Warm Handoffs: The Duty of and Legal Issues Surrounding Emergency Departments in Reducing the Risk of Subsequent Drug Overdoses

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I. INTRODUCTION

Around 11 p.m. on October 30, 2015, Brandon Goldner’s parents received a devastating phone call—Brandon, their 23-year-old son, had died of a heroin overdose. 1 Blindsided, they were completely unaware that Brandon used heroin. Nor were they aware that emergency responders had revived their son and taken him to the emergency department seven times in the previous two months for opioid-related overdoses, including three times in one six-day period. 2 While it was clear that Brandon had a substance use disorder (“SUD”), 3 Brandon’s parents later learned that emergency department

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2. Id.

providers never performed a substance abuse or psychological evaluation, intervention, or referral to treatment during any of the seven hospital visits. Upon discharge after each overdose, hospital staff never provided more than mere informational materials to Brandon to take with him, and no one ever contacted Brandon’s parents to alert them to Brandon’s situation, even though Brandon had listed his mother as his emergency contact. As a result, Brandon never got the treatment he needed, instead experiencing a potentially avoidable overdose death.

According to a December 2017 National Center for Health Statistics report, life expectancy in the U.S. fell for the second year in a row in 2016, due in large part to unintentional, fatal opioid-related overdoses. In fact, deaths involving an opioid nearly tripled between 2002 and 2015, and an estimated 131 people die per day from an opioid-related overdose. While overdose death rates attributable to prescription opioids have remained relatively steady since 2011, the U.S. saw more than a six-fold increase in heroin overdose deaths between 2002 and 2015. During the same period, combined

use disorder fall into four major groupings: impaired control, social impairment, risky use, and pharmacological criteria (i.e., tolerance and withdrawal).” Id.  
4. Miller, supra note 1.  
5. Id.  
7. The opioid drug class includes three subclasses of prescription medications: (1) natural opiates (e.g., morphine, codeine, thebaine); (2) semi-synthetic opioids (e.g., hydrocodone, oxycodone, hydromorphone, oxymorphone, buprenorphine); and (3) synthetic opioids (e.g., methadone, propoxyphene, fentanyl, meperidine); and one class of illicit substances, which include heroin and counterfeits or analogs of prescription opioids (e.g., carfentanil). NAT’L INST. ON DRUG ABUSE, URINE DRUG TESTING FOR CHRONIC PAIN MANAGEMENT (n.d.), https://www.drugabuse.gov/sites/default/files/files/UrineDrugTesting.pdf.  
overdose deaths from heroin and non-methadone synthetic opioids increased nearly sixfold, due in large part to a rise in deaths from illicit fentanyl.11 Of the more than 64,000 drug overdose deaths estimated in 2016, experts estimated that more than 20,000 were related to fentanyl and fentanyl analogs.12

Yet emergency department practitioners could have helped avoid many of these deaths with proper identification of SUD and referral to treatment. Nearly 3 million people in the U.S. have an opioid use disorder (“OUD”), and hospitalizations related to opioid misuse and abuse have increased significantly.13 Emergency departments provide an ideal opportunity for intervention, and yet interventions are not occurring. According to a 2014 study, individuals who visit the emergency department for nonfatal overdoses present a high likelihood of future hospitalization and fatal or near-fatal events,14 partially due to the lack of follow-up treatment. According to data on privately insured individuals aged 18 to 64, 40% of patients who received hospital care for opioid-related conditions did not receive any follow-up services whatsoever within 30 days of the hospitalization.15 Of those who did receive treatment, 6.0% of patients received medications only, 43.3% received behavioral therapy only, and 10.7% received the hospital-recommended combination of both medication and behavioral therapy services.16

As the overdose epidemic has intensified over the past 15 years, so has the discussion around how to effectively address the epidemic

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11. Id. As used in this statistic by NIDA, “deaths involving heroin and non-methadone synthetics” means deaths from heroin and synthetic opioids other than methadone (e.g., fentanyl, propoxyphene, meperidine), and also captures deaths from illicit opioids other than heroin (e.g., illicit fentanyl, carfentanil). Id.

12. Id.


15. CTRS. FOR BEHAVIORAL HEALTH STATISTICS & QUALITY, supra note 13.

16. Id.
and reduce the occurrence of fatal overdose. The federal government, states, and other public bodies are increasingly assembling committees (often referred to as “task forces”) of politicians, medical experts, and others to analyze the epidemic and make recommendations. In addition, states have passed laws and regulations aimed at preventing overdoses and saving lives. For example, all states have passed laws to increase access to naloxone, an overdose rescue medication, and nearly every state has passed “Good Samaritan” laws to encourage those who witness an overdose to call for emergency assistance without fear of prosecution.

As Brandon Goldner’s story demonstrates, however, improving the opportunity and ability to revive individuals who experience an overdose cannot make a meaningful impact on reducing overdose deaths unless overdose survivors have the opportunity to receive specialized treatment to address their SUDs. Unfortunately, stories like Brandon Goldner’s are common and represent a failure to conduct timely assessments of the severity of substance use, intervene, and offer to initiate treatment at a point when individuals are often most vulnerable and at risk of subsequent overdose. As a result, some states, counties, and health care systems have implemented emergency care “warm handoff” programs. A warm handoff is the process of transitioning a patient with SUD from an intercept point, such as an emergency department, to a treatment provider once the patient is stable. Warm handoffs provide a pathway to treatment and recovery for those with SUDs and can decrease the risk of subsequent overdose.

Still, throughout the country, hospitals discharge individuals who present with overdose shortly after intervening or turn them over

to law enforcement rather than transfer them to treatment. 21 Without an intervention and referral to treatment, these patients suffer an increased risk of experiencing a subsequent overdose death. 22 Some public health and safety officials have shied from implementing warm handoff policies, fearing liability for improper disclosure of patient information under state and federal privacy laws and regulations. 23 Hospitals that fail to provide warm handoff services, however, expose themselves to negligence liability. 24

This Article shows that not only can warm handoff programs comply with federal and state privacy and prescribing laws, but also that it is in hospitals’ best interests to provide warm handoff services to avoid negligence claims. Part II provides background on psychosocial treatment, revival treatment, medication-assisted treatment (“MAT”), and Screening, Brief Intervention, and Referral to Treatment (“SBIRT”) protocols. Part III discusses examples of efforts to implement emergency care warm handoff programs, namely current state laws and regulations that require emergency care providers to attempt warm handoffs. Part IV examines legal issues pertaining to warm handoff programs, including limitations to Good Samaritan laws, the initiation of MAT, medical malpractice, and patient privacy. Finally, after concluding, the authors provide a model warm handoff policy in the Appendix for hospitals to implement in their emergency department that reflects the legal considerations that this Article discusses.

II. BACKGROUND

Numerous modalities and several medications currently exist to treat OUD. Warm handoff policies help to ensure that first responders, emergency department personnel, treatment providers, and others not

only revive individuals who experience nonfatal overdoses but the appropriate party also earnestly offers the individual such treatment to prevent future overdoses. This Part provides an overview of existing treatments and evidence of their effectiveness, shedding light on why warm handoff policies are so vital.

A. Revival Medications and SUD Treatment

The National Institute on Drug Abuse defines addiction as a “chronic, relapsing brain disease that is characterized by compulsive drug seeking and use, despite harmful consequences.” Due to its chronic nature, addiction must be managed using long term treatment approaches. Several evidence-based treatment and medication modalities currently exist to first revive an individual from an opioid overdose, and then assist the individual in achieving chronic maintenance management of an OUD.

1. Naloxone

Naloxone is an opioid antagonist that blocks opioid receptors and reverses the toxic effects of an opioid overdose, including extreme drowsiness, slowed breathing, or loss of consciousness. Naloxone has a rapid onset and is administered when a patient is showing signs of opioid overdose. Currently, naloxone is administered by intranasal spray or by intramuscular (into the muscle), subcutaneous (under the skin), or intravenous injection.

26. See id.
27. Id. OUD is a lifelong condition. The goal of treatment is to achieve long-term stability and periods of abstinence. CTR. FOR SUBSTANCE ABUSE TREATMENT, U.S. DEP’T HEALTH & HUMAN SERVS., TREATMENT FOR STIMULANT USE DISORDER: TIP 33 (2009), https://www.ncbi.nlm.nih.gov/books/NBK64334/.
30. SAMHSA, Naloxone, supra note 28.
Naloxone carries its own risks. Side effects of naloxone include opioid withdrawal symptoms, such as nervousness, restlessness, or irritability; body aches; dizziness; diarrhea; stomach pain; nausea; and fever or chills.\textsuperscript{(31)} Other side effects include hallucinations, irregular heartbeat, loss of consciousness, and seizures.\textsuperscript{(32)} Additionally, the effects of a potent analog opioid, such as carfentanil, or heroin combined with a benzodiazepine,\textsuperscript{(33)} for example, can last longer than the effects of naloxone.\textsuperscript{(34)} Therefore, if the patient does not receive proper treatment, he or she could experience “re-toxicity,” which can result in respiratory depression and death after the naloxone revival.\textsuperscript{(35)} In addition, the dose and route of administration of naloxone can impact the adverse events and withdrawal symptoms.\textsuperscript{(36)} For instance, “intravenous administration and higher doses” of naloxone “produce more adverse events and more severe withdrawal symptoms in” individuals with OUD.\textsuperscript{(37)} Given the severity of the withdrawal, many individuals choose to ingest more opioids.\textsuperscript{(38)} As a result, once the

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\textsuperscript{33} Benzodiazepines (e.g., alprazolam, diazepam, clonazepam) are a type of prescription medication commonly prescribed to treat anxiety and insomnia. Like opioids, benzodiazepines have sedative effects. Combining opioids and benzodiazepines can impair cognitive function and cause respiratory depression, which can be fatal. The U.S. Food and Drug Administration now requires both prescription opioids and benzodiazepines to include labeling with “black box” warnings describing the risks of using these drugs together. Benzodiazepines and Opioids, NAT’L INST. ON DRUG ABUSE, https://www.drugabuse.gov/drugs-abuse/opioids/benzodiazepines-opioids (last updated Sept. 2017).

\textsuperscript{34} Edward W. Boyer, Management of Opioid Analgesic Overdose, 367 NEW ENG. J. MED. 146, 150 (2012).


\textsuperscript{37} Id.

naloxone wears off, the individual has an exceptionally high dose of the opioid in his or her system, putting him or her at risk for another overdose. For these reasons, hospitals should carefully consider discharge timing for individuals who are administered naloxone after an opioid overdose.

Medical first responders often use naloxone, but individuals with no formal training can also administer it. Until recently, laws and regulations in place prior to the overdose epidemic largely have limited community access to naloxone. Those laws are beginning to change. States have passed legislation to address at least some of the barriers to naloxone access and the provision of timely medical care. All 50 states and the District of Columbia now have laws intended to improve the availability of naloxone. These laws vary from state to state, but common characteristics include civil, criminal, or disciplinary immunity for medical professionals who prescribe or dispense naloxone and laypeople who administer it; authorization to prescribe naloxone to individuals other than those at risk of overdose; authorization to prescribe naloxone via a standing order; and authorization for organizations that are not otherwise permitted to dispense naloxone (for example, non-profit organizations) to distribute the medication.

39. Id.  
40. NETWORK FOR PUB. HEALTH L., supra note 18, at 1. See also Maya Doe-Simkins et al., Overdose Rescues by Trained and Untrained Participants and Change in Opioid Use Among Substance-Using Participants in Overdose Education and Naloxone Distribution Programs: A Retrospective Cohort Study, 14 BMC PUB. HEALTH 297 (2014).  
41. For example, state laws generally prohibit health care providers from prescribing a medication to anyone other than the patient to whom they will be administered (i.e., a third-party prescription), or to a patient with whom the provider does not have a provider-patient relationship (i.e., prescription via a standing order). NETWORK FOR PUB. HEALTH L., supra note 18, at 1. In addition, some providers are hesitant to prescribe or dispense naloxone due to fear of liability, even though there is rarely a legal basis for any such liability. Id. Similarly, individuals who witness an overdose may be afraid to call for medical assistance over fear of prosecution for possession of illicit drugs or paraphernalia, or other crimes, thereby preventing access to potentially life-saving care. Id.  
42. Id.  
43. Id.  
44. Id. at 2.
2. SBIRT

SBIRT is an evidence-based practice used to help identify, reduce, and prevent problematic substance use.\textsuperscript{45} The goal of SBIRT is to prevent adverse health consequences among individuals whose use may not have reached the diagnostic level of a SUD, and to help those with SUD enter and remain in treatment.\textsuperscript{46} As such, SBIRT principles are the heart of a warm handoff policy.

