

2020

Buprenorphine: Medication-Assisted Treatment: The Role of Informed Consent

John Tyler Stocking

University of Louisville Brandeis School of Law

Follow this and additional works at: <https://digitalcommons.wcl.american.edu/hlp>



Part of the [Health Law and Policy Commons](#)

Recommended Citation

Stocking, John Tyler (2020) "Buprenorphine: Medication-Assisted Treatment: The Role of Informed Consent," *Health Law and Policy Brief*. Vol. 14 : Iss. 1 , Article 3.

Available at: <https://digitalcommons.wcl.american.edu/hlp/vol14/iss1/3>

This Article is brought to you for free and open access by Digital Commons @ American University Washington College of Law. It has been accepted for inclusion in Health Law and Policy Brief by an authorized editor of Digital Commons @ American University Washington College of Law. For more information, please contact kclay@wcl.american.edu.

BUPRENORPHINE MEDICATION-ASSISTED TREATMENT: THE ROLE OF INFORMED CONSENT

*John Tyler Stocking**

TABLE OF CONTENTS

INTRODUCTION	29
I. BACKGROUND	31
A. History of Drug Regulation	31
B. Statistics	35
C. Treatment Options	37
II. ANALYSIS	38
A. The Current OUD “Treatment Gap”	38
B. The Doctor-OUD Patient Relationship and the Role of Informed Consent	40
C. The Role of Hospitals and Treatment Centers in Providing Institutional Support to Doctors and Information to OUD Patients	43
D. Unfair Business Practices and False Advertising by OUD Treatment Facilities	45
III. BEST PRACTICES FOR OBTAINING INFORMED CONSENT FROM OUD PATIENTS	46
A. Scope and Timing	47
B. The Treatment Agreement Requirement	47
C. Methods of Informing Patients of Available Treatment Alternatives	48

* John Tyler Stocking, J.D. Candidate, University of Louisville Brandeis School of Law, 2020; B.A., Union University, 2016. The author would like to thank Professor Leslie W. Abramson for his advice and mentorship through the writing process. The author also wishes to thank his wife, Emily K. Stocking, for her unwavering and reassuring love and encouragement, and his mother, Pamela R. Stocking, for her consistent and endless support. The author dedicates this article to his father, John E. Stocking, for seeing the value of each individual—for listening first and then spending countless hours searching for solutions. Finally, the author would like to thank the editors and staff of the *Health Law & Policy Brief* for their efforts in editing this article.

D. The Decision-Making Process.....	49
i. The Patient-Centered Approach.....	49
ii. Elimination of Bias	50
iii. Providers Must Offer Advice, Not Make the Patient’s Decision	50
iv. No Therapeutic Privilege Not to Disclose Alternative Treatments	50
v. Mutual Decision-Making and Participation.....	51
vi. Honest Communication	52
vii. “Reasonable Patient” and “Specific Patient” Standards.....	52
E. Business Practices, Advertising, and Facility Responsibility	53
i. Extension of Liability to Facilities	53
ii. Disclosure of Treatments Not Offered at the Facility	53
iii. Scope of Application.....	53
CONCLUSION.....	54

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

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 Moffett 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-OD patient relationship is patient discrimination; doctors often see OD 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 OD 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-OD patient relationship. Regardless of the existing bias, OD patients should have the right to self-determination.¹⁸

Given its life-and-death ramifications, OD 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

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-address-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

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

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-us-canada (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/2108cfr.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 Commission⁴⁶ 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

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

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 have 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 fivefold/nearly 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 infections⁶⁵

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/wnk/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 Ahrensbrak 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

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://www.dasis.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/doi/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

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 Therapies/Tackling 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 (OTP) 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

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

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-OD 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 OD patients, a wider variety of effective treatment options will be available.

B. The Doctor-OD 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

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 OD); 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

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-dodds> (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

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

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.

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.hopkinscm.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

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

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-OD 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 OD. Anytime that a prospective OD patient seeks advice or treatment from a medical provider, and the provider in turn agrees to render such advice or treatment, the provider-OD patient relationship is created.¹⁷⁰ With the existence of such a relationship, informed consent for the provider-OD patient relationship is applicable.

The scope of application for these best practices should include, but is not limited to, the four points where OD 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-OD patient relationship, the OD patient should receive a written contract (“treatment agreement”) that outlines the available treatments for OD 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 OD.¹⁷⁶ Unfortunately, OD patients typically do not have the

“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-OD patient relationship narrows the treatment gap by informing patients of all alternative options for OD 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” treatments¹⁸³ 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

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-ODD patient relationship.¹⁹⁰ While providers often adopt a paternalistic approach with ODD 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 process³⁴he would just prefer the best available treatment. However, with the unique treatment of ODD, 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.

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-ODD 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 ODD 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 ODD patients because the disclosure of options and the patient decision are significant

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

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

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

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 options^{3/4}not guilty into choosing an outdated, unsuccessful program that offers little chance of success.²³⁴

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-ODU 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.*