treatable, chronic medical disease involving complex interactions among brain circuits, genetics, the environment, and an individual's life experiences. People with addiction use substances or engage in behaviors that become compulsive and often continue despite harmful consequences. Prevention efforts and treatment approaches for addiction are generally as successful as those for other chronic diseases." *Id.*

[78] Nora D. Volkow et al., *Medication-Assisted Therapies¾Tackling the Opioid-Overdose Epidemic*, 370 N. Engl. J. Med., 2063, 2064–65 (2014).

[79] *Id.* at 2065; Haiden A. Huskamp et al., *Coverage of Medications that Treat Opioid Use Disorder and Opioids for Pain Management in Marketplace Plans, 2017*, 56 Med. Care 505, 506 (2018).

[80] Huskamp, *supra* note 79.

[81] Volkow, *supra* note 78, at 2065.

[82] *Id.*

[83] *Naltrexone,* SAMHSA, https://www.samhsa.gov/medication-assisted-treatment/treatment/naltrexone (last visited Nov. 17, 2019).

[84] *Id.* (stating that "it is possible that the dosage of opioid that was previously used may have 'life-threatening' consequences").

[85] Huskamp, *supra* note 79; *Oversight of Opioid Treatment Program (OTC) Accrediting Bodies*, SAMHSA, https://www.samhsa.gov/medication-assisted-treatment/legislation-regulations-guidelines/oversight (last visited Oct. 22, 2019) (explaining how SAMHSA obtained administrative responsibility over the use of opioid medications in maintenance and detoxification of substance abused disorders).

[86] Volkow, *supra* note 78, at 2065. SAMHSA has administrative responsibility over the use of opioid medications in maintenance and detoxification treatment of substance use disorders and has established procedures for an entity to become an approved accrediting body. *See Certification of Opioid Treatment Programs (OTPs)*, SAMHSA, https://www.samhsa.gov/medication-assisted-treatment/opioid-treatment-programs.

creates hardships for patients because it may interfere with their daily schedule, family, work, and other responsibilities.[87] The required monitoring may also be embarrassing and stigmatizing to patients.[88]

Finally, buprenorphine can be prescribed in an office-based setting, which does not interfere with patients' work and family schedules but can only be prescribed by practitioners who receive an authorization from the DEA.[89] Buprenorphine suppresses symptoms more effectively than methadone, while still allowing for once daily dosing.[90]

Currently, the standard of care for the treatment of OUD is extended maintenance on an opioid agonist.[91] Because the medical profession played a role in the emergence of the recent opioid epidemic through aggressive management of pain, and because physicians play a central role in the treatment of OUD, regulators have focused much of their efforts on regulating physicians.[92] The regulatory framework governing physicians prescribing buprenorphine for OUD markedly departs from the typical regulation of the professional practice of medicine.[93] In the area of OUD treatment, regulations have limited physician autonomy more than in any other area of medicine.[94] Given the definition of OUD as a chronic medical disease, along with the strong research support for treatment with medication, preserving the physician-patient relationship model of care is particularly important.[95]

II. ANALYSIS

A. The Current OUD "Treatment Gap"

The National Survey of Substance Abuse Treatment Services (NSSATS) indicates that in 2016 over one million patients were treated at 15,000 substance abuse treatment facilities.[96] Today's OUD treatment environments include general hospitals, behavioral

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87 Huskamp, *supra* note 79.

88 *Id.*

89 *See supra* notes 51–55 and accompanying text.

90 *See* Volkow, *supra* note 78, at 2065 (presenting a chart comparing the advantages, disadvantages, uses, and effects of methadone, buprenorphine, and naltrexone).

91 Andrew S. Huhn & Kelly E. Dunn, *Why Aren't Physicians Prescribing More Buprenorphine*, 78 J. Substance Abuse Treatment 1, 2 (2017). Opioid agonists are drugs that activate the opioid receptors in the brain. *What is this agonist/antagonist stuff?*, Nat'l Alliance of Advoc. for Buprenorphine Treatment, https://www.naabt.org/faq_answers.cfm?ID=5.

92 *See Special Circumstances for Providing Buprenorphine*, SAMHSA (Mar. 4, 2019) https://www.samhsa.gov/medication-assisted-treatment/legislation-regulations-guidelines/special (describing limitations placed on physicians by the Controlled Substances Act and the Narcotic Addiction Treatment Act).

93 *See supra* notes 52–58 and accompanying text.

94 *See supra* notes 52–58 and accompanying text.

95 *See supra* notes 77–80 and accompanying text.

96 Notably, although buprenorphine is considered the standard of care for OUD, only twenty-seven percent of the facilities provided that treatment regimen. *National Survey of Substance Abuse Treatment Services (N-SSATS): 2016 Data on Substance Abuse Treatment Facilities*, SAMHSA, at 1–3, 24, https://www.samhsa.gov/data/sites/default/files/2016_NSSATS.pdf (stating that the survey divided treatment into categories of outpatient, residential, and hospital inpatient. According to the

health hospitals, recovery centers, and opioid treatment programs ("OTP").[97] Two major legal issues affecting these environments are unfair business practices and a lack of informed consent.[98]

False advertising is a persisting unfair business practice in some facilities. For example, Richard Taite, the owner of Cliffside Malibu, a "world class luxury drug and alcohol treatment center," advertises that his center provides an evidence-based model that offers the "very best [treatment] science has to offer."[99] In Taite's publications in Psychology Today, he states that using MAT is simply trading one drug for another, and he asserts that doctors who prescribe medications for OUD are trying to "keep people dependent on drugs" for financial reasons, claiming that participating in an abstinence in-patient treatment program for over ninety days is the best opportunity for long-term recovery.[100] Taite also suggests that it is unsafe to leave children with anyone being treated by MAT, but these statements contradict outcomes-based research and are detrimental to the provider-OUD patient relationship.[101]

Further, many existing facilities deviate from established standards for informed consent.[102] The treatment of OUD with Office-Based Opioid Treatment ("OBOT") using

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survey, outpatient treatment was offered by 82% of facilities, and 91% of the patients received that treatment. Residential treatment was offered by 24% of facilities and received by 1% of patients. Inpatient was offered by 5% of facilities and received by 1% of patients. Eighty-four percent of all facilities had websites that provide information about a facility's substance abuse treatment programs, and sixty percent of all facilities provided outreach to persons in the community needing treatment) [hereinafter N-SSATS].

97 *Id.*

98 *See generally infra* notes 99–103 and accompanying text.