The first major component of SBIRT—screening—allows health care providers to quickly identify risky substance use through standardized screening tools.\textsuperscript{47} During the screening process, a health care provider typically asks the patient one to three questions.\textsuperscript{48} If the screen is positive, the patient undergoes a more thorough evaluation using a standardized risk assessment tool.\textsuperscript{49}

Brief Intervention is a strategy intended to encourage the patient to modify his or her behavior and prevent the progression of substance use.\textsuperscript{50} A health care provider or a behavioral health provider engages the patient in a short conversation (5–10 minutes) and provides feedback and advice while discussing topics, such as how substance use can cause or worsen health problems or result in dangerous interactions with medications.\textsuperscript{51} Practitioners generally perform brief interventions for patients with less severe substance use and who may not need a referral to addiction treatment.\textsuperscript{52} Patients with SUDs may require longer, more intensive interventions (20–30 minutes). Health care providers may conduct these more intensive sessions, but often behavioral health professionals conduct them.\textsuperscript{53}


\textsuperscript{46} Id.
\textsuperscript{47} Id. at 2.
\textsuperscript{48} Id.
\textsuperscript{49} Id.
\textsuperscript{50} Id. at 3.
\textsuperscript{51} Id. at 2–3.
\textsuperscript{52} Id. at 3.
\textsuperscript{53} Id. at 2.
For some patients, a referral to treatment may be appropriate. The referral process includes helping patients access and select treatment programs, and identifying barriers to treatment, such as cost or lack of transportation. Ideally, health care providers will establish and cultivate relationships with addiction treatment providers to whom they refer patients, share pertinent patient information with the addiction treatment providers, and ensure that the patients receive necessary care coordination and follow-up support services.

It is possible to implement SBIRT in a variety of medical settings, and it has proved successful in hospitals and emergency departments. Implementing SBIRT protocols in emergency departments, however, can be challenging. A recent qualitative evaluation on the implementation of a novel SBIRT protocol into normal emergency department workflow suggested that impediments to implementation “include views of SBIRT appropriateness in the [emergency department], the need for continuous reinforcement and refinement of personnel training and protocol execution, and fostering of additional administrative and financial champions.”

Nevertheless, successful implementation of SBIRT in emergency departments can lead to overwhelmingly positive results. For example, the Washington State SBIRT Program has demonstrated the effectiveness of providing SBIRT to high-risk substance abusers who frequent hospital emergency departments, with substantial declines in illicit drug use. Among high-risk users of prescription opioids, at six-month follow-up, there was a 41% reduction in days of

54. Id. at 3.
55. Id.
56. Id.
57. Id.
60. Id.
drug use (from 12.8 to 7.5 days) for individuals who received only a brief intervention, and a 54% reduction (from 14.4 days to 6.6 days) for individuals who received a brief intervention, followed by brief therapy or SUD treatment.\textsuperscript{61} Among high-risk heroin users, at six-month follow-up, there was a 45% reduction in days of drug use (from 15.8 to 8.7 days) for individuals who received only a brief intervention, and a 50% reduction (from 16.5 days to 8.3 days) for individuals who received a brief intervention, followed by brief therapy or SUD treatment.\textsuperscript{62}

3. Substance Use Treatment

One cannot overstate the importance of referring SUD patients to treatment. Patients who receive psychosocial treatment have better outcomes than patients who do not.\textsuperscript{63} Psychosocial treatment, also known as behavioral health treatment, may include individual or group counseling; referrals to community-based services; contingency management, which is an intervention that provides tangible rewards for abstaining from substance use; and connection to family support systems.\textsuperscript{64} Mutual help programs, such as twelve-step facilitation treatments, may also provide relief.\textsuperscript{65}

Researchers have demonstrated that MAT, also known as medical therapy, which combines psychosocial treatment and FDA-approved medication, has been more effective than either behavioral interventions or medication alone in treating OUD.\textsuperscript{66} Compared to

\textsuperscript{61} Id. at 6.
\textsuperscript{62} Id. at 5.
\textsuperscript{63} See generally Lissa Dutra et al., \textit{A Meta-Analytic Review of Psychosocial Interventions for Substance Use Disorders}, 165 \textit{Am. J. Psychiatry} 179 (2008).
\textsuperscript{65} Id.
nondrug approaches, MAT significantly reduces problematic opioid use and improves adherence to treatment. Moreover, increased community access to MAT can reduce overdose deaths.

FDA-approved medications to treat OUD include methadone, buprenorphine, and naltrexone. Methadone treats OUD by suppressing withdrawal, blocking the euphoric effects of opioids, and reducing cravings. As a general rule, practitioners who dispense methadone to individuals for detoxification or maintenance treatment must annually obtain a registration for that purpose. Only federally regulated opioid treatment programs ("OTPs") may dispense

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69. PEW CHARITABLE TRS., supra note 64.


71. 21 U.S.C. § 823(g)(1) (2012). See also 42 C.F.R. § 8.2 (2017) ("Detoxification treatment means the dispensing of an opioid agonist treatment medication in decreasing doses to an individual to alleviate adverse physical or psychological effects incident to withdrawal from the continuous or sustained use of an opioid drug and as a method of bringing the individual to a drug-free state within such period . . . . Maintenance treatment means the dispensing of an opioid agonist treatment medication at stable dosage levels for a period in excess of 21 days in the treatment of an individual for [OUD].") (emphasis added).
methadone for OUD. These OTPs typically observe patients’ methadone consumption and limit take-home doses.

Buprenorphine effectively fills opiate receptors in the brain, thereby reducing opioid withdrawal symptoms and cravings without increasing opioid sensitivity and the risk of overdose. Buprenorphine has a “ceiling effect,” which prevents additional biological responses, including euphoria, intoxication, and respiratory depression, and reduces the possibilities for both abuse and overdose.

Qualified


74. CTR. FOR SUBSTANCE ABUSE TREATMENT, supra note 70.

75. See CTR. FOR SUBSTANCE ABUSE TREATMENT, U.S. DEP’T OF HEALTH & HUMAN SERVS., CLINICAL GUIDELINES FOR THE USE OF BUPRENORPHINE IN THE TREATMENT OF OPIOID ADDICTION: TIP 40 (2004), http://lib.adai.washington.edu/clearinghouse/downloads/TIP-40-Clinical-Guidelines-for-the-Use-of-Buprenorphine-in-the-Treatment-of-Opioid-Addiction-54.pdf [hereinafter CLINICAL GUIDELINES]. Some oral buprenorphine products contain naloxone as an additional ingredient. See id. “Naloxone is added to buprenorphine to decrease the likelihood of diversion and misuse of the combination drug product.” Buprenorphine, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., https://www.samhsa.gov/medication-assisted-treatment/treatment/buprenorphine (last updated May 31, 2016). Combination products are available as sublingual (under the tongue) tablets, sublingual film, and buccal (inside the cheek) film. Id. Buprenorphine is better absorbed orally than naloxone. See id. Therefore, when buprenorphine-naloxone combination products are taken as prescribed, buprenorphine’s effects dominate, and naloxone does not induce opioid withdrawal. Id. If oral products are manipulated and injected, however, “the naloxone effect dominates and can bring on opioid withdrawal,” thus discouraging intravenous abuse of the product. Id. Oral buprenorphine combination products are generally recommended over oral buprenorphine monoprodut, given the combination products’ injection-detering features. Mark L. Kraus et al., Statement of the American Society of Addiction Medicine Consensus Panel on the Use of Buprenorphine in Office-Based Treatment of Opioid Addiction, 5 J. ADDICTION MED. 254, 255 (2011). The primary exception is pregnant women, for whom
health care providers can prescribe buprenorphine, which the FDA has approved in oral, injectable, and implantable forms, in office-based settings; federal law, however, requires providers to obtain a waiver to treat patients with OUD using buprenorphine and limits the number of patients they may treat at any one time.\textsuperscript{76}

Finally, naltrexone treats opioid addiction by blocking the effects of opioids in the brain’s reward system.\textsuperscript{77} It is not an opioid, it has a low potential for diversion and abuse, and any health care provider who is licensed to prescribe medicines may prescribe it.\textsuperscript{78} Health care providers must administer injectable naltrexone directly to patients; it is not available to patients for self-administration.\textsuperscript{79}
Naltrexone-assisted treatment cannot begin until an individual has stopped using opioids for seven to ten days.\footnote{80}{SAMHSA, EXTENDED-RELEASE INJECTABLE NALTREXONE, supra note 78, at 3.}

Given the proven effectiveness of SBIRT and substance use treatment, every emergency department should implement a policy to ensure that all patients who experience a nonfatal overdose receive, at a minimum, an assessment for substance use, a brief intervention, and, if appropriate, referral to treatment.

III. WARM HANDOFF LAWS AND LEGISLATION

Recognizing that revival from an overdose alone is insufficient to prevent future overdose deaths, some states have committed to ensuring that their emergency departments implement protocols for screening overdose survivors for SUD, seeking patient consent to contact the patient’s emergency contact or other caregiver, and referring patients for SUD treatment if appropriate.

A. Florida

In June 2017, Florida Governor Rick Scott signed H.B. 249 into law, which requires each hospital with an emergency department to develop a best-practices policy to prevent unintentional drug overdoses.\footnote{81}{H.B. 249, at 6 (Fla. 2017), https://www.flsenate.gov/Session/Bill/2017/249/BillText/er/PDF.} The policy may include, but is not limited to, the use of SBIRT protocols in the emergency department; the use of licensed or certified behavioral health professionals or peer specialists in the emergency department to encourage the patient to seek substance use treatment; guidelines for emergency department practitioners authorized to prescribe controlled substances to reduce the risk of opioid abuse; a process for providing an overdose patient or the patient’s next of kin with information about licensed substance use treatment services; and a process to obtain the patient’s consent to notify the patient’s next of kin and each practitioner who prescribed a controlled substance to the patient regarding the patient’s overdose, the
patient’s location, and the nature of the substance involved in the overdose.  

B. Rhode Island

In an attempt to decrease high hospital readmission rates in general, Rhode Island law requires each hospital and freestanding, emergency care facility to submit to the Director of the Department of Health a comprehensive discharge plan. The plan may include evidence that the hospital or emergency-care facility is participating in a “high-quality comprehensive discharge-planning and transitions-improvement project” that a Rhode Island nonprofit operates. Alternatively, the hospital may submit a plan for how it will provide comprehensive discharge planning and information to the patients transitioning from the hospital’s or freestanding, emergency-care facility’s care. Such a plan must employ evidence-based practices, including providing education prior to discharge; attempting to identify the patient’s primary care providers; prior to discharge, assisting with scheduling post-discharge follow-up appointments; and coordinating and improving communication with outside providers.

The law also contains several provisions that are specific to individuals who experience an opioid overdose. For example, with patient consent, a patient who presents with indication of SUD or opioid overdose must receive a substance abuse evaluation before discharge. If, after the evaluation, clinically appropriate inpatient or outpatient services are not immediately available, the facility must provide medically necessary services with patient consent until the facility can complete a transfer of care.

82. Id. at 6–7.
84. § 23-17.26-3(a)(1).
85. § 23-17.26-3(a)(2).
86. Id.
88. § 23-17.26-3(a)(3)(ii). In addition, with the patient’s consent, a physician may administer to the patient buprenorphine or other narcotic for the purpose of
Finally, the law requires that each patient presenting to a hospital or freestanding, emergency-care facility with an indication of SUD or opioid overdose receive information about the availability of clinically appropriate inpatient and outpatient services for the treatment of SUDs or opioid overdose, including detoxification; stabilization; medication-assisted treatment services; inpatient and residential treatment; licensed clinicians with expertise in the treatment of SUDs and opioid overdoses; and certified recovery coaches. Moreover, the law mandated that, by January 1, 2018, the Department of Health develop a strategy to assess, create, implement, and maintain a database of real-time availability of clinically appropriate inpatient and outpatient services. Once the database becomes available, the hospital or freestanding, emergency-care facility must provide real-time information to patients about the availability of clinically appropriate inpatient and outpatient services.

C. Massachusetts

In 2016, Massachusetts Governor Charles D. Baker signed an act relative to substance use treatment, education and prevention (“STEP Act”). The STEP Act, among other things, requires that a person presenting in an acute-care hospital or a satellite emergency facility, whom the attending physician reasonably believes to be experiencing an overdose involving an opioid, or who has received a naloxone administration prior to arriving at the hospital or facility, receive a substance abuse evaluation within 24 hours of receiving emergency room services. A “substance abuse evaluation” is an assessment that a licensed mental health professional or emergency...
services program conducts, and it must include collecting the patient’s history of substance use; substance use by family members; types of and responses to previous treatment for SUD or other psychological disorders; an assessment of the patient’s psychological status including co-occurring disorders, trauma history, and history of compulsive behaviors; and an assessment of the patient’s human immunodeficiency virus, hepatitis C, and tuberculosis risk status.