99 *See How We Treat*, Cliffside Malibu, https://www.cliffsidemalibu.com/how-we-treat/ (last visited Sept. 16, 2019). The Cliffside Malibu seeks the best evidence-based counseling, but the previous attacks on the use of MAT are clear. This Article proposes that in the same way that those supporting MAT should not say psychosocial counseling should not be used, a supporter of abstinence-based treatment oversteps when stating that MAT should not be used. The decision should ultimately lie with the patient.

100 Richard Taite, *Appropriate Uses for Suboxone and Subutex Therapies*, Psychology Today (Mar. 18, 2013), https://www.psychologytoday.com/us/blog/ending-addiction-good/201303/appropriate-uses-suboxone-and-subutex-therapies (stating that these medications "keep the individual just high enough not to have to deal with their underlying pain or trauma and maintain some ability to function in the world."); Richard Taite, *The Move Away From Abstinence Based Addiction Treatment*, Psychology Today (Jan. 07, 2015), https://www.psychologytoday.com/us/blog/ending-addiction-good/201501/the-move-away-abstinence-based-addiction-treatment (asserting that the doctors and the pharmaceutical industry push these medications solely for financial reasons).

101 Richard Taite, *Suboxone and Methadone Maintenance Therapy: As a Father, My Heart Belongs to My Children*, Psychology Today (Nov. 3, 2015), https://www.psychologytoday.com/hk/blog/ending-addiction-good/201511/suboxone-and-methadone-maintenance-therapy?amp; *see generally* Laura B. Monico et al., *Buprenorphine Treatment and 12-step Meeting Attendance: Conflicts, Compatibilities and Patient Outcomes,* 57 J. Substance Abuse Treatment 89, 89–95 (2015) (explaining the antagonistic effects of abstinence in comparison with MAT).

102 *See generally* Azar, *supra* note 13 (stating "[g]iven what we know, and given the scale of this epidemic, having just one-third of treatment programs offer the most effective intervention for opioid addiction is simply unacceptable.").

buprenorphine is effective, but only about a third of facilities offer such treatment.[103] This Article argues that the source of this shortage is multifactorial and can be best understood by reviewing the effect of these factors on the physician-OUD patient relationship. While specific solutions have been proposed to address the treatment gap,[104] this Article focuses on legal principles surrounding the doctor-patient relationship. If these legal principles are used properly in the care of OUD patients, a wider variety of effective treatment options will be available.

B. The Doctor-OUD Patient Relationship and the Role of Informed Consent

In *Cruzan v. Director, Missouri Dept. of Health*,[105] the Supreme Court described the doctrine of informed consent as "the [sacred] right of every individual to the possession and control of his own person," which ensures that "every human being of adult years and sound mind has a right to determine what shall be done with his own body."[106] This right to the "possession and control" of one's own person was first recognized by the Supreme Court in 1891 in a negligence action against a railroad company that arose from an injury caused by a falling train bed.[107] In the medical context, failure to obtain informed consent is viewed as a breach of a professional duty.[108]

The decision in *Canterbury v. Spence*[109] replaced the "professional practice" standard in medical malpractice cases with the "reasonable person" standard, which led to an increase in litigation and to an increase in the number of physicians who were willing to testify against each other in court.[110] In this case, a nineteen-year-old patient sued his physician after a routine back surgery left his legs permanently paralyzed.[111] Under

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[103] *Id.*

[104] *See*, *e.g.*, *Blueprint for Health: Hub and Spoke*, Vermont, http://blueprintforhealth.vermont.gov/about-blueprint/hub-and-spoke (last visited Oct. 22, 2019) (discussing "Hub and Spoke," Vermont's system of MAT, which supports people in recovery from OUD); Daniel P. Alford, *Collaborative Care of Opioid-Addicted Patients in Primary Care Using Buprenorphine: Five-Year Experience*, JAMA Network (Mar. 14, 2011), https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/226781 (discussing a program started at Boston Medical Center which used a three-stage model of collaborative care, between nurse care managers and generalist physicians, to treat patients addicted to opioids); *See Opioid Addiction Treatment*, Baltimore City Health Dep't, https://health.baltimorecity.gov/opioid-addiction-treatment (last visited Oct. 22, 2019) (discussing Baltimore City Health Department's use of a combination of MAT, psychosocial support, and wraparound social services).

[105] 497 U.S. 261, 269 (1990).

[106] *Cruzan*, 497 U.S. at 269 (citing Schloendorff v. Society of New York Hospital, 211 N.Y. 125, 129–130 (N.Y. 1914)).

[107] Union Pacific R. Co. v. Botsford, 141 U.S. 250, 251 (1891).

[108] *See* Paula Walter, *The Doctrine of Informed Consent: To Inform or Not to Inform?*, 71 St. John L. Rev. 543, 558 (1997) (explaining that injuries claimed in lack of consent actions arise from a physician's breach of his or her duty to adequately inform the patient).

[109] 464 F.2d 777 (D.C. Cir. 1972).

[110] *Id.* at 780. Sam Roberts, *Jerry Canterbury, Whose Paralysis Led to Informed Consent Laws, is Dead at 78*, NY Times (May 16, 2017). https://www.nytimes.com/2017/05/16/us/jerry-canterbury-medical-consent-paralysis.html.

[111] *Canterbury*, 464 F.2d at 777–80; Roberts, *supra* note 110.

Canterbury, "true consent to what happens to one's self is the informed exercise of a choice, and that entails an opportunity to evaluate knowledgeably the options available and the risks attendant upon each."[112] After this case, the standard for informed consent considers what information was "material to the patient's decision," not what the "medical custom in the community would demand."[113]

If applied correctly in the OUD context, the patient-oriented standard of disclosure expressed in *Canterbury* requires a physician to discuss the effectiveness of both an abstinence program and buprenorphine treatment with his patient.[114] The average patient has little or no medical knowledge, so he typically must rely on his doctor to help him make the best medical decision.[115] This reliance creates obligations for the doctor associated with "fiducial qualities," which include the "duty to reveal to the patient that which in his best interests it is important that he should know."[116]

A physician should inform a patient not only of the risks involved with the proposed treatment, but also of any alternatives that might offer greater benefits than the current treatment.[117] For some patients, B-MAT promises greater results than the abstinence model of treatment, which "has one of the worst success rates in all of medicine."[118] Therefore, doctors should inform each patient about both the risks of abstinence treatment and about more effective treatment alternatives such as B-MAT.[119] Using the reasonable patient standard of informed consent shifts the doctor's focus from playing the role of a paternalistic provider, controlling the care of an untrustworthy and morally flawed patient, to a patient-centered approach that respects the patient's autonomy and his right to self-determination.[120] While OUD patients have become largely accustomed to being "beaten down" and treated as moral failures, it is vital that these patients are treated with respect and afforded the opportunity to make decisions.[121]

While there is a concern that the average patient will be unable to understand his condition and treatment options, *Canterbury* insists that only "the exceptional patient" cannot gain at least a basic understanding of his condition.[122] While the physician's required disclosures need not amount to a "medical education," they must inform the

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112 *Canterbury*, 464 F.2d at 780.

113 *Id.* at 786–87.

114 *Id.*

115 *Id.* at 780.

116 *Id.* at 782 (explaining the difference between contractual and property relations and doctor-patient relationships).

117 *Id.* at 781.

118 Lance Dodds, *Harvard Doctor Debunks 'Bad Science' Behind 12-Step Programs*, Radio Boston (Mar. 31, 2014), http://www.wbur.org/radioboston/2014/03/31/12-step-dodes (noting that the abstinence model is only successful for five to ten percent of patients).

119 *See generally Canterbury*, 464 F.2d (holding that a physician is under a duty to disclose all risks that a reasonable patient would find significant or material in making an informed medical decision).

120 Richard E. Shagrue, *The Practitioner's Guide to Informed Consent*, 24 Creighton L. Rev. 881, 885 (1991).

121 Heimer, *supra* note 15, at 548.

122 *Canterbury*, 464 F.2d at 782 n. 27.

patient about available alternative therapies, discuss the results that the patient can expect to achieve, explain the risks that may ensue from a particular treatment, and highlight the potential consequences of receiving no treatment."[123] Because many OUD patients are desperate by the time they obtain treatment, a doctor must take extra precautions to properly inform these patients.[124] Even though many OUD patients are suffering from severe withdrawal symptoms such as nausea, vomiting, and chills, they are nonetheless capable of giving informed consent.[125]

To establish the ideal doctor-patient relationship, both the doctor and the patient must understand the context of the patient's condition.[126] For example, there is a significant difference in appropriate informed consent for the treatment of a disorder that only the physician can clearly and fully understand, and a condition for which the treatment options and studies detailing the outcomes are readily available to patients.[127] Fortunately, OUD treatments fall in the latter category because patients can easily obtain an accurate comparison of available treatments.[128] While it may be difficult for some patients to understand certain technical aspects of OUD treatments, such as the makeup of a medication or how the medication interacts with the body, most patients can understand the statistical likelihood of success and the steps that each treatment option involves.[129]

OUD treatment is both effective and addresses the treatment gap because physicians can disseminate information about the treatment to the patient.[130] Patients with an existing doctor-patient relationship can extend their care to include OUD by the same physician in a familiar environment.[131] Likewise, patients creating a new doctor-patient relationship can receive treatment by one provider both for their primary care and for their OUD

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[123] *Id.; see also* Stinnett v. Price, 446 S.W.2d 893 (Tex. App. 1969) (finding that a doctor telling a patient that a procedure was more serious than the patient's previous procedure and that the procedure could cause a stroke was sufficient to satisfy informed consent).

[124] *See generally Canterbury*, 464 F.2d at 782. These precautions will be addressed through tailored informed consent requirements in this Article's Resolution.

[125] Edmund Henden, *Heroin Addiction and Voluntary Choice: The Case of Informed Consent*, 27 Bioethics 395, 395–401 (2013).

[126] *See* Susan Dorr Goold & Mack Lipkin, Jr, *The Doctor-Patient Relationship: Challenges, Opportunities, and Strategies,* 14 J. Gen. Internal Med. S26, S29 (1999) (stating that physicians talking critically with their patients is important for a strong doctor-patient relationship).

[127] *Id.* (stating that informed consent requires the doctor to disclose information necessary for the patient to evaluate available options).

[128] *See e.g.*, N-SSATS, *supra* note 96 (comparing information on mechanisms, phases or treatment, adverse side-effects, and availability of OUD treatments).

[129] *Canterbury,* 464 F.2d at 782.

[130] *See Office-Based Opioid Use Disorder Treatment: A Reference Guide for Family Medicine Physicians,* Nat. Inst. on Drug Abuse, http://www.familydocs.org/wp-content/uploads/2019/06/infographic-office-based-opioid-use.pdf (last visited Oct. 7, 2019) (reporting that Office-Based Opioid Treatment works for 50–80 percent of patients) [hereinafter NIDA].

[131] *See* Leslie R. Martin et al., *The Challenge of Patient Adherence* 3 Therapeutics & Clinical Risk Mgmt. 189, 192–93 (2005) (stating that familiarity between the doctor and patient improves patient outcomes).

needs, as long as the provider is qualified to prescribe buprenorphine.[132] Strengthening these supportive relationships will help overcome patient resistance to treatment.

C. The Role of Hospitals and Treatment Centers in Providing Institutional Support to Doctors and Information to OUD Patients

A treatment center should ensure that its service delivery is aligned with the best treatment options for the community and that its providers inform patients of the alternative treatments available and the risks and benefits of each treatment.[133] As the court noted in *Darling v. Charleston Community Memorial Hospital*,[134] the patient who enters a hospital for treatment expects that the hospital will attempt to cure his condition, not that its employees will "act on their own responsibility."[135] Similarly, in *Thompson v. Nason Hospital*,[136] a case in which a patient recovered against a hospital because of the hospital employees' negligent acts, the court held that a hospital could be held liable for corporate liability if it "fails to uphold the proper standard of care owed [to its] patient."[137] Under *Thompson*, a hospital has a duty to maintain safe facilities, employ and retain competent physicians, oversee physicians who practice medicine in the hospital, and formulate, adopt, and enforce adequate rules.[138]

Applying *Thompson* to the OUD epidemic, facilities that fail to oversee their providers or to "formulate, adopt, and enforce adequate rules" would be subject to legal ramifications.[139] Treatment facilities should not be able to ignore current research-backed best practices. Current prescription policy does not provide resources or institutional support for providers who want to prescribe MAT.[140] This lack of support for MAT providers is a noted reason for doctors not seeking to become authorized to provide MAT, or becoming authorized but not fully utilizing the authorization by prescribing to fewer patients than permitted.[141]

Research shows that educating doctors and patients improves treatment outcomes; therefore, institutional support for OUD treatment facilities is crucial in improving patients' chances of successful rehabilitation.[142] Specific training regarding medication

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[132] *Id.*

[133] *See* Magana v. Elie, 439 N.E.2d 1319, 1321 (Ill. App. Ct. 1982) (stating that the duty of a hospital includes the duty to "conform to the legal standard of reasonable conduct in light of the apparent risk").