The law requires that a substance abuse evaluation conclude with a diagnosis of the status and nature of the patient’s SUD using standardized definitions as set forth in the American Psychiatric Association’s Diagnostic and Statistical Manual of Mental Disorders, or a mental or behavioral disorder due to the use of psychoactive substances, as the World Health Organization defines and codes it. Furthermore, each patient must receive the findings of the evaluation in person and in writing, and such findings must include recommendations for further treatment, if necessary, with an assessment of the appropriate level of care needed. Providers must also enter the findings from the evaluation into the patient’s medical record.

The STEP Act also prohibits an acute-care hospital or satellite emergency facility from permitting early discharge—less than 24 hours after admission or before the conclusion of a substance abuse evaluation, whichever comes sooner. If a patient does not receive an evaluation within 24 hours, the attending physician must note in the medical record the reason the evaluation did not occur and authorize the discharge of the patient.

93. “Licensed mental health professional” is defined as “a licensed physician who specializes in the practice of psychiatry or addiction medicine, a licensed psychologist, a licensed independent social worker, a licensed mental health counselor, a licensed psychiatric clinical nurse specialist or a licensed alcohol and drug counselor I as defined in section 1 of chapter 111J” of the General Laws of Massachusetts. Id.

94. Id.
95. § 51 1/2(b).
96. Id.
97. Id.
98. Id.
99. Id.
Finally, a patient may consent to further treatment after the provider performs a substance abuse evaluation. Should a patient refuse further treatment after the evaluation is complete, and otherwise be medically stable, the hospital or facility may initiate discharge proceedings. The patient, however, must receive information on local and statewide treatment options upon discharge, and any other information the attending physician deems appropriate.

On November 14, 2017, Governor Baker proposed legislation that intended in part to improve the effectiveness of substance abuse evaluations required under the STEP Act. The governor’s proposal expanded the range of medical professionals authorized to perform the evaluation and required that the emergency department affirmatively connect the patient with the appropriate level of care.

D. Pennsylvania

In 2016, the Pennsylvania Department of Drug and Alcohol Programs began implementing a warm-handoff process intended to help overdose survivors who appear in emergency departments receive

100. § 51 1/2(c).
101. Id.
102. Id.
104. The bill would add to the definition of “licensed mental health professional” as “a healthcare provider defined in section 1 of chapter 111 [of the General Laws of Massachusetts] whose scope of practice allows such evaluations pursuant to medical staff policies and practice or other professional authorized by the department through regulation.” Id. Section 1 of chapter 111 defines “healthcare provider” as any doctor of medicine, osteopathy, or dental science, or a registered nurse, social worker, doctor of chiropractic, or psychologist licensed under the provisions of chapter one hundred and twelve, or an intern, or a resident, fellow, or medical officer licensed under section nine of said chapter one hundred and twelve, or a hospital, clinic or nursing home licensed under the provisions of chapter one hundred and eleven and its agents and employees, or a public hospital and its agents and employees.

counseling and a referral to treatment. As part of the implementation, the Department incorporated contractual changes in its grant agreement with the Single County Authorities (“SCA”), which are publicly funded organizations responsible for planning and evaluating community drug and alcohol prevention, intervention, and treatment services. The contractual changes establish overdose survivors as a priority population and require each SCA to create a process whereby such patients receive a direct treatment referral from the emergency department. In February 2017, the Department and the Pennsylvania Department of Health developed a list of local treatment providers and a flowchart designed to help health care providers in emergency departments implement warm handoffs.

According to the Department’s flowchart, if a patient presents to the emergency department with an opioid overdose or other signs and symptoms of opioid abuse, then the patient should receive a screening for OUD, a physical exam, and laboratory testing, and the patient’s history should be documented. If the provider considers the patient to be safe for discharge but believes the patient has OUD, then a physician, registered nurse, or advance care practitioner orders and documents a warm handoff in the electronic medical record. Then, per SCA protocol, a designated emergency department staff member contacts a “drug and alcohol assessor,” and the patient meets confidentially with the assessor. If the patient agrees to further treatment, the initial provider facilitates a warm handoff to an addiction treatment provider, and the patient’s primary care physician


107. Id.


109. Addressing Overdose, supra note 106.


111. PA., EMERGENCY DEP’T WARM HAND-OFF, supra note 110.

112. Id.

113. Id.
receives notification through discharge notes. If the patient refuses the warm handoff, then the provider discharges the patient with a naloxone prescription and information on local treatment and resources.

According to an August 2017 news report, the warm handoff program has shown promise. In Dauphin County, in particular, 50 of 116 overdose survivors who received an offer for treatment actually entered treatment. Even those patients who chose not to enter treatment received a caseworker who explained the benefits and availability of treatment and, in most cases, a patient’s family member also received the information. As part of the implementation of the warm handoff program, Dauphine County hired two caseworkers “who are available at all hours and who will arrive at the hospital within 30 minutes to meet with an overdose survivor.”

E. Louisiana

In January 2016, the Louisiana Department of Health and Hospitals promulgated regulations setting forth training and monitoring requirements “for a licensed medical practitioner who prescribes, dispenses, or administers naloxone or another opioid antagonist to a person reasonably believed to be undergoing an opioid-related drug overdose.” The regulations require that, upon stabilization of the patient, the treating practitioner refer the patient to substance use treatment and offer information regarding substance use treatment.

114. See id.
115. Id.
116. David Wenner, “Warm Handoffs” Working in Pa. to Connect Overdose Survivors with Treatment, PA REAL-TIME NEWS (Aug. 16, 2017), http://www.pennlive.com/news/2017/08/pa_makes_progress_toward_offer.html. However, the report also noted that some counties face certain shortages, such as a lack of treatment providers, that must be addressed before warm handoffs can be implemented statewide. Id.
117. Id.
118. Id.
119. Id.
121. Id. at 65.
In January 2018, a New Jersey lawmaker introduced legislation that would require caregivers to provide information concerning substance abuse treatment programs and resources to individuals who experience an overdose and receive an opioid antidote from a health care professional or first responder. Specifically, if a health care facility or the emergency department of a facility admits the individual, a staff member designated by the facility must provide the information to the person any time after treatment for the overdose is complete, but before discharge. The designated staff member may, in collaboration with an appropriate health care professional, additionally develop for the individual a substance abuse treatment plan.

IV. LEGAL ISSUES SURROUNDING WARM HANDOFF PROGRAMS

A. Getting Patients in the Door: Good Samaritan Laws

Fear of prosecution is a significant barrier to treatment for those who experience an overdose; the individual and his or her peers may be reluctant to call emergency responders for fear of being arrested in light of illicit substance use. Acknowledging this barrier, at least forty states and the District of Columbia have passed overdose “Good

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“Good Samaritan” laws as of July 15, 2017. However, the laws vary in their protections from state to state. In fifteen states, the Good Samaritan laws provide protection from arrest or prosecution for certain crimes if an individual experiences a medical emergency after ingesting or using a controlled substance and makes a good-faith request for medical assistance. In these states, laws protect both the individual who experienced the overdose as well as individuals in his or her presence who sought medical care on the overdosing individual’s behalf.

Depending on the state, these laws may provide protection from arrest, charge, and prosecution for controlled substance and paraphernalia possession; protective or restraining orders; probation or parole violations; and various other crimes. Good Samaritan laws can also prohibit the prosecution from using any evidence obtained solely as a result of seeking medical assistance for the overdose. Moreover, Good Samaritan laws in several states provide that reporting an overdose can be a mitigating factor in sentencing for


128. Id. While “good faith” may not be defined, if the individual does not call for assistance until after he or she has hidden evidence of illegal conduct, such activity may be considered not acting in good faith. See, e.g., People v. Taylor, 60 N.Y.S.3d 779, 780 (Cnty. Ct. Aug. 14, 2017).


131. E.g., Shuey, 2016 Md. App. LEXIS 728 at *1 (holding that Maryland’s Good Samaritan law protected an individual who overdosed on heroin from prosecution for possessing controlled paraphernalia because he was experiencing a medical emergency). See also Network for Pub. Health L., Naloxone and Samaritan Laws, supra note 127.

crimes for which immunity does not exist. Less commonly, these laws can protect individuals from civil forfeiture.

In some counties, police departments have adopted policies requiring their officers to take intoxicated individuals to the hospital to avoid potential overdose—a potential first step in the warm handoff policy. In such cases, however, when a police officer transports an individual to a hospital, Good Samaritan laws do not necessarily protect the individual under the influence. Courts have noted that Good Samaritan laws do not provide immunity simply to an individual under the influence, but rather to “those individuals who are actually

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133. See Network for Pub. Health L., Naloxone and Samaritan Laws, supra note 127. But see People v. Teper, 74 N.E.3d 1011 (Ill. App. 2016) (holding that a woman could not invoke the Good Samaritan law as a defense to a conviction for unlawful possession of a controlled substance because the possession was not “acquired as a result of” defendant “seeking or obtaining emergency medical assistance,” and the police “had probable cause to arrest defendant based on evidence that was ‘not obtained as a direct result of’ defendant ‘seeking or obtaining emergency medical assistance.’”).


135. A recent working paper by the National Bureau of Economic Research (“NBER”) examined the effect of naloxone access laws and Good Samaritan laws on opioid-related deaths. See Daniel I. Rees et al., With a Little Help from My Friends: The Effects of Naloxone Access and Good Samaritan Laws on Opioid-Related Deaths (National Bureau of Economic Research, Working Paper No. 23171, 2017), https://www.nber.org/papers/w23171.pdf. Using data from the National Vital Statistics System multiple cause-of-death mortality files for the period 1999–2014, the authors found that the adoption of naloxone access laws was associated with a 9–11% reduction in opioid-related deaths to be of comparable magnitude, but not statistically significant at conventional levels. Id. The NBER study was the first of its kind in the U.S. Its findings are consistent with a much narrower study that examined the impact of a naloxone training and distribution program implemented by several communities in Massachusetts. The observational study found that the program reduced opioid-related mortality in the communities in which reduction in opioid-related deaths. Id. In addition, the NBER study was consistent with a 2011 study examining the initial impact of Washington State’s Good Samaritan overdose law several months after the law was passed. The study found that 88% of opiate users surveyed would be more likely to call 911 when witnessing an overdose after becoming aware of the law. Id.
experiencing the deadly throes of overdose.” 136 In other words, the condition must be “severe and life threatening.” 137

For instance, in State v. Wolf, police received an anonymous call about a possibly drunk trespasser—the defendant. 138 Upon arresting the defendant, a police officer found heroin and drug paraphernalia on the defendant’s person. 139 Officers noted that the defendant appeared to be under the influence because “[h]is pupils appeared constricted, his eyelids were droopy, his speech was slow and slurred,” and he would nod off easily. 140 Fearing that a county jail would not accept an individual who was under the influence, the officer took the defendant to the local hospital, which administered naloxone. 141 Once the hospital cleared the defendant medically, police took him to the county jail. 142 Prosecutors indicted the defendant with possession of a controlled substance, and he received a four-year prison sentence. 143 The defendant filed a motion to dismiss pursuant to New Jersey’s Good Samaritan law. 144 In his motion, the defendant argued that “mere intoxication will not suffice to invoke the broad protection granted under the act.” 145

Moreover, in order for immunity to apply, evidence of the drug possession must be “acquired as a result of” the person seeking or obtaining emergency medical assistance. 146 For example, in People v. Teper, 74 N.E.3d 1011, 1013 (Ill. App. Ct. 2016). For example, Illinois law provides that

[a] person who is experiencing an overdose shall not be charged or prosecuted for Class 4 felony possession of a controlled, counterfeit, or look-alike substance or a controlled substance analog if evidence for the Class 4 felony possession charge was
Warm Handoffs

Teper, police officers “found [the] defendant slumped over in the driver’s seat” of her car, unresponsive, and having trouble breathing. She suffered a heroin overdose, and officers injected her with naloxone. After reviving her, officers found heroin and hypodermic needles in her car. A jury convicted her of unlawful possession of a controlled substance. In her motion to dismiss, she argued that the Good Samaritan law applied because she was experiencing an overdose, and the evidence obtained was acquired as a result of “a person seeking or obtaining emergency medical assistance.”

acquired as a result of the person seeking or obtaining emergency medical assistance . . . .