[134] 211 N.E.2d 253 (Ill. 1965).

[135] *Id.* at 257.

[136] 591 A.2d 703 (Pa. 1991).

[137] *Id.* at 707.

[138] *Id*.

[139] *Id.*

[140] *See* Haffajee, *supra* note 38, at S230.

[141] *Id*.

[142] *See* Amanda J. Abraham et al., *Counselor Attitudes Toward Pharmacotherapies for Alcohol Dependence*, 70 J. Stud. Alcohol & Drugs 628, 628 (2009) (arguing that treatment methods outside of the dominating twelve-step program including counseling and patient education have effective results).

use and observation of that use leads to significant changes in counselors' perceptions of the effectiveness and acceptability of the medications available for the treatment of substance use disorders.[143]

The authors of *Using Medication-Assisted Treatment for Substance Use Disorders: Evidence of Barriers and Facilitators of Implementation* note that a significant number of physicians currently involved with treatment programs are not prescribing buprenorphine.[144] According to them, of those with physician access, forty-nine percent among private sector programs and sixty-seven percent among public programs did not prescribe buprenorphine.[145] Additionally, the authors note that the public knows very little about buprenorphine and other substance use disorder medications.[146] They hypothesize that if more information was given to the public regarding buprenorphine, its demand would also increase, thus increasing buprenorphine's availability at public treatment centers.[147]

As mainstream facilities, such as Massachusetts General Hospital, Johns Hopkins, and Yale New Haven Hospital,[148] start implementing MAT, other hospitals will likely follow.[149] Because of the prestige of these hospitals, patients, the general public, and other hospitals are likely to learn about the procedures and practices these facilities implement.[150] As more hospitals and facilities integrate and implement these new procedures that larger hospitals have had success with, the standards of communities across the country will begin to change.[151] The pressure to follow community standards and the demand for optimal treatment will make it increasingly difficult for facilities to continue to promote outdated models of treatment.

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143 *Id.* at 634 (discussing a survey showing that "those who had been directly exposed to training on buprenorphine were significantly more likely to rate it as effective and as acceptable for their patients").

144 Paul M. Roman et al., *Using Medication-Assisted Treatment for Substance Use Disorders: Evidence of Barriers and Facilitators of Implementation*, 36 Addictive Behaviors 584, 588 (2011); Huhn & Dunn, *supra* note 91, at 2.

145 Roman, *supra* note 144, at 588.

146 *Id*.

147 *Id*.

148 Martha Bebinger, *MGH Becomes 1st Mass. ER to Offer Addiction Medication Maps Seamless Path to Recovery*, CommonHealth (Mar. 7, 2018), http://www.wbur.org/commonhealth/2018/03/07/mgh-addiction-medication.

149 *Id.*; *see Breaking the Cycle of Opioid Dependence*, Johns Hopkins Ctr. Innovative Med., http://www.hopkinscim.org/breakthrough/holiday-2017/breaking-cycle-opioid-dependence; Abby Goodnough, *This ER Treats Opioid Addiction on Demand That's Very Rare*, NY Times (Aug. 18, 2018), https://www.nytimes.com/2018/08/18/health/opioid-addiction-treatment.html; *see also* Gail D'Onofrio et al., *Emergency Department-Initiated Buprenorphine/Naloxone Treatment for Opioid Dependence*, 313 Jama Network 1636, 1636–44 (2015) (stating that testing this MAT treatment shows positive results but needs to be replicated before wide usage).

150 Bebinger, *supra* note 148.

151 *Id.*

D. Unfair Business Practices and False Advertising by OUD Treatment Facilities

Unfair business practices used by OUD treatment facilities also contribute to the treatment gap.[152] There are many documented accusations alleging that OUD treatment facilities make false claims about their services.[153] Since the FTC has the authority to prohibit "unfair or deceptive acts or practices," it also has a responsibility to protect patients from unfair business practices that jeopardize public health.[154] The agency has already taken action by issuing warning letters to multiple marketers and distributors who were making false claims about their opioid cessation products.[155] Additionally, the FTC has worked with SAMHSA to better inform patients who were misguided by false claims about MAT,[156]and the agency provides other resources to help those in need get the "right" help for addiction and withdrawal.[157]

States also have the power to regulate physician advertising that is "false, fraudulent, deceptive . . . misleading," or that "tends to injure the public by lowering or demoralizing professional standards."[158] Amid the current opioid epidemic, states have a legitimate interest in promoting the public health and safety of their residents; thus, states can regulate misleading medical advertising to protect their residents from suffering health consequences as a result of such advertisements.[159]

Similarly, medical associations play a role in ensuring that physicians do not mislead or deceive patients. The American Medical Association (AMA) provides ethical standards for physician advertising and states that advertising should be "explicitly and implicitly truthful and not misleading."[160] Further, the American Osteopathic Association warns against deceptive statements that are "likely to lead a patient to a misinformed choice

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[152] *See e.g.,* Andersen, *supra* note 12 (reporting that certain treatment facilities claim to treat OUD addiction without the use of MAT prescriptions).

[153] *E.g., Tennessee Substance Abuse Treatment Facility Agrees to Resolve False Claims Act Allegations for $9.25 Million,* DOJ (Apr. 16, 2014), https://www.justice.gov/opa/pr/tennessee-substance-abuse-treatment-facility-agrees-resolve-false-claims-act-allegations-925; Jeff Blumenthal, *Montco Hospital Pays $2.85M to Settle Allegations From Whistleblower,* Phila. B. J. (Jul. 24, 2019, 2:56 PM), https://www.bizjournals.com/philadelphia/news/2019/07/24/montco-hospital-pays-2-85m-to-settle-allegations.html.

[154] 15 U.S.C. § 45(a)(1) (2012). *FTC, FDA Warn Companies about Marketing and Selling Opioid Cessation Products,* FTC (Jan. 24, 2018), https://www.ftc.gov/news-events/press-releases/2018/01/ftc-fda-warn-companies-about-marketing-selling-opioid-cessation.

[155] *Id.*

[156] *Getting the Right Help for Opioid Dependence or Withdrawal*, FTC: Consumer Info. (Jan. 24, 2018) https://www.consumer.ftc.gov/articles/0223-getting-right-help-opioid-dependence-or-withdrawal (stating that "[p]atients receiving FDA-approved medication-assisted treatment cut their risk of death in half, according to SAMHSA").

[157] *Id.*

[158] 61 Am. Jur. 2d *Physicians, Surgeons, and other Healers* § 13 (1981).

[159] *Cf.* Chen, *supra* note 19 (reporting the cost of the opioid epidemic and the projected increase of the cost in the coming years).

[160] *AMA Code of Medical Ethics*, Am. Med. Ass'n, https://www.ama-assn.org/topics/ama-code-medical-ethics.

and unjustified expectations."[161] OUD patients are accustomed to being beaten down, and they may be desperate for any type of treatment, making them more vulnerable and susceptible to misleading advertisements or statements.[162] Therefore, OUD providers should exercise extra care when making statements or advertising treatment outcomes, and should be held accountable for the impacts of such statements.

Similarly, medical boards should ensure that providers are informing their patients of all available treatments, especially those with lifesaving potential. In its Model Policy for Opioid Treatment, the Federation of State Medical Boards recognized that treatment with medication should be considered for every OUD patient.[163] Because of the current treatment gap and the projected increase in deaths from OUD, there is a need for informed consent that takes the dynamics of an OUD patient into consideration.[164]

III. BEST PRACTICES FOR OBTAINING INFORMED CONSENT FROM OUD PATIENTS

As standards for informed consent and the physician-patient relationship have evolved, the current OUD treatment dynamic clearly demonstrates the ongoing conflict between physician paternalism and patient autonomy.[165] The treatment of OUD patients with B-MAT represents a unique test case for informed consent because of the potential therapeutic value it may bring to a patient group that has historically been discriminated against.[166] In this setting, a mutual provider-patient decision, which once seemed inconceivable, may now be a possible end goal of the use of informed consent to treat the OUD patient.[167]

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[161] *AOA Interprets Code of Ethics,* Am. Osteopathic Ass'n, https://osteopathic.org/about/leadership/aoa-governance-documents/code-of-ethics/aoa-interprets-sections-of-code-of-ethics-1996-present.

[162] Jake Harper, *Addiction Clinics Market Unproven Treatment to Desperate Patients*, ABC News (Aug. 27, 2019), https://abcnews.go.com/Health/addiction-clinics-market-unproven-treatments-desperate-patients/story?id=65203013.

[163] *See Model Policy on DATA 2000 and Treatment of Opioid Addiction in the Medical Office*, Fed'n State Med. Boards 7 (2013), http://www.fsmb.org/siteassets/advocacy/policies/model-policy-on-data-2000-and-treatment-of-opioid-addiction-in-the-medical-office.pdf (stating that under this model, providers are not required to inform patients of MAT options) [hereinafter *Model Policy*].

[164] *See* Chen, *supra* note 19, at 8 (predicting that the annual number of opioid overdose fatalities in the United States will reach over eighty-one thousand by 2025).

[165] *See* Robert Walker et al., *Informed Consent to Undergo Treatment for Substance Abuse: A Recommended Approach*, 29 J. Substance Abuse Treatment 241, 246 (2015) (attributing the difficulty to "a lack of clear and distinct substance abuse treatment procedures"). The extensive outcomes research in this area helps address the historic dilemma of balancing patient autonomy against physician decision-making. Research results in this area help guide both patients and care providers.

[166] *Id.*

[167] Salgo v. Leland Stanford Jr. Univ. Bd. of Trustees, 317 P.2d 170 (Cal. Ct. App. 1957). Justice Bray, writing for the California District Court of Appeals in his *Salgo v. Leland Stanford, Jr., University Board of Trustees* opinion used both the term "full disclosure" and the term "discretion" in the same sentence describing informed consent under the category of "duty to disclose." *Id.* at 181. Subsequently, Katz has pointed out that this combination is very difficult and that the central problem of true informed consent is the conflict between "patient self-determination" and

Because of the life-and-death ramifications of the current treatment environment,[168] a clear definition of informed consent is important for the development of the provider-OUD patient relationship. Perhaps a tailored definition would later become applicable to other areas of medicine, but as Jay Katz has suggested, informed consent could contain different specifications for different categories of cases.[169]

A. Scope and Timing

These proposed best practices should be implemented whenever a patient enters care for OUD. Anytime that a prospective OUD patient seeks advice or treatment from a medical provider, and the provider in turn agrees to render such advice or treatment, the provider-OUD patient relationship is created.[170] With the existence of such a relationship, informed consent for the provider-OUD patient relationship is applicable.

The scope of application for these best practices should include, but is not limited to, the four points where OUD patients typically enter care: primary care providers (such as family practice providers, internists, and gynecologists);[171] behavioral health facilities (such as Universal Health Services ("UHS") and mental health units within general hospitals);[172] commercial addiction treatment centers (such as Passages Malibu);[173] and emergency rooms and urgent care centers.[174]

B. The Treatment Agreement Requirement

At the outset of the provider-OUD patient relationship, the OUD patient should receive a written contract ("treatment agreement") that outlines the available treatments for OUD and clarifies the patient's right to be informed about each of the available treatments before deciding whether to be treated.[175] Contracts are not a foreign concept in the treatment of OUD.[176] Unfortunately, OUD patients typically do not have the

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"physician paternalism." Jay Katz, *Informed Consent- A Fairy Tale? Law's Vision*, 39 U. Pitt. L. Rev. 137, 138 (1977).

168 *See generally* Chen, *supra* note 19 (concluding that under the status quo, the number of opioid overdose deaths is projected to continue to increase).

169 *See* Katz, *supra note* 167, at 173.

170 61 Am. Jur. 2d *Physicians, Surgeons, and Other Healers* § 130 (2019).

171 *Primary Care*, Am. Acad. Fam. Physicians, https://www.aafp.org/about/policies/all/primary-care.html (last visited Sept. 16, 2019).

172 *See generally Behavioral Health*, Universal Health Serv., https://www.uhsinc.com/about-uhs/behavioral-health (last visited Sept. 16, 2019) (providing an overview of universal health services).

173 *Our Philosophy*, Passages Malibu, https://passagesmalibu.com/philosophy/the-four-causes-of-addiction (last visited Nov. 2, 2019).

174 Goodnough, *supra* note 149.

175 *See TIP 63: Medications for Opioid Use Disorder Part 5: Resources Related to Medications for Opioid Use Disorder for Healthcare and Addiction Professionals, Policymakers, Patients, and Families*, SAMSHA, 52–53, https://store.samhsa.gov/system/files/sma18-5063pt5.pdf. The first two statements in the sample treatment agreement ensure that the risks and benefits of alternate treatments are explained to the patient. *Id*.