720 ILL. COMP. STAT. § 570/414(c) (West 2014). However, such limited immunity shall not be extended if law enforcement has reasonable suspicion or probable cause to detain, arrest, or search the person . . . for criminal activity and the reasonable suspicion or probable cause is based on information obtained prior to or independent of the individual . . . . taking action to seek or obtain emergency medical assistance and not obtained as a direct result of the action of seeking or obtaining emergency medical assistance. § 570/414(e).

148. Teper, 74 N.E.3d at 1013.
149. Id. at 1013–14. Narcan is a brand name of naloxone. Id. at 1014 n.1.
150. Id. at 1014.
151. The court convicted the defendant of unlawful possession of a controlled substance because she unlawfully possessed less than 15 grams of heroin. Id. at 1013. She was also charged with unlawful possession of hypodermic syringes because she possessed two hypodermic syringes to inject the heroin. Id. at 1016.
152. Id. at 1014. The defendant cited 720 ILL. COMP. STAT. § 570/414, which is entitled “Overdose, limited immunity from prosecution” and provides, in relevant part:

(b) A person who, in good faith, seeks or obtains emergency medical assistance for someone experiencing an overdose shall not be charged or prosecuted for Class 4 felony possession of a controlled, counterfeit, or look-alike substance or a controlled substance analog if evidence for the Class 4 felony possession charge was acquired as a result of the person seeking or obtaining emergency medical assistance and providing the amount of substance recovered is within the amount identified in subsection (d) of this Section.

(c) A person who is experiencing an overdose shall not be charged or prosecuted for Class 4 felony possession of a
court, however, held that the Good Samaritan law did not apply because evidence of the defendant’s drug possession was not “acquired as a result of” the defendant seeking or obtaining emergency medical assistance.\textsuperscript{153} Police officers had probable cause before they administered naloxone because the defendant had parked incorrectly during rush hour, was unconscious and turning blue, and the needles and a substance in the cup holder were in plain sight.\textsuperscript{154} While the court acknowledged that the police officer provided emergency medical assistance by administering naloxone, it found that the “‘triggering fact’ for the defendant obtaining emergency medical assistance controlled, counterfeit, or look-alike substance or a controlled substance analog if evidence for the Class 4 felony possession charge was acquired as a result of the person seeking or obtaining emergency medical assistance and providing the amount of substance recovered is within the amount identified in subsection (d) of this Section.

(d) For the purposes of subsections (b) and (c), the limited immunity shall only apply to a person possessing the following amount:

(1) less than 3 grams of a substance containing heroin;

\ldots

(e) The limited immunity described in subsections (b) and (c) of this Section shall not be extended if law enforcement has reasonable suspicion or probable cause to detain, arrest, or search the person described in subsection (b) or (c) of this Section for criminal activity and the reasonable suspicion or probable cause is based on information obtained prior to or independent of the individual described in subsection (b) or (c) taking action to seek or obtain emergency medical assistance and not obtained as a direct result of the action of seeking or obtaining emergency medical assistance. Nothing in this Section is intended to interfere with or prevent the investigation, arrest, or prosecution of any person for the delivery or distribution of cannabis, methamphetamine or other controlled substances, drug-induced homicide, or any other crime.

720 ILL. COMP. STAT. § 570/414 (West 2014).


154. \textit{Id.} at 1015.
assistance did not occur until [after] the officers noticed the drugs and paraphernalia, which gave them probable cause.” Therefore, the evidence was not “acquired as a result of” providing the emergency medical assistance.\(^{155}\)

Moreover, while improved naloxone access and Good Samaritan laws may help save lives, such measures alone do not prevent subsequent opioid-related overdose. Similar to a nonfatal heart attack patient who, once stable in the emergency department, would receive a referral to a cardiologist, physicians should likewise refer a patient with an SUD who survives an overdose to appropriate treatment.\(^{157}\) Given that a single overdose episode can predict a subsequent overdose,\(^{158}\) and given the proven effectiveness of substance use treatment, it is paramount that patients have the opportunity to receive SUD treatment. Additionally, if states want people experiencing an overdose to seek help without fear of prosecution, more states need to strengthen their Good Samaritan laws to protect the individual experiencing an overdose from criminal charges, such as possession of a non-prescribed controlled substance.\(^{159}\)

**B. Initiation of MAT in the Emergency Department**

Practitioners who dispense methadone to individuals for detoxification or maintenance treatment for OUD must annually obtain a registration for that purpose.\(^{160}\) In addition, practitioners who prescribe buprenorphine for detoxification or maintenance treatment must apply for and obtain a waiver from the OTP registration

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155. Id. at 1015–16.
156. Id. at 1013, 1015–16.
159. NETWORK FOR PUB. HEALTH L., NALOXONE AND SAMARITAN LAWS, supra note 127.
requirement under the Drug Addiction Treatment Act of 2000 ("DATA 2000"). Under DATA 2000, prescribers may obtain a waiver to treat up to 30 patients with buprenorphine during the first year of certification, up to 100 patients the following year, and up to 275 patients the year after (the “30/100/275 patient limit”).

An exception to the 30/100/275 patient limit, known as the “three-day rule,” allows hospital practitioners who are not registered as OTPs or waived under DATA 2000 to administer (but not prescribe) narcotic drugs, including methadone or buprenorphine, to a person for relieving acute opioid withdrawal symptoms if necessary while arrangements are being made to refer the patient to treatment.

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161. § 823(g)(2). Recent studies have demonstrated that initiating treatment with buprenorphine in the emergency department can have a positive impact on treatment engagement and illicit opioid use. First, a randomized clinical trial published in 2015 compared the efficacy of three interventions for opioid dependence: (1) screening and referral to treatment (“intervention one”); (2) screening, brief intervention and facilitated referral (“intervention two”); and (3) screening, brief intervention, emergency department-initiated treatment with buprenorphine/naloxone, and referral to primary care (“intervention three”). The authors hypothesized that, given the “profound neurobiological and behavioral changes that characterize opioid dependence, it is likely that a more potent intervention, such as emergency department-initiated treatment including buprenorphine, will be needed to produce optimal outcomes.” Gail D’Onofrio et al., Emergency Department-Initiated Buprenorphine/Naloxone Treatment for Opioid Independence: A Randomized Clinical Trial, 313(16) J. AM. MED. ASS’N 1636 (2015). The authors found that, among opioid-dependent patients, intervention three compared to interventions one and two “significantly increased engagement in addiction treatment, reduced self-reported illicit opioid use, and decreased use of inpatient addiction treatment services.” Id. In another study published in 2017, emergency department-initiated buprenorphine with 10-week continuation in primary care was compared to both referral and brief intervention. Long-term outcomes at 2, 6, and 12 months were evaluated for these interventions. The authors found that emergency department-initiated buprenorphine was associated with increased engagement in addiction treatment and reduced illicit opioid use during the two-month interval when buprenorphine was continued in primary care. Outcomes at 6 and 12 months were comparable across all groups. See generally Gail D’Onofrio et al., Emergency Department-Initiated Buprenorphine for Opioid Dependence with Continuation in Primary Care: Outcomes During and After Intervention, 32 J. GEN. INTERNAL MED. 600 (2017), https://link.springer.com/article/10.1007/s11606-017-3993-2.

162. 21 C.F.R. § 1301.28(b) (2017).

163. Id.
the three-day rule, a practitioner cannot administer or give more than one day’s medication to a patient at one time and cannot carry out treatment for more than 72 hours. The rule does not allow renewal or extension of such emergency treatment.

The intent of “three-day rule” is to provide practitioners with flexibility in emergency situations where they may face an individual undergoing withdrawal, and it would be impractical to require and improbable to obtain a waiver, given the time constraint. While the practitioner can, therefore, provide detoxification treatment over a three-day period, Congress did not intend the rule to circumvent the separate registration requirement. Moreover, detoxification alone is insufficient to properly treat an OUD; it must be part of an integrated continuum of services that promote ongoing SUD treatment. Yet studies have shown that up to three quarters of individuals with SUDs who receive detoxification do not receive any continued treatment afterward. As a result, many individuals experience subsequent overdoses, requiring further emergency treatment. Therefore, hospitals must adopt warm handoff programs to ensure that patients receive a referral to the appropriate care once they leave the hospital, even if they receive detoxification services during their hospital admission.

164. Id.
165. Id.
167. Id.
170. Id.
C. Civil Liability: Wrongful Death Claims for Medical Malpractice

In reviewing analogous attempted suicide cases, one can argue that hospitals that fail to implement a warm handoff policy face increased risk of civil liability, namely wrongful death claims for medical malpractice, if it releases a patient who subsequently experiences a fatal overdose.\textsuperscript{171}

Originally, common law denied recovery in tort once a tort victim died, and it also refused to recognize a new and independent cause of action for the victim’s family members for their own loss.\textsuperscript{172} As a result, it was cheaper for a defendant to kill, rather than injure, a plaintiff, and the plaintiff’s family had no civil remedy.\textsuperscript{173} Over time, however, states have addressed this illogical result by passing wrongful death statutes.\textsuperscript{174}

State wrongful death statutes vest a right of recovery in certain enumerated heirs or representatives of a decedent, allowing such parties to sue for economic and non-economic damages resulting from the death of the decedent that another’s wrongful act caused.\textsuperscript{175} The statutes focus on the harm the plaintiff family members suffer as a result of the decedent’s death.\textsuperscript{176} Wrongful death statutes require plaintiffs to satisfy the same burden of proof that the decedent would have had to meet had the decedent lived.\textsuperscript{177} Therefore, in order for a plaintiff who brings a statutory wrongful death claim for malpractice to succeed, the plaintiff must prove the elements of medical

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\item[171.] It should be noted, however, that case law in this area is still developing. In addition, given that a high percentage of medical malpractice lawsuits settle, there is not an abundance of case law analyzing this specific fact pattern. Therefore, this Section is intended to provide an overview and brief analysis of possible civil claims that hospitals and practitioners could be subject to and forced to commit valuable resources to defend.
\item[173.] \textit{Id.} at 583.
\item[174.] \textit{Id.}
\item[176.] Harrison, \textit{supra} note 172, at 584–85.
\item[177.] See, e.g., \textit{740 ILL. COMP. STAT. ANN. § 180/1} (West 1993).
\end{enumerate}
malpractice and show that the defendant’s negligent conduct caused the decedent’s death. The essential elements of a medical malpractice claim are the same as those in an ordinary negligence action: duty, breach, causation, and damage.

1. Duty: Establishing a Standard of Care

Ordinary negligence law imposes a duty on most persons in most situations to act with reasonable care, which a court tests by asking how a reasonably prudent person would act under particular circumstances to avoid harming others. The law compares a defendant’s conduct to this objective, external standard to determine whether he or she breached the duty to act reasonably under the circumstances. Yet, while the law measures most adults against the reasonable prudent person standard, it requires that health care practitioners, given their greater-than-normal skills and learning, exercise the level of skill they actually or should reasonably possess in their profession. In other words, a health care practitioner has a duty to exercise a degree of care and skill that is expected of a reasonably competent practitioner in the same class to which the practitioner belongs, acting under similar circumstances.

Unlike ordinary negligence claims, a plaintiff in a medical malpractice case must establish this reasonably prudent practitioner standard through expert testimony. The rationale for this requirement is that a layman does not possess the requisite knowledge to determine whether the defendant gave proper treatment and followed proper procedures. As to the existence of the duty itself, a health care practitioner’s duty arises once he or she establishes a

180. Owen, supra note 179, at 1677.
181. Id.
182. Id. at 1677–78.
183. Lynn, supra note 179, at 388.
184. Id. at 384.
185. Id. at 385.
practitioner-patient relationship with the plaintiff. Generally, an agreement or undertaking to render medical care is adequate to establish the duty of care, which continues until either the patient terminates the relationship or the provider terminates the relationship upon reasonable notice or by arranging substitute care.

Based on an expert witness’s opinion in Bevan v. Valencia, warm handoff policies are the standard of care when treating a patient who experienced an overdose. In that case, the plaintiffs alleged that an emergency room physician prematurely discharged a patient from the hospital after treating her for a heroin overdose with naloxone and lorazepam. The doctor kept the patient for observation for two hours after administering naloxone. He noted that the patient was alert and oriented, and he recommended “no further cares.” Along with discharging the patient, the doctor medically cleared her for incarceration. The police took the patient from the hospital to a youth development program for incarceration. Several hours later, the patient stopped breathing; she later died of “toxic effects of heroin.” The plaintiffs brought a wrongful death claim for negligence against the hospital, alleging that the hospital (1) negligently failed to adopt a policy related to the treatment of patients who overdose on heroin, (2) failed to have adequate discharge instructions, and (3) failed to obtain informed consent from the patient.