176 *See id.*; *see also Sample Treatment Agreement,* ASAM, https://www.asam.org/docs/default-source/advocacy/sample-treatment-agreement30fa159472bc604ca5b7ff000030b21a.pdf?sfvrsn=bd4675c2_0 [hereinafter *Sample Treatment Agreement*].

opportunity to analyze treatment options at the outset, but instead receive a written contract explaining potential side effects of the medication only after choosing to pursue B-MAT.[177] Use of a contract at the formation of the provider-OUD patient relationship narrows the treatment gap by informing patients of all alternative options for OUD treatment and places the patient in the position to make an informed decision.

In the same way that patients are informed about the risk of death from mixing buprenorphine with benzodiazepines, the need for additional counseling, and the lack of a fixed time for the completion of treatment, they should be made aware of the potential positive outcomes of treatment with buprenorphine.[178] This disclosure should be made at the formation of the relationship, simultaneously with the disclosure of potential outcomes of alternative treatment methods.[179] The distribution and execution of a treatment agreement at the beginning of the relationship allows the patient to see the "big picture" and to choose a path based on his own personal preferences and needs.[180]

Before deciding on a treatment method, the patient should sign the treatment agreement, which should state that the provider has informed her of the associated risks and possible alternative treatment options.[181] The treatment agreement should specifically mention those alternative options and include a description of the available outcome-based research and government funded resources.[182]

C. Methods of Informing Patients of Available Treatment Alternatives

The provider should disclose "medically reasonable alternative" treatments[183] by either discussing the specific results of outcome-based research and the government funded resources that are available, or providing those materials for the patient to read on his own.[184] If the provider chooses to provide the materials to the patient, the provider should offer to discuss any questions that the patient has about the material.[185] This approach also allows the patient an opportunity to reflect and make an informed decision.[186]

Providers should be aware of potential litigation that they could be subject to if they fail to inform patients of medication-assisted treatment options.[187] Although settled outside of court, *Osheroff v. Chestnut Lodge*,[188] a case in which a provider relied solely

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177 *Id.*

178 *Id.*

179 *See supra* notes 117–119 and accompanying text.

180 *See generally Sample Treatment Agreement*, supra note 176.

181 *Id.*

182 *Id.*

183 Matthies v. Mastromonaco, 733 A.2d 456, 457, 457 (N.J. 1999).

184 *TIP 63: Medications for Opioid Use Disorder Part 2: Addressing Opioid Use Disorder in General Medical Settings For Healthcare Professionals*, SAMSHA, 17–18, https://store.samhsa.gov/system/files/sma18-5063pt2.pdf [hereinafter *TIP 63*].

185 *Id.* at 18.

186 *Matthies*, 733 A.2d at 462–64.

187 *Osheroff v. Chestnut Lodge Inc.*, 490 A.2d 720 (Md. App. 1985).

188 490 A.2d 720 (Md. App. 1985).

on psychotherapy in treating a patient suffering from depression, invited an influx of malpractice claims on the basis of providing treatment without medication when medication was available.[189] Treatment facilities should ensure that providers inform patients about available medications even if the facility does not offer medication-assisted treatment. Providers should be ready to inform a patient when the patient can receive medication-assisted treatment and of alternate locations that offer MAT.

D. The Decision-Making Process

i. The Patient-Centered Approach

A "patient-centered approach," in which the patient is an active participant, is critical to the provider-OUD patient relationship.[190] While providers often adopt a paternalistic approach with OUD patients, due to preconceived notions that the patient has a history of poor judgement, the best treatment for a patient requires respecting the patient's autonomy and freedom by allowing the patient to choose from treatment options as shown through the tenets of motivational interviewing.[191] A patient with a broken leg, for example, may not need to feel central in his treatment decision-making process¾he would just prefer the best available treatment. However, with the unique treatment of OUD, the patient-centered approach may be instrumental. Under this approach, "the physician tries to enter the patient's world, to see the illness through the patient's eyes."[192]

Physicians should adopt motivational interviewing techniques to help facilitate the use of informed consent. Through motivational interviewing, an empathetic, "client-centered counseling style for eliciting behavior change," patients play an active role in their healing.[193] One of the basic principles of motivational interviewing is acceptance, which involves "honoring and respecting each person's autonomy, their irrevocable right and capacity of self-direction."[194] Providers who incorporate motivational interviewing into their practice should inform the patient of the available treatment options, place the patient in the decision-making position, and listen to and empathize with him so that he has the best chance to get the most effective treatment.

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189 *Id.*

190 *See generally* Ronald M. Epstein & Richard L. Street, *The Values and Value of Patient Centered Care*, 9 Annals Fam. Med. 100, 100–03 (2011) (stating that "[p]atient-centered care is a quality of personal, professional, and organizational relationships").

191 *See generally* William R. Miller & Stephen Rollnick, Motivational Interviewing: Helping People Change (3rd ed. 2013) (discussing motivational interviewing, a counseling style in which health care professionals work with patients faced with behavioral changes to encourage them to incorporate lifestyle modifications to prevent disease complications and alleviate their symptoms).

192 Ian R. McWhinney, *The Need for a Transformed Clinical Method*, *in* Stewart M. & Roter D., Communicating With Medical Patients 111 (1989).

193 Stephen Rollnick and William R. Miller, *What is Motivational Interviewing?*, 23 Behavioral and Cognitive Psychotherapy, 325–34 (1995), https://doi.org/10.1017/S135246580001643X.

194 Miller & Rollnick, *supra* note 191, at 18.

ii. Elimination of Bias

What a provider believes is the best treatment method should be irrelevant to the determination of which alternatives should be disclosed. The provider should, in an unbiased fashion, discuss treatment alternatives based on available research.[195] Informed consent has the potential to transform the doctor-OUD patient relationship because of the therapeutic value that patients may receive from being closely involved in their own decision-making.[196] Informed consent "forces the therapist to examine his biases in regard to valuing his system over other available systems," which causes the therapist to "join the patient in the major therapeutic task of searching out distortions and misperceptions."[197] This "mutual participation" has been shown to curb the tendency toward a "one-size-fits-all treatment."[198]

iii. Providers Must Offer Advice, Not Make the Patient's Decision

The provider must use his knowledge of the patient's situation to assist the patient in making an informed decision, but the provider should be careful not to make the choice for the patient.[199] Through motivational interviewing and a strong OUD provider-patient relationship, the provider learns information unique to the patient.[200] Using this information, the provider can advise the patient without steering him or effectively making a decision for him.[201] The provider is in the best position to weigh the risks and benefits because of the provider's knowledge about the patient's situation.[202]

iv. No Therapeutic Privilege Not to Disclose Alternative Treatments

The "therapeutic privilege not to disclose"[203] should not be used with the treatment of OUD patients because the disclosure of options and the patient decision are significant

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195 *TIP 63: Medications for Opioid Use Disorder Part 3: Pharmacotherapy for Opioid Use Disorder for Healthcare Professionals*, SAMSHA, 9, https://store.samhsa.gov/system/files/sma18-5063pt3.pdf.