186. Id. at 386–87.
187. Id.
189. Id. Lorazepam primarily is prescribed to treat anxiety and belongs to a class of drugs called benzodiazepines. U.S. Nat’l Library of Med., Lorazepam, MEDLINEPLUS, https://medlineplus.gov/druginfo/meds/a682053.html (last updated Oct. 22, 2018). Lorazepam may also be prescribed to treat irritable bowel syndrome, epilepsy, insomnia, and nausea and vomiting from cancer treatment and to control agitation caused by alcohol withdrawal. Id. Combining a benzodiazepine with an opioid can increase the risk of life threatening breathing problems, sedation, coma, or death. Id.
191. Id. at *6.
192. Id. at *2.
193. Id. at *1.
194. Id.
to administer lorazepam, a drug that “can potentiate any narcotic that is still in the body.”

As to the failure to have a hospital policy on treating heroin overdose patients, the plaintiff’s expert opined that the hospital breached “the standard of care of a reasonably well-qualified hospital” by not implementing such a policy. He also explained, however, that a doctor may exercise independent judgment as to whether to discharge a patient, and, as such, it would be speculation to suggest that such a policy would have resulted in a different outcome in the case. The case suggests that some medical experts may consider

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195. Bevan v. Valencia, No. CV 15-73 KG/SCY, 2017 WL 4797788, at *1 (D.N.M. Oct. 24, 2017). The plaintiffs also brought a wrongful death claim alleging negligence against the doctor for prematurely discharging the patient, failing to appropriately monitor her condition, failing to provide appropriate monitoring instructions to the youth program staff and police, and failing to obtain informed consent for the patient’s discharge. Bevan, 2017 WL 5054703, at *1. The plaintiff also argued that if the patient had remained in the hospital when her condition worsened, she would have survived. Id.

As of the writing of this Article, the court had not ruled on the issue of the physician’s negligence in this particular case. However, in response to the physician’s motion for summary judgment on the issue of punitive damages, the court’s opinion included statements from the plaintiff’s expert regarding the defendant’s negligence. Id. at *4. For example, the expert noted that, if naloxone is administered alone, patients should be kept in the emergency department for two to three hours. Id. Further, he noted that, when naloxone is administered along with lorazepam, physicians must use their clinical judgment to determine the length of observation, but that the observation period should be longer than two to three hours, and that the physician should have monitored the patient for a longer period than he did. Id. Additionally, the expert opined that “[a] single recording of a heart rate one beat shy of being abnormal is not sufficient to safely discharge a patient” who had suffered respiratory arrest, overdosed on heroin, and was given lorazepam, and also that a physician should not discharge a patient like the decedent to a juvenile detention center where non-medical staff would only observe her every 15 minutes. Id. at *4.


197. While the plaintiff also presented additional expert testimony stating that the decedent likely would have survived her overdose had she been kept in the hospital, the court found that such testimony did not relate to whether an overdose policy would have prevented the decedent’s harm. Id. at *4. With regard to whether the hospital was negligent in failing to provide adequate discharge instructions and failing to obtain informed consent, the court found that the plaintiff did not present expert testimony to support such a finding. Id. at *4–5. As such, the court granted the hospital’s motion for summary judgment on these claims. Id. at *5.
implementation of a warm handoff policy to be the standard of care for emergency departments.

More experts are likely to find that warm handoff policies are the standard of care, especially as associations and thought-leaders publish guidelines encouraging the adoption of warm handoff policies and states implement warm handoff legislation. For example, Pennsylvania’s Department of Drug and Alcohol Programs has implemented a warm handoff process throughout the state.\textsuperscript{198} Likewise, the Joint Commission, an established health care program accreditation organization, has encouraged the adoption of adequate handoff policies.\textsuperscript{199} Emergency departments often serve as a gateway into the health care system and are well positioned to start the substance use treatment process. Moreover, given the extent of the overdose epidemic and growing pressure on all stakeholders, including emergency departments, to prevent fatal overdoses, the view that warm handoff programs are the standard of care for emergency departments in treating patients presenting with nonfatal overdose is gaining widespread recognition.

2. Breach

Once the plaintiff establishes the standard of care in a medical malpractice case, she must then prove that the defendant failed to satisfy, or deviated from, that standard, thereby breaching his or her duty to the patient.\textsuperscript{200} The plaintiff also establishes this deviation through expert testimony.\textsuperscript{201}

Similar to limiting the risk of subsequent overdose in a patient who experiences a nonfatal overdose, warm handoffs and other interventions in emergency departments to prevent re-attempts by those who survive a suicide attempt have become the standard of

\begin{footnotesize}
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\item \textsuperscript{198} Addressing Overdose, supra note 106.
\item \textsuperscript{200} See Lynn, supra note 179, at 383–406 (outlining the elements of medical malpractice claims in the state of Connecticut).
\item \textsuperscript{201} \textit{Id}. at 384.
\end{enumerate}
\end{footnotesize}
Among other interventions, clinical recommendations include performing and documenting an appropriate evaluation and risk assessment, carefully formulating a discharge plan, and ensuring to obtain follow-up services when caring for both suicidal and overdose patients. Therefore, breach of such a standard can illustrate a breach of the standard of care in overdose cases.

For example, in *Tkacheff v. Roberts*, an inpatient treatment facility admitted the decedent after she complained of anxiety and depression. Two weeks after her discharge, a hospital admitted her for major depression and suicidal ideation. An attending physician discharged her nearly one week later with an instruction “to return to the hospital if her depression worsened and, if it did not, to take certain prescription medications and follow up with an outpatient provider.” Four days later, the decedent met with an outpatient psychiatric nurse practitioner. After the decedent took her own life several days later, her parents sued the hospital, the hospital’s attending physician, and the outpatient psychiatric nurse practitioner, asserting claims for wrongful death and medical malpractice. The lower court granted the defendants’ motion for summary judgment.

On appeal, the court reversed the finding that the plaintiffs failed to present material questions of fact as to whether the physician’s and nurse practitioner’s actions departed from that accepted standard of care. Specifically, while the attending physician claimed to have conducted and documented the results of a suicide risk assessment, her discharge summary did not state that such an assessment occurred or document its findings; rather, it set forth a care plan that “amounted to little beyond directing that [the] decedent take her medication and present herself to an outpatient care provider over a week later.”

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203. *Id.*


205. *Id.*

206. *Id.*

207. *Id.*

208. *Id.* at 783–84.

209. *Id.*

210. *Id.* at 785.
plaintiffs’ expert opined that, by failing to document a proper risk assessment and then discharging the decedent without ensuring that she obtain psychotherapy and medication management within 2 days, the physician did not satisfy the minimum standard of care.\textsuperscript{211}

In regard to the nurse practitioner, the plaintiffs showed that the nurse practitioner’s psychiatric assessment stated that the decedent was sad and anxious, presented with suicidal ideation, was cutting herself, and had planned to overdose in the past.\textsuperscript{212} The practitioner diagnosed the decedent with severe major depressive disorder and “noted that [the] decedent’s suicidal thoughts increased in tandem with her diagnosed panic disorder.”\textsuperscript{213} Yet the practitioner’s plan withheld further “psychotherapy and medication review until the decedent decided whether to check herself into an inpatient treatment facility and also provided to the practitioner more information about the facility.”\textsuperscript{214} In the opinion of the plaintiffs’ expert, the nurse practitioner failed to satisfy the minimum standard of care by not properly conducting and documenting a suicide-risk assessment of the decedent, “who was experiencing triggering anxiety and untreated depression.”\textsuperscript{215} In addition, the expert opined that the nurse practitioner had not met the minimum standard of care because the practitioner set forth a contingent treatment plan by “placing medication adjustment and psychotherapy on hold in the expectation that a ‘severely compromised’ person would provide more information on an inpatient treatment facility that she was curious about.”\textsuperscript{216}

Cases like \textit{Tkacheff} are instructive in the context of the care and discharge of a patient who presents in an emergency setting with nonfatal overdose. A plaintiff may be able to show that a health care provider breached the warm handoff protocol by, for example, failing to hold and monitor the patient for a sufficient amount of time to ensure that any illicit substances still in the patient’s system will not cause additional harm, conducting and documenting an appropriate assessment and risk evaluation prior to discharge, arranging for

\begin{itemize}
\item \textsuperscript{211} \textit{Id.}
\item \textsuperscript{212} \textit{Id.}
\item \textsuperscript{213} \textit{Id.}
\item \textsuperscript{214} \textit{Id.}
\item \textsuperscript{215} \textit{Id.} at 785–86.
\item \textsuperscript{216} \textit{Id.} at 786.
\end{itemize}
appropriate follow-up care, or contacting the plaintiff’s other health providers and emergency contact or other caregiver.

3. Causation

Once the plaintiff establishes that the defendant owed a duty of care and breached that duty, the plaintiff must show an actual connection between the defendant’s negligence and the plaintiff’s harm before the court will assign to the defendant responsibility for such harm. In assessing causation, most courts apply a “but-for” test, whereby the plaintiff must show that the plaintiff’s harm would not have occurred but for the defendant’s negligence. In situations where several causes could have resulted in the plaintiff’s harm, some courts will consider a defendant’s negligence a cause-in-fact of the harm if it was a substantial factor in producing it.

Moreover, the connection between the defendant’s negligence and the harm suffered must be reasonably close. Proximate cause considers whether in “logic, fairness, policy, and practicality” the law should hold a defendant accountable for harm that is remote from the defendant’s conduct. Today, foreseeability is the cornerstone of proximate cause analysis. To avoid holding defendants liable for harm that falls beyond the scope of their wrongdoing and moral accountability, courts will consider whether a consequence resulting from a chosen action was foreseeable. If the harm resulting from the defendant’s negligence was not foreseeable, then the law will insulate the defendant from liability. Again, given the complexity

218. *Id.*
219. *Id.* at 1681.
220. *Id.*
221. *Id.* at 1683.
222. *Id.*
223. *Id.* Stated differently, if an independent cause intervenes between the defendant’s negligence and the harm, the defendant may be relieved of liability. The question in an intervening cause case is whether the intervening conduct “so dominates the consequences of the defendant’s negligence as to trivialize the defendant’s role in causing the plaintiff’s harm . . . .” *Id.* at 1684. If the finder of fact concludes that such an intervening cause was significant enough to break the chain of proximate causation, the intervening cause is considered to supersed the defendant’s
of medical malpractice cases, plaintiffs must generally provide expert testimony to support causation.\footnote{224}

For example, in \textit{Procaccini v. Lawrence & Mem’l Hospital}, a patient died of a methadone overdose after the hospital emergency room discharged her.\footnote{225} In that case, paramedics brought the unresponsive decedent to the hospital emergency department.\footnote{226} “M.,” the attending emergency department physician, treated the decedent for a suspected methadone overdose.\footnote{227} The physician discharged her after her vital signs improved and she stabilized.\footnote{228} The next morning, however, a friend of the decedent found her unresponsive.\footnote{229} The plaintiff brought a wrongful death claim for vicarious liability for medical malpractice against the hospital because the doctor discharged the patient after only four-and-a-half hours of medical monitoring instead of monitoring her for a full 24 hours, which is the period of time that the fatal side effects of methadone toxicity may occur.\footnote{230} The plaintiff claimed that, if the hospital had held the decedent for 24 hours, then treatment could have averted her death.\footnote{231} At trial, the jury returned a plaintiff’s verdict and awarded $500,000 in non-economic damages and $12,095 in economic damages.\footnote{232}

On appeal, the court held that there was sufficient evidence to support a finding that the hospital’s negligence caused the decedent’s death.\footnote{233} Although the jury heard conflicting expert testimony on how negligence, insulating the defendant from liability. \textit{Id.} at 1684–85. For example, in \textit{Foister v. Purdue Pharma L.P.}, several plaintiffs sued a manufacturer of a certain opioid analgesic, arguing that the manufacturer failed to warn them about the product’s risks of addiction. The court concluded that the plaintiffs’ conduct, including intentional alteration and misuse of the product, was a superseding cause severing the causal connection between the opioid product and the plaintiff’s injuries. \textit{See} 295 F. Supp.2d 693, 703–04 (E.D. Ky. 2003).


\footnote{225} \textit{Procaccini}, 168 A.3d at 545.

\footnote{226} \textit{Id.} at 543–44.

\footnote{227} \textit{Id.} at 544.

\footnote{228} \textit{Id.} at 545.

\footnote{229} \textit{Id.}

\footnote{230} \textit{Id.} at 546.

\footnote{231} \textit{Id.} at 546.

\footnote{232} \textit{Id.}

\footnote{233} \textit{Id.} at 561.
soon a methadone overdose patient would experience recurring overdose symptoms after receiving naloxone, the jury was free to believe the opinion of the plaintiff’s expert witness that respiratory depression can occur in methadone overdoses, even if such a phenomenon defied undisputed and settled toxicology principles.\textsuperscript{234} The plaintiff’s expert testified that the standard of care applicable to possible methadone overdoses required the doctor to monitor the decedent for 24 hours for signs of recurrent opiate overdose, and it found that the lack of such monitoring in the case caused the decedent’s death.\textsuperscript{235}

\textit{Procaccini} demonstrates the importance of implementing emergency department warm handoff policies. There, had a policy existed, the hospital could have saved a life and averted a lawsuit. For example, a proper warm handoff policy, such as the one that this Article proposes in the Appendix, should ensure that emergency practitioners identify the substance or substances responsible for the overdose, obtain the patient’s history, screen for problematic substance use, and determine the patient’s drug or drugs of choice. This information can be helpful in overdose risk-reduction planning and informing treatment decisions.\textsuperscript{236}

Importantly, for patients with a SUD, a warm handoff policy should require that a practitioner attempt to transition a patient with a SUD directly to a treatment provider through an in-person introduction. If a provider at the recommended level of care is not available, the emergency facility can provide medically necessary care in an acute stabilization unit or the current clinical setting until the facility can complete or arrange the transfer. In addition, the emergency department must keep practitioners trained in addiction medicine, as well as a DATA 2000-waived physician, on-call 24 hours per day to allow a patient with OUD, under medically appropriate circumstances, to initiate treatment before leaving the hospital. Such

\textsuperscript{234}Id. at 555–56.
\textsuperscript{235}Id. at 546.
\textsuperscript{236}See generally R.I. DEP’T OF HEALTH, LEVELS OF CARE FOR RHODE ISLAND EMERGENCY DEPARTMENTS AND HOSPITALS FOR TREATING OVERDOSE AND OPIOID USE DISORDER (2017), http://health.ri.gov/publications/guides/LevelsOfCareForTreatingOverdoseAndOpioidUseDisorder.pdf.
providers have specialized training and can consult on treatment planning and discharge timing, among other things.

Even if the patient does not consent to a warm handoff, and does not wish to initiate treatment prior to discharge, the practitioner should attempt to contact the patient’s emergency contact or other caregiver who may convince the patient to obtain further care. Furthermore, the practitioner must provide discharge instructions to the patient and the patient’s emergency contact or other caregiver, if possible, which would detail signs and symptoms that could indicate that a return to the hospital is necessary. Emergency contacts and other caregivers are often in a position to monitor the patient after discharge and also ensure that the patient receives treatment and follow-up services. Finally, a facility must dispense or prescribe naloxone to at-risk patients prior to discharge, which can be administered to a patient who experiences a subsequent opioid overdose after discharge. Such efforts would further reduce patient risk, including patients who do not consent to treatment prior to discharge.

Therefore, in cases like Procaccini, warm handoff policies provide patients an opportunity prior to discharge to seek specialized treatment, initiate MAT if appropriate, and consequently extend the period of monitoring by a health care practitioner or other treatment provider. By implementing a thoughtfully structured warm handoff policy, diligently following its requirements, and documenting in the medical record the steps it took pursuant to the policy, emergency departments and their practitioners can, therefore, reduce the risk of discharging the patient without care and experience a subsequent and potentially fatal overdose, thereby breaking the causal link in a medical malpractice claim.

4. Damages

Finally, a plaintiff must show damages to establish a claim for medical malpractice. In a wrongful death claim for medical malpractice, the decedent’s death easily satisfies this element. The type of damages plaintiffs may seek in a wrongful death action, however, vary from jurisdiction to jurisdiction. In Connecticut, for example, a plaintiff is “entitled to ‘just damages’ together with the cost

of reasonably necessary, medical, hospital and nursing services, and including funeral expenses.\footnote{238}

Yet, even if a plaintiff prevails in showing that medical malpractice caused the death of the decedent, a court may bar or reduce the plaintiff’s damages if a jury finds that the decedent’s negligence contributed to his or her death.\footnote{239} A small minority of states follow a “pure” contributory negligence scheme whereby the plaintiff cannot recover if the decedent’s negligence contributed at all to his or her death, even if the jury finds him or her to be only 1% at fault.\footnote{240} Most states, however, have adopted either a “pure” or “modified” comparative negligence approach.\footnote{241} In pure comparative negligence states, a court will reduce damages to reflect the exact percentage of fault the jury attributes to the decedent.\footnote{242} Alternatively, under one form of modified comparative negligence, some states will permit a plaintiff to recover in the same manner he or she would under a pure comparative negligence scheme, provided that the decedent’s negligence was not as great as the defendant’s (that is, the decedent must be no more than 49% at fault).\footnote{243} Under the other form of modified comparative negligence, the decedent’s negligence can be no greater than the defendant’s in order for the plaintiff to recover (that is, the decedent must be no more than 50% at fault).\footnote{244}

\footnote{238} Procaccini, 168 A.3d 538 at 563 (explaining that “just damages” includes “(1) the value of the decedent’s lost earning capacity less deductions for her necessary living expenses and taking into consideration that a present cash payment will be made, (2) compensation for the destruction of her capacity to carry on and enjoy life’s activities in a way she would have done had she lived, and (3) compensation for conscious pain and suffering”).
\footnote{241} See, e.g., Nelson v. Concrete Supply Co., 399 S.E.2d 783, 784 (S.C. 1991) (stating South Carolina is “join[ing] the vast majority of our sister jurisdictions and adopt[ing]” the comparative negligence approach).
\footnote{242} Amy L. Bernstein, Into the Red Zone: How the National Football League’s Quest to Curb Concussions and Concussion-Related Injuries Could Affect Players’ Legal Recovery, 22 SETON HALL J. SPORTS & ENT. L. 271, 298 (2012). For example, if a jury awards a plaintiff $100,000 and the jury finds that the decedent was 60% at fault, then the award would be reduced by $60,000.
\footnote{243} Id. at 298–99.
\footnote{244} Id.
In defending wrongful death medical malpractice suits, practitioners, hospitals, and emergency departments will most certainly argue that the decedent was negligent in causing his or her own fatal drug overdose or that the decedent’s conduct leading to the overdose was wrongful. Some courts will bar recovery for harm that a decedent’s illegal conduct caused. Yet, while such arguments have prevailed in the past, views regarding SUD are changing. There is increased awareness that SUD is a chronic, relapsing disease and not a moral failing. It is not appropriate to use a decedent’s disease alone as a basis for determining whether the decedent’s own negligence causing his or her death. Such changing attitudes, along with the fact that we are in the midst of a drug overdose epidemic,

245. Richard C. Ausness, The Role of Litigation in the Fight Against Prescription Drug Abuse, 116 W. VA. L. REV. 1117 (2014). For example, in Price v. Purdue Pharma Co., the plaintiff sued the manufacturer of a certain opioid analgesic and several doctors who had prescribed him the medication, among others, arguing that the medication was addictive and its addictive nature caused him injury. Id. at 1132. His claims included negligence, products liability, malicious conduct, malpractice, and fraud. Price v. Purdue Pharma Co., 920 So. 2d 479, 482 (Miss. 2006). The court granted the defendants’ motion for summary judgment, finding that the plaintiff visited several physicians at multiple clinics and used several pharmacies in multiple cities to obtain enough of the opioid medication to support his addiction. Ausness, supra, at 1133. The court declared that such “doctor shopping” by the plaintiff violated federal law, and such violation was “not merely a condition, but instead an integral and essential part of his case and the contributing cause of his alleged injury.” Price, 920 So. 2d at 485 (Miss. 2006).

246. Price, 920 So. 2d at 485.


could have an impact on courts’ rulings regarding whether a decedent with SUD was negligent in cause his or her own death.

D. Patient Privacy

Implementing an effective warm handoff policy and decreasing the risk of subsequent overdose requires strong communication between the emergency department and other parties involved in patients’ care. Such parties may include the patient’s primary care providers; the physician or medical director of a treatment program, if the patient is currently in substance use treatment; and the patient’s emergency contact or other caregiver. When sharing patients’ information with these parties, health care providers must bear in mind whether patient privacy laws permit the provider to share information without the patient’s consent. Federal patient privacy laws permit emergency care providers to share information with other health care providers without a patient’s consent, and likely permit emergency care providers to notify a patient’s emergency contact or other caregiver regarding an overdose in order to facilitate a warm handoff.

1. Health Insurance Portability and Accountability Act

Congress enacted the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) in part to protect patients’ private health information from disclosure.\(^\text{249}\) HIPAA generally prohibits covered health care providers from disclosing protected patient health information (“PHI”) without the patient’s consent.\(^\text{250}\) However, HIPAA provides exceptions to the general nondisclosure rule. Three of those exceptions likely apply when an emergency department provider notifies other parties involved a patient’s care of the patient’s overdose without the patient’s consent: health-care-provider, good-faith-belief, and best-interest exceptions.

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\(^{250}\) 45 C.F.R. § 164.502(a) (2017).
i. Health-Care-Provider Exception

HIPAA’s health-care-provider exception allows an emergency care provider to disclose PHI to other health care providers.\textsuperscript{251} Therefore, emergency care providers may notify an individual’s primary care physician and, if applicable, addiction treatment physician or medical director under HIPAA. Pursuant to the health-care-provider exception, a “covered entity” may disclose PHI for “treatment activities of a health care provider.”\textsuperscript{252} A covered entity is a health care provider that transmits any health information in electronic form.\textsuperscript{253} Health care providers include “providers of medical or health services” and include non-institutional providers, such as physicians and other practitioners.\textsuperscript{254} Treatment activities include “the provision, coordination, or management of health care and related services,” including consultation or referral between providers.\textsuperscript{255}

Emergency-care practitioners who transmit PHI in electronic form qualify as covered entities. Primary care physicians, addiction treatment physicians, and medical directors meet HIPAA’s definition of “health care provider.” Warm handoff policies may require the emergency care practitioner to inform the patient’s primary care physician, or addiction treatment medical director if the patient is currently in treatment for SUD, that the patient has suffered a nonfatal overdose. In this role, the emergency-care practitioner “coordinates health care related services” by contacting the patient’s physician or medical director. Therefore, disclosure of PHI between the emergency care practitioner and other providers falls under the health-care-provider exception and does not violate HIPAA.

ii. Good-Faith-Belief Exception

HIPAA’s good-faith-belief exception may permit an emergency care provider to notify an individual’s emergency contact or other caregiver without his or her consent because a person suffering

\begin{flushleft}
251. 45 C.F.R. § 164.506(a) (2017).
252. § 164.506(c)(2).
254. \textit{Id}.
255. \textit{Id}.
\end{flushleft}
a nonfatal overdose is a threat to himself or herself. Pursuant to the good-faith-belief exception, a provider may disclose PHI if the provider has a good faith belief that disclosing the PHI is “necessary to prevent or lessen a serious and imminent threat to the health or safety of a person” and the person to whom the provider is disclosing the information is a person “reasonably able to prevent or lessen the threat.”

HIPAA presumes that the provider had a good faith belief when his or her belief is based upon the provider’s actual knowledge (that is, based on the provider’s own interaction with the patient) or in reliance on a credible representation by a person with apparent knowledge or authority.

For example, the U.S. Department of Health and Human Services (“HHS”) has stated that, if a doctor knows that, when a patient’s medication is not at a therapeutic level, the patient is at high risk of committing suicide, then the doctor may believe in good faith that disclosure is necessary to prevent or lessen the threat of harm to the health or safety of the patient who has stopped taking the prescribed medication, and may share information with the patient’s family or other caregivers who can lessen or avert the threat.

Overdoses likely qualify as a serious and imminent threat to health and safety. Overdoses are serious because they can lead to severe complications, such as seizures, organ failure, neurologic deficits, and death. An overdose is also a predictor of a subsequent overdose. One study found that individuals with a history of a prior overdose are nearly three times more likely to overdose than those

without a history of overdose. 260 Another study revealed that, among the individuals who died of an opioid-related overdose, 62% had previously experienced at least one overdose, 22% had previously experienced at least two overdoses, and 17% had experienced three to six nonfatal overdoses. 261

A person who has received naloxone for a non-fatal overdose is also likely to be of imminent threat to himself or herself. Administration of naloxone to opioid-dependent patients induces severe withdrawal symptoms. 262 During withdrawal, individuals experience severe cravings for opioids, which can precipitate relapse and overdose. 263 Additionally, the overdose reversal effects of naloxone last at most 90 minutes; the effects of some opioids, however, may last beyond 90 minutes. 264 Therefore, a person may experience a rebound overdose after the naloxone wears off. Such a person would be in imminent danger and in need of medical attention.