196 *See* Gerald Epstein, *Informed Consent and the Dyadic Relationship*, 6 J. Psychiatry & L. 359, 361 (1978) (asserting that discussing the risks and alternatives of treatment options with a patient acknowledges that he or she is capable of making appropriate decisions and thus "promotes an important shift in therapeutic focus") .

197 *Id.* at 362.

198 *See Substance Abuse Counseling Techniques*, DrugRehab.com (June 4, 2018), *https://www.drugrehab.com/treatment/types-of-therapy* (noting that therapy is not a one-size-fits-all process because different approaches are often effective for different patients).

199 *See* Matthies v. Mastromonaco, 733 A.2d 456, 462–63 (N.J. 1999) (stating that "[p]hysicians may neither impose their values on their patients nor substitute their level of risk aversion for that of their patients").

200 *See generally* Miller & Rollnick, *supra* note 191.

201 *Matthies*, 733 A.2d at 462.

202 *See* Walls v. Alpharma USPD, Inc., 887 So. 2d 881, 883 (Ala. 2004) (describing the doctor as a "learned intermediary" between the patient and the pharmacy because of the doctor's medical knowledge and understanding of his patient).

203 *See* Matthew Wynia, *Invoking Therapeutic Privilege*, AMA J. Ethics (Feb. 2004), https://journalofethics.ama-assn.org/article/invoking-therapeutic-privilege/2004-02 (stating that "[t]herapeutic privilege is an exemption from informed consent guidelines and is, most would say, a frank exercise of paternalism. The AMA *Code of Medical Ethics* says that physicians may withhold

components of a recognized treatment method (e.g. motivational interviewing) for the OUD patient.[204] Additionally, unlike many illnesses, treatment information is readily available in patient-readable formats through sources such as the HHS and SAMHSA (e.g., Treatment Improvement Protocol 63 ("TIP 63"), a document that reviews the use of FDA approved medications used to treat opioid use disorder).[205] When a potentially lifesaving decision is at hand, the importance of the decision likely outweighs any reason to forego full discussion of alternative treatments.

v. Mutual Decision-Making and Participation

The struggle between autonomy and paternalism should be met with mutual decision-making, which may not be possible in some areas of medicine.[206] In the OUD context, research provides a clear picture of available alternatives, and a doctor should effectively communicate those alternatives.[207] Providers should build an environment in which true decision-making can occur and the doctor's expertise is valued and weighed, but the patient holds the ultimate decision-making authority.

Ideally, the provider and patient assess the likelihood of success together and mutually decide the best course of treatment.[208] Katz identified several factors as impediments to a patient's self-determination, two of which include the doctor's valuable time and the patient's limited medical knowledge.[209] These two problems can be alleviated through the distribution of materials that are easy to understand that the patient can read on his own time.

Instead of using short-term objective management, the provider-OUD patient relationship requires communication of the patient's feelings and a discussion of his triggers so that the physician can better understand the patient's motivations for treatment.[210] To facilitate the formation of a trusting provider-patient relationship, a provider should, when possible, learn about the patient's background to offer optimal advice about a full treatment plan.[211] A comprehensive plan may incorporate recommendations on how to

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information about a patient›s diagnosis or treatment when disclosing it would pose a serious psychological threat, so serious a threat as to be medically contraindicated. But, the *Code* opinion continues, this privilege is not to be used merely because a physician thinks the information, if disclosed, might cause the patient to forgo needed treatment. Competent patients retain the right to refuse treatment and must be given as much information as necessary to help them make informed decisions about consent or refusal.").

[204] *Id.*

[205] *Medications for Opioid Use Disorder*, SAMHSA, https://store.samhsa.gov/system/files/sma18-5063fulldoc.pdf (last accessed Dec. 15, 2019).

[206] *See e.g.,* Wynia, *supra* note 203.

[207] *Medications for Opioid Use Disorder, supra* note 205.

[208] *See e.g., TIP 63*, *supra* note 184, at 18–19 (discussing tips for shared decision making).

[209] Katz, *supra* note 167, at 139.

[210] *See Medications for Opioid Use Disorder, supra* note 205, at 2–8 (suggesting motivational doctor-patient interventions to "promote safer behavior and foster effective treatment engagement").

[211] *See Washington v. Glucksberg*, 521 U.S. 702, 779 (1997) (Souter, J., concurring) (stating that "[t]his idea of the physician as serving the whole person is a source of the high value traditionally placed on the medical relationship.")

avoid triggering situations, or advice to seek outside counseling when doing so would benefit the patient.[212]

A joint provider-patient decision is especially important in the treatment of the OUD patient because of OUD's classification as a chronic condition.[213] The patient's active participation in his own care is essential for successful treatment, as daily medicines and frequent counseling are usually required.[214] This unique provider-OUD patient relationship contrasts significantly with the short-term management of such emergency events as cardiac arrest or trauma.[215]

vi. Honest Communication

A strong provider-OUD patient relationship encourages patients to be honest and disclose to the physician when they fail to meet the treatment guidelines. The provider will be in the best position to detect the patient's failure and help the patient take appropriate steps to move forward with the treatment.[216] Because of the nature of the relationship, a patient trusts that his provider has his best interests in mind and he feels more comfortable disclosing sensitive information, even when the information may elicit negative consequences.[217]

vii. "Reasonable Patient" and "Specific Patient" Standards

A provider should tell an OUD patient all information that a reasonable patient would consider important in making a treatment decision and information that the provider knows that the specific patient would consider important.[218] However, a patient has the right to choose any treatment option, including no treatment at all.[219] While it seems that requiring "truly informative" informed consent closes the treatment gap, a provider's respect for patient autonomy allows for patients to decide not to accept treatment even when fully informed.[220]

Patients cannot have autonomy when they are uninformed. Katz argues that the reasonable patient standard may "abrogate the very right at issue in cases of informed consent," which he alleges is "the right of the individual choice;" however, the reasonable patient standard is used to convince providers to thoroughly inform patients because providers are bound to inform patients of all information that a reasonable patient would find important in making a treatment decision.[221] A reasonable patient likely finds information about the most successful treatment for a life-threatening condition

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212 *See Medications for Opioid Use Disorder, supra* note 205 (stating that patients can benefit from "individual psychosocial supports").