Given that a person who has overdosed is at serious risk of complications and is an imminent threat to himself or herself, an emergency contact or other caregiver is likely in the best position to lessen or avert the threat once the emergency department releases the patient. Many times, “family members . . . are . . . the actual first responders and are best positioned to intervene within an hour of the onset of overdose symptoms.” 265 Therefore, if a person starts showing signs of overdose-related symptoms or complications, for example, the emergency contact or other caregiver is in the best position to call 911. The HHS example above lists family and caregivers as examples of people who are likely to lessen or avert a serious or imminent threat.

261. Stoové et al., supra note 158, at 349.
263. NIDA, MEDIA GUIDE, supra note 248, at 3.
Moreover, when the patient’s health care providers and emergency contact or other caregiver coordinate their efforts, they can improve treatment of painful symptoms and minimize the increased risk of subsequent overdose, overdose mortality, and other life-threatening complications, such as seizures, organ failure, and neurological deficits. These individuals are in the best position to intervene, support treatment, and foster recovery.

Therefore, given that nonfatal overdoses likely qualify as a serious and imminent threat pursuant to HIPAA, and familial support decreases life-threatening risks associated with overdose, an emergency care provider may be permitted to notify a patient’s emergency contact or other caregiver under HIPAA’s good-faith-belief exception.

**iii. Best-Interest Exception**

HIPAA’s best-interest exception may also permit emergency care providers to notify an individual’s emergency contact or other caregiver without his or her consent. Under HIPAA’s best-interest exception, when a patient is unable to practically object to the disclosure because the patient is either incapacitated or is in an emergency treatment situation, HIPAA permits the covered health care provider to disclose a patient’s PHI to the patient’s family, friend, or other designated person (“Interested Person”) if it is in the patient’s best interest. While the health care provider must give the patient an opportunity to consent or decline when it becomes practicable to do so, the point of when it is practicable to do so is in the health care provider’s discretion. The health care provider must limit the PHI that it discloses to the Interested Person’s involvement with the patient’s care or payment.

While HIPAA does not explicitly define “incapacity or an emergency treatment situation,” HHS guidance on this topic states that a patient is incapacitated if he or she is unconscious.

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267. Id.
268. Id.
A physician may disclose PHI if it is in the patient’s best interest. Furthermore, HHS has stated that incapacitation or emergency treatment situations may also include circumstances in which a patient is suffering from temporary psychosis or is under the influence of drugs or alcohol. An opioid overdose is consistent with HHS’s examples of incapacitation or emergency treatment situations. With an opioid overdose, the patient may lose consciousness and also remains at risk of the continued dangerous effects of respiratory depression and psychosis, which can extend for more than 24 hours due to the potency of the opioids on which the patient overdosed. The patient may also experience severe withdrawal symptoms after opioid reversal, which include cravings strong enough to impair the patient’s judgment. Therefore, a person who has experienced an opioid overdose will likely fall under the incapacitation or emergency treatment situation exception.

In cases of incapacitation or an emergency care situation, a provider may disclose PHI related to the patient’s care to an Interested Person if it is in the patient’s best interest. It is often in the patient’s best interest for the emergency care practitioner to notify the patient’s emergency contact or other caregiver if the patient has experienced an overdose because, when a person has overdosed, he or she is likely still at risk of serious overdose-related symptoms and complications. An emergency contact or other caregiver can adequately support the individual only if that person knows of the overdose and related symptoms and complications. Therefore, it is likely in the patient’s best interest that the health care provider notify the emergency contact or other caregiver.

2. 42 C.F.R. Part 2

42 C.F.R. Part 2 (“Part 2”) also protects patients who receive substance abuse treatment. Part 2’s privacy protections are even more stringent than HIPAA, and HHS premised them on the understanding that stigma and fear of prosecution could discourage individuals with

270. *Id.*


272. van Dorp et al., *supra* note 262, at 89.
SUDs from obtaining treatment. Part 2 prohibits the disclosure of medical information, which includes records of identity, diagnosis, prognosis, or treatment, if the provider maintains the medical records in connection with any federally assisted drug abuse prevention program, except under limited circumstances. A provider may disclose medical information to other medical personnel in a medical emergency without the patient’s permission.

Part 2 applies to federally assisted drug abuse programs. Federal regulations define “program” as any individual or entity that receives federal assistance and holds itself out as providing, and provides, alcohol or drug abuse diagnosis, treatment, or referral for treatment. Part 2 specifically provides that the regulations do not apply “to emergency room personnel who refer a patient to the intensive care unit for an apparent overdose unless the primary function of such personnel is the provision of substance abuse diagnosis, treatment, or referral, and they provide such services or the emergency room has promoted itself to the community as a provider of such services.

If a hospital has a co-located, federally assisted addiction treatment program, however, one could argue that Part 2 covers the hospital’s emergency department. In that case, pursuant to Part 2, emergency care practitioners may disclose information without patient permission to other medical personnel in a medical emergency. Specifically, the emergency care practitioner may disclose PHI to medical personnel “to the extent necessary to meet a bona fide medical emergency in which the patient’s prior informed consent cannot be obtained.” The regulation does not define “immediate threat”; as Part II of this Article describes, however, a nonfatal overdose poses an


276. Id.


278. § 2.12(e)(1).

279. § 2.51.

280. § 2.51(a).
immediate threat to an individual’s health given that the person is at an increased risk for a subsequent relapse, overdose, overdose mortality, and other life-threatening complications, such as seizures, organ failure, and neurologic deficits.

A warm handoff policy may require the emergency care practitioner to notify the patient’s primary care physician and, if applicable, the patient’s addiction treatment physician or medical director if the patient overdoses. By notifying these individuals, the emergency care practitioner makes a disclosure to medical personnel. The medical personnel receive the information in order to treat the patient’s nonfatal overdose and related substance use, which is an immediate threat to the patient. Therefore, an emergency care practitioner’s release of protected information regarding nonfatal overdoses satisfies Part 2’s medical emergency exception.

Part 2 does not allow disclosure of PHI to non-medical personnel. Therefore, in the event an emergency department also qualifies as a federally assisted drug treatment program, and Part 2 governs, the emergency department cannot disclose PHI to non-medical personnel.

3. Prescription Monitoring Programs

Individuals who obtain MAT at the hospital should be aware that, if a provider prescribes a controlled substance, as opposed to dispensing or administering it, such information will appear in the state prescription monitoring program. A prescription monitoring program (“PMP”) is “an electronic database that tracks controlled substance prescriptions in a state.” PMPs can provide practitioners, state medical and pharmacy boards, and others with “timely information about prescribing and patient behaviors[;]” alert such parties to signs of prescription drug diversion, misuse, and abuse; and help practitioners form an appropriate treatment program for the patient.

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281. § 2.11.
282. § 2.51(a).
284. Id.
In some states, hospital staff must check and report to the PMP when they prescribe, administer, or dispense a controlled substance, including those used for detoxification purposes. Even in states where the law permits but does not require checking the PMP, hospital staff should do so to determine if the patient has received a prescription for any controlled substances or received MAT. The hospital practitioner can then notify the patient’s other practitioners that the patient has overdosed so they can modify their treatment plans accordingly, and the hospital staff together with the patient’s current medical team can facilitate the warm handoff.

V. CONCLUSION

Given the risk of subsequent overdose and death for patients who experience a nonfatal overdose, as well the risk of litigation by decedent’s estates and family members for medical malpractice, all emergency departments should implement a warm handoff policy to ensure patients receive proper screening for problematic substance use and, if appropriate, the opportunity to receive substance use treatment and follow-up services. In doing so, emergency departments should be mindful of surrounding legal issues, including ensuring that they adequately protect the patient’s privacy.

285. In Alabama, medications dispensed in a hospital outpatient setting must be reported to the PMP, unless the medication is administered and used by the patient on the premises of the facility. ALA. ADMIN. CODE r. 420-7-2-.12(2)(a) (2017). In Arkansas, a licensed hospital pharmacy does not need to report to the PMP when it distributes controlled substances as part of outpatient services, inpatient hospital care, or at the time of discharge from the hospital. ARK. CODE ANN. § 20-7-603(5)(B)(i) (2017).

286. Implementation of warm handoff programs has shown promising results. For example, in just over a year after the implementation of a warm handoff program in Westmoreland County, Pennsylvania, 267 patients had been identified through the program, 190 assessments had been completed, and 61 patients had successfully completed the recommended level of care. See generally MILLER ET AL., supra note 20.
APPENDIX. SAMPLE WARM HANDOFF POLICY

Emergency Department Response to Nonfatal Drug Overdose

Model Policy287

Section 1. Purpose

The purpose of this policy is to establish procedures for responding therapeutically to nonfatal drug overdoses in the emergency department (“ED”).288 [Insert statement on requirement under state law to develop this policy, if applicable].

This policy aims to reduce the risk of subsequent drug overdoses by providing Screening, Brief Intervention, and Referral to Treatment (“SBIRT”); notifying parties involved in patients’ care, including primary care providers and emergency contacts; educating patients and their emergency contacts or other caregivers on available treatment options; and initiating treatment in the ED.

Drug overdose deaths have reached an all-time high in the U.S. and are increasing at unprecedented rates. Preliminary estimates show that approximately 64,000 people died from drug overdose in 2016, which would be the largest annual increase in fatal overdoses in U.S. history.289 The steady increase in overdose-related deaths can be


288. This policy is intended for the treatment of adults in the ED. It may be further customized to address the treatment of special populations, including minors and pregnant patients.

289. Josh Katz, Drug Deaths in America are Rising Faster Than Ever, N.Y. TIMES, (June 5, 2017),
largely attributed to the opioid overdose epidemic, and, in particular, a significant rise in fatal overdose from heroin and non-methadone synthetic opioids, including illicit fentanyl.\footnote{Overdose Death Rates, supra note 8.} At the same time, overdose deaths involving benzodiazepines more than quadrupled between 2002 and 2015, and cocaine-related deaths have nearly doubled since 2010.\footnote{Id.}

In addition, [insert overdose statistics specific to the state or county in which the ED sits].

An overdose can predict subsequent overdose.\footnote{Stoové et al., supra note 158, at 350. The study lasted for a period of 5 years and 3 months. Id.} Therefore, when patients present with a nonfatal overdose in the ED, it is imperative that protocols exist to help practitioners prevent, identify, and reduce problematic substance use.\footnote{ESTEE ET AL., supra note 59.}

For individuals with substance use disorders (“SUDs”), including opioid use disorder (“OUD”), specialized treatment has improved patient outcomes.\footnote{Lissa Dutra et al., A Meta-Analytic Review of Psychosocial Interventions for Substance Use Disorders, 2 AM. J. PSYCHIATRY 179, 185 (2008).} Institutionalized discrimination against people with SUDs, however, often prevents individuals from acknowledging their disease, asking for help from their loved ones, or seeking addiction treatment.

EDs can play a critical role in addressing the overdose epidemic. Similar to a nonfatal heart attack patient who, once stable in the ED, would receive a referral to a cardiologist, a patient with a SUD who survives an overdose should likewise receive referral and treatment.
Section 2. Definitions

Overdose. A condition, including, but not limited to, extreme physical illness, decreased level of consciousness, respiratory depression, coma, death, [or cardiac arrest] resulting from the consumption or use of any controlled substance [or other substance of abuse] that requires medical attention, assistance or treatment, [and laboratory testing for substance use] without other conditions to explain the clinical condition.295

Nonfatal overdose. An overdose that does not result in death.

Warm handoff. An approach to care-transition in which a health care provider in the ED does a face-to-face introduction of a patient with substance abuse problems to an addiction treatment provider or to an individual who can facilitate a referral to an addiction treatment provider.

Section 3. Policy

When a patient presents to the ED with a nonfatal drug overdose, the ED’s response shall include, but not be limited to, the following:

A. Conduct a Physical Assessment and Toxicology Testing

The [designated ED practitioner] shall conduct and document a detailed physical assessment that includes toxicology testing. Concurrent use of multiple prescription medications or illicit substances can lead to an overdose. Furthermore, patients who overdose may have ingested a substance different from what they expected or a substance that may have been contaminated. Identifying the substance that caused an overdose may help the patient and ED practitioner in overdose risk-reduction planning and in making informed decisions about treatment. The information will also be useful for the patient’s primary care provider, as well as any existing substance use treatment provider, or such provider to whom the patient

will be referred. Therefore, the [designated ED practitioner] shall order a blood or urine drug test that includes substances that are known to be in the community (for example, fentanyl).

The [designated ED practitioner] shall review the results prior to discharge. If results are not available prior to discharge, the [designated ED practitioner] shall review the results as soon as practicable once they become available and shall provide the results to the patient’s primary care physician and substance use treatment provider in accordance with Section 3-D of this policy.

Notwithstanding the requirements of this section, ED practitioners must remember that, in an emergency setting, stabilizing the patient is of primary importance. Once the patient is stable, however, it is appropriate to conduct a comprehensive physical exam.

B. Obtain the Patient’s History

The [designated ED practitioner] shall attempt to obtain and document historical facts in the patient’s record. Historical facts shall include at least the following:

- the type of substance(s) involved, time of exposure, amount taken, and route of administration (for example, ingestion, intravenous, or inhalation);
- why exposure to the substance occurred (for example, accidental, medical misuse, intentional abuse, or suicide attempt);
- whether and at what time naloxone was administered;
- whether and to what extent the patient has a history of substance use, psychiatric illness, or past suicide attempts; and
- all substances of abuse, prescription medications, over-the-counter medications, vitamins, and herbal supplements the patient uses.

Reliable toxicology results are typically not immediately available. Patients presenting with a nonfatal overdose may provide unreliable information, especially if presenting under the influence of
illicit drugs, with suicidal ideation, or other altered mental status. In addition, patients may unintentionally incorrectly name drugs being used. Therefore, the [designated ED practitioner] shall consider other sources of information, in addition to the patient, including:

- paramedics and emergency medical technicians;
- the patient’s other health care providers;
- the patient’s family members or friends; and
- the state prescription monitoring program ("PMP") database.

C. Review the Prescription Monitoring Program Database

An ED practitioner authorized to review the state PMP database shall check the patient’s PMP record. The PMP is a statewide database that collects, maintains, and reports information on controlled prescription medications ("CPMs") dispensed to individuals. The PMP is intended to give practitioners a tool to aid in making diagnoses and treatment decisions, prescribing CPMs, avoiding drug interactions (for example, concurrent use of opioids and benzodiazepines or other sedatives), and identifying potential diversion, medical misuse, or intentional abuse of CPMs. For example, the PMP can help reveal which substances have been legally dispensed to the patient and whether the patient has been prescribed the same CPM from more than one health care provider, which may be a sign that the patient has a SUD and needs treatment.

The [designated ED practitioner] shall document the search and findings in the patient’s medical record.

D. Notify Controlled Substance Prescribers and Emergency Contacts

Prior to discharge, the [designated ED practitioner] shall contact each health care provider who prescribed a CPM to the patient to inform the health care provider of the patient’s overdose and the class of substance involved in the overdose. The [designated ED practitioner] shall recommend that the prescriber conduct a full evaluation of the prescribing regimen to address whether the patient’s
dose is too high or whether it is too low, which may have contributed to non-prescribed substance use and overdose. CPM prescribers shall be identified via a patient interview and review of the PMP. In addition, the [designated ED practitioner] shall contact the patient’s primary care provider, if known or disclosed by the patient or the patient’s emergency contact, to help arrange follow-up care, preferably making an appointment before the patient’s discharge from the ED.

The [designated ED practitioner] shall record all attempts to contact such providers in the medical record. If the patient does not have a primary care provider, or the [designated ED practitioner] cannot ascertain the primary care provider, the [designated ED practitioner] shall provide the patient with a list of local primary care providers.

Optional language:296 Prior to discharge, the [designated ED practitioner] shall seek the patient’s consent to contact the patient’s emergency contact or other caregiver. If the patient consents, and the [designated ED practitioner] obtains contact information, then the [designated ED practitioner] shall contact the patient’s emergency contact or other caregiver regarding the patient’s overdose and class of substance involved in the overdose. If the patient does not consent, the practitioner shall document the patient’s refusal in the medical record.

E. Screen for Problematic Substance Use

A [designated ED practitioner] shall conduct a brief 1–3 question screen using a standardized tool (for example, the National Institute on Alcohol Abuse and Alcoholism’s single-question screen or the National Institute on Drug Abuse’s quick screen). If the patient screens positive using one of these instruments, then an ED practitioner shall use a standardized screening tool (for example, ASSIST, CRAFFT, AUDIT, or DAST) to assess a patient for risky substance use.

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296. This model language is for a policy that requires patient consent. Consent is not legally required in every instance. See supra Section IV.D.
The [designated ED practitioner] shall document the results of the screen in the patient’s medical record.

**F. Conduct Brief Intervention**

A [designated ED practitioner] shall engage in a short conversation with a patient showing risky substance use behaviors, providing feedback and advice.

If the [designated ED practitioner] determines that a more intensive intervention is appropriate, then a behavioral health professional or ED practitioner with specialized training in addiction treatment shall conduct a more intensive intervention.

**G. Provide Information on Peer Recovery Support**

Prior to discharge, the [designated ED practitioner] shall introduce the patient to a [state-licensed peer recovery support specialist] as soon as clinically appropriate, if one is available and the patient consents, to ensure that each overdose patient has the chance to benefit from this service. Alternatively, the [designated ED practitioner] shall provide the patient and, if possible, the patient’s emergency contact or other caregiver, with information on peer recovery support services. The practitioner shall record such efforts and consents in the patient’s medical record.

Patients who survive an overdose may be influenced to enter treatment if they talk with a peer who shares his or her experiences of addiction and recovery. Peer recovery support services may offer several types of support, including peer mentoring and coaching, recovery resource connecting, and facilitating and leading support groups.

**H. Administer Medication to Relieve Acute Opioid Withdrawal Symptoms, if Clinically Appropriate**

Some opioid-dependent patients who survive an opioid-related overdose may experience acute withdrawal symptoms. If clinically appropriate, the [designated ED practitioner] shall administer, with the
patient’s consent, buprenorphine or other medication approved by the FDA for relieving acute opioid withdrawal symptoms while the patient is in the ED and arrangements are being made for treatment referral. Administration of medication under such circumstances does not require the [designated ED practitioner] to have a Drug Addiction Treatment Act of 2000 (DATA 2000) waiver, which is generally required to administer such medication. However, the practitioner may administer no more than one day’s worth of such medication to the patient per day. The [designated ED practitioner] may carry out such treatment for not more than three days and may not renew or extend it.

I. Discuss and Initiate Medication Assisted Treatment, if Clinically Appropriate

Prior to discharge, the [designated ED practitioner] shall educate a patient with OUD and, if possible, the patient’s emergency contact or other caregiver, about medication-assisted treatment (MAT). MAT, also known as medication-assisted therapy, is an evidence-based method that combines psychosocial treatment and medications approved by the U.S. Food and Drug Administration (“FDA”) for the treatment of OUD. The [designated ED practitioner] shall discuss the risks and benefits of MAT and all FDA-approved medications for the treatment of OUD, including long-acting, practitioner-administered medications, which could assure treatment adherence and eliminate the possibility of post-dispensing diversion of the treatment medication.

MAT may be initiated in the ED if clinically appropriate. The ED shall establish clear criteria for assessing clinical appropriateness for MAT. Patients who have experienced an opioid overdose need careful assessment concerning whether they might be candidates for MAT induction. Therefore, the ED shall keep on-call trained physicians in addiction medicine or addiction psychiatry who respond for real-time consultation as needed within [x hours] of being called. Medical staff trained in addiction medicine shall also be available as

297. An ED that adopts this model language should insert a response time that is consistent with the ED’s on-call policies and procedures.
needed for subject matter expertise in local policy development as well as ongoing clinical consultation.

J. Refer the Patient to Treatment

Prior to discharge, the [designated ED practitioner] shall attempt to facilitate a warm handoff for someone with an SUD who has survived an overdose. If it is clinically appropriate, and the patient consents, then the [designated ED practitioner] shall refer and transition the patient to an appropriate American Society of Addiction Medicine level of care for the patient’s SUD. If that level of care is not available, medically necessary care may be provided in an acute stabilization unit or other appropriate clinical setting until transfer is completed or arranged.

If a patient declines a warm handoff, the [designated ED practitioner] shall ensure that the patient and, if possible, the patient’s emergency contact or other caregiver, receives information about state-licensed addiction treatment services and admission procedures.

The [designated ED practitioner] shall document attempts to facilitate a warm handoff in the patient’s medical record.

K. Keep a DATA 2000-Waived Physician On Call 24 Hours per Day

The ED shall keep a health care provider qualified under the DATA 2000 to prescribe or administer buprenorphine for the treatment of OUD on-call twenty-four hours per day. To prescribe buprenorphine, health care providers must qualify for a waiver under DATA 2000.

Research has consistently demonstrated that buprenorphine is an effective treatment for OUD. 298 Long-lasting changes in brain chemistry can make it difficult for people with OUD to abstain from

opioids because physical withdrawal symptoms and cravings can be overwhelming. Treatment with buprenorphine reduces the symptoms of opioid withdrawal and curbs opioid cravings by blocking the effects of other opioids and heroin. When an appropriate dose of buprenorphine is reached, the medication has a “ceiling effect,” which increases its safety profile by lowering the risk of respiratory depression and overdose.

Patients and physicians surveyed by the Substance Abuse and Mental Health Services Administration about the effectiveness of buprenorphine reported an average of 80% reduction in illicit opioid use, along with significant increases in employment and other indices of recovery. Moreover, recent research comparing treatment approaches for patients with OUDs in EDs suggests that combining buprenorphine with ongoing care is more effective than simply providing referrals to addiction treatment, with or without a brief intervention. Specifically, the study showed that patients who received buprenorphine, along with a brief intervention to discuss opioid use, and up to 12 weeks of buprenorphine maintenance, were more likely to get follow-up addiction treatment and had reduced self-reported illicit opioid use. In addition, they were also less likely to need inpatient addiction treatment services, reducing health care costs.


300. CLINICAL GUIDELINES, supra note 75, at 71.

301. Id. at 18.


L. Dispense Naloxone to Patients at Risk

The [designated ED practitioner] shall determine whether it is medically appropriate to prescribe or dispense naloxone to a patient treated for a nonfatal opioid overdose. In making his or her determination, the practitioner may consider, among other things, whether the patient:

- has a history of problematic substance use, is identified as being at risk for OUD, or is diagnosed with OUD, or;
- is prescribed both a benzodiazepine and an opioid;
- is currently taking an opioid and has a documented diagnosis of a co-morbid condition; or
- requests naloxone.

If it is not possible to dispense naloxone directly to the patient in the ED, the practitioner shall provide a prescription.

The [designated ED practitioner] shall educate the patient and, if appropriate, in accordance with Section 3-D of this policy, the patient’s emergency contact or other caregiver, about how to administer naloxone. The practitioner may use a web-based educational tool to supplement in-person training.

M. Educate Patients Prescribed Opioids on Safe Use, Storage, and Disposal

If the patient is prescribed an opioid and not a candidate for OUD treatment, the [designated ED practitioner] shall educate the patient regarding safe use, storage, and disposal of the medication. Patient education shall include, but not be limited to:

- the risks, benefits, and alternatives of opioid medications;
- the need to reevaluate the prescription regimen with the patient’s CPM prescriber;
- the risks of medical misuse, intentional abuse, and diversion of opioids;
an acknowledgment that it is the patient’s responsibility to safeguard all medications and keep them in a secure location; and

• safe disposal options for unused medication.

Safe storage and disposal of opioid medications reduces opportunities for diversion and the potential for accidental exposure. Most drugs should not be flushed given the potential harm to the environment. The FDA, however, recommends flushing certain prescription pain medications. To prevent diversion and accidental exposure, patients should immediately flush these drugs when they no longer need them. In addition, some national pharmacies may have available opioid disposal packets whereby patients can chemically treat unused opioid medications and dispose of them in the trash. Patients can ask their pharmacies for more information.

N. Comply with Reporting Requirements

The [designated ED practitioner] shall follow all state law requirements for reporting overdoses.

[Describe state law requirements and procedures here.]

O. Provide Discharge Instructions and Ensure Understanding

At discharge, the [designated ED practitioner] shall provide written discharge instructions for drug overdose to the patient. The [designated ED practitioner] shall also discuss discharge instructions with the patient and, if possible, in accordance with Section 3-D of this policy, the patient’s emergency contact or other caregiver. The patient and the patient’s emergency contact or caregiver should demonstrate

an understanding of relevant aspects of patient education and the practitioner shall establish a clear follow-up. The practitioner shall record evidence of patient and caregiver understanding in the medical record.