213 ASAM, *supra* note 77.

214 *TIP 63*, *supra* note 184.

215 *Id*.

216 *Id.*

217 *See generally* Miller & Rollnick, *supra* note 191.

218 Canterbury v. Spence, 464 F. 2d. 772, 780 (1972).

219 *Id.*

220 *Id.* at 782.

221 Katz, *supra* note 167, at 164.

important in making a treatment decision.[222] Further, if a provider has reason to believe that a specific patient would find the information important in making a decision, the provider must also inform that patient of such information.[223] This standard forces providers to think through the eyes of the patient and encourages the provider to develop an understanding of the patient's perspective.

E. Business Practices, Advertising, and Facility Responsibility

i. Extension of Liability to Facilities

Informed consent requirements extend to hospitals and treatment centers.[224] To the extent that false advertising and unfair business practices still exist, providers should be aware of the role that states, medical associations, and government agencies play in regulating false or misleading statements about the effectiveness of OUD treatment methods.[225] Facilities must play an active role in promoting the best treatment options through the distribution of accurate and non-deceptive materials.[226]

ii. Disclosure of Treatments Not Offered at the Facility

As community standards improve, businesses and facilities should implement the treatments that have proved most effective through outcomes research. To the extent that the facility is unable to implement those treatments, the providers at the facility are obligated to inform patients of the effectiveness of the alternate treatments not offered at that facility and allow and encourage the patient to consider the possibility of receiving that treatment elsewhere.[227]

iii. Scope of Application

Informed consent should apply to non-physician providers in the OUD setting. It is understood that OUD treatment involves not only medication, but also some sort of counseling in many cases.[228] Further, for prescribers to receive authorization they must attest that they have access to counseling resources.[229] Often, counseling resources will occur through a prescriber's referral, and such resources will be provided by outside psychologists, social workers, or other providers.[230] Because of the important role of

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222 *Canterbury*, 464 F.2d at 782.

223 *Id*.

224 Keel v. St. Elizabeth Medical Center, 842 S.W.2d 860, 861–62 (Ky. 1992) (explaining that under KRS 304.40-320, "health care providers," including hospitals have a duty to inform patients).

225 *See supra* notes 160–161 and accompanying text.

226 *See supra* notes 160–161 and accompanying text.

227 *TIP 63*, *supra* note 184, at 17–18.

228 *TIP 63: Medications for Opioid Use Disorder Part 4: Partnering Addiction Treatment Counselors with Clients and Healthcare Professionals*, SAMSHA, 4-1, https://store.samhsa.gov/system/files/sma18-5063pt4.pdf.

229 *30–100 Patient Limit, supra* note 9 ("physicians must attest that they have the capacity to refer addiction treatment patients for appropriate counseling and other non-pharmacologic therapies").

230 *Id.*; *see also* Elyn R. Saks & Shahrokh Golshan, Informed Consent to Psychoanalysis: The Law, the Theory, and the Data (2013).

non-physician providers in OUD treatment, it is critical that these providers are aware of and prepared to support a patient's decision to receive medication-assisted treatment. To be able to inform patients in an honest and ethical manner, these non-physician providers need to be informed of treatments and prepared to confront their own biases so that they do not undermine medication treatment. Across the nation there are various state laws that discuss informed consent standards for psychologists, social workers, and other providers, so informed consent is not limited to physicians. [231]

CONCLUSION

The unfortunate reality of the current status of B-MAT treatment is that scientific and medical research is seemingly ignored because of the existing bias against OUD patients.[232] The benefits of informed consent could be portrayed through B-MAT treatment if the informed consent requirement is consistently enforced.[233] While new challenges regarding B-MAT may arise in the future, or a new treatment option may become available, the use and enforcement of informed consent is crucial to the narrowing and elimination of the treatment gap.

Because of the unique factors related to the OUD epidemic, specialized informed consent requirements should be implemented for the provider-OUD patient relationship. Before addressing regulations at the top level or deciding which treatment program is optimal, it is imperative that OUD patients are placed in the decision-making position and fully informed of all available treatments. As these patients learn about the comparative success of B-MAT, the disparity of the current treatment gap will become apparent. Legislators will be compelled to act and facilities will be forced to confront the research-backed best practices and adapt to the demand for implementation of such practices.

By trusting OUD patients to make decisions and to control their own treatments and futures, a strong provider-patient relationship will overcome the biases of the community and penetrate all models of OUD treatment. The past moral choices of a patient should have no bearing on the duties of a provider treating that patient. Whenever a provider-OUD patient relationship is formed, the OUD patient should be informed of the available treatment options¾not guilted into choosing an outdated, unsuccessful program that offers little chance of success.[234]

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[231] Social workers and psychologists are often involved with assessment, counseling, and formulating treatment plans, and these are non-invasive components of OUD treatment. *See* Saks & Golshan, *supra* note 230. Informed consent applies to non-invasive treatments. For example, in *Matthies*, where a patient sued her physician for failing to inform her of the potential effects of a procedure on her quality of life, the Supreme Court of New Jersey held that informed consent applied "even when the course of a treatment implemented by the physician is non-invasive." Matthies v. Mastromonaco, 733 A.2d 456, 456–58 (N.J. 1999).

[232] *See* Heimer, *supra* note 15, at 548 (pointing out the common misconception which views addiction as a moral failure, despite scientific evidence to the contrary).

[233] *Id.* at 549.

[234] Ethridge, *supra* note 21 (citing Lindsey Vuolo's finding that many centers do not offer any medication assisted treatment even though 50% of patients are successfully treated with medication assisted treatment compared to a less than 10% success rate for those treated without medication).

While this Article specifically examines the important role of informed consent in the doctor-OUD patient relationship, the principles of patient autonomy apply broadly to patient care. Healthcare is a dynamic field.[235] Diseases and their prevalence change with time as available information and treatments evolve.[236] A strong provider-patient relationship is an important foundation in any patient care.

[235] John G. Liebler & Charles R. McConnell, Management Principles for Health Professionals: The Dynamic Environment of Healthcare, 1–2 (7th ed. 2016).

[236] *Id.*

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