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HEALTHCARE'S BIGGEST LITTLE LIE: RAMPANT HOSPITAL DRUG THE DIVERSION HIDDEN BEHIND STETHOSCOPES AND WHITE COATS.

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Abstract

The opioid epidemic is widely recognized as one of the most dangerous issues facing America today. Opioid overdose accounts for approximately 130 deaths every day. While the majority of the country is focused on preventing patient misuse, hospital-based clinicians who divert controlled substances are largely overlooked. To effectively address the issue, this Article advocates for a two-pronged approach to identify and prevent diversion—stolen medication—by prescribing and administering practitioners.

First, Congress should pass legislation establishing a federally run Medication Order Monitoring Program (MOMP) for prescribing practitioners to effectively track all hospital medication orders for controlled substances. This program allows for early identification and investigation of any providers who are diverting drugs by over prescribing. Second, the Department of Health and Human Services should add a section to the Conditions of Participation (CoP) regarding the preparation and administration of controlled substances, update the regulatory definition of an emergency situation, and add a section to the CoP governing pharmacy review and reconciliation requirements. The redefinition of emergency situation eliminates a commonly used excuse that allows diversion. Additions to the CoP close gaps that enable diversion and provide detailed policies and procedures for review and reconciliation processes to identify diversion by administering practitioners.

This Article fills the void of clinician focused scholarly work by targeting clinician drug diversion in a hospital setting. This narrow focus allows for a deep dive into clinical workflows and practical hospital considerations while leveraging the author's experience in hospital operations. The proposed solutions provide a significant yet feasible plan of action to effectively decrease diversion. These solutions

close many of the loopholes exploited by clinicians and provide sustainable systems that are universally applicable. Application of the solutions set forth in this Article will provide a workable framework to address and remedy the opioid epidemic.

I. Introduction

The opioid epidemic is widely recognized as one of the most dangerous issues facing America today. Opioid overdose accounts for approximately 130 deaths every day.[2] While the majority of the country is focused on preventing patient misuse, hospital-based clinicians who divert controlled substances are largely overlooked.[3] The true scope of the problem is hidden by ineffective oversight of prescribing practitioners, lack of consistent hospital mechanisms to detect diversion, and the skills savvy clinicians have developed to exploit weaknesses in the system to avoid detection. Shifting focus to prevention of clinician diversion is a critical step towards combatting the opioid epidemic.

To demonstrate the severity of the issue, and strength of solution, this Article will look at a hypothetical hospital employee, Randy. Randy is a travel nurse who primarily works in the emergency room (ER), and consistently takes advantage of many gaps in the healthcare system to divert a variety of controlled substances.[4] Randy

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[2] Nat'l Inst. on Drug Abuse, *Opioid Overdose Crisis*, DRUGABUSE.GOV, drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis (May 20, 2020) [hereinafter Nat'l Inst. on Drug Abuse, *Opioid Overdose Crisis*].

[3] *E.g.*, *id.* (the five major priorities for the Department of Health and Human Services are "improving access to treatment and recovery services promoting use of overdose-reversing drugs strengthening our understanding of the epidemic through better public health surveillance providing support for cutting-edge research on pain and addiction advancing better practices for pain management.").

[4] *What is a Travel Nurse?*, TRAVELNURSING.COM (Mar. 18, 2020), https://www.travelnursing.org/what-is-travel-nursing/ (defining travel nurse (traveler) as a short-term contract employee by an independent agency who then contracts with the hospital with the ability to move state to state multiple

prefers to never extend his contracts, instead staying at each hospital for only 10 weeks. In the past five years he has worked at hospitals across seven states. Randy is addicted to opioids and frequently steals from his hospitals. He manages to escape notice by continually moving. Because he is a traveler, constant movement between facilities and states does not raise any red flags.

Randy's diversion started by stealing extra OxyContin tablets. He figured out that if he said he dropped or lost the medication he could pull twice as much as the physician had ordered. He then simply pocketed the surplus. He also discovered that if he documents that the "patient refused" the medication, he could steal that excess too; all he needed to do was persuade another nurse to sign off that he brought the medication back to the automated dispensing cabinet without actually witnessing the waste.

Randy waits until the ER is busiest to start diverting tablets. This allows him to convince other nurses to sign off on his actions without actually witnessing them. Realistically, nobody has time for a two-nurse check when they are slammed with all kinds of patients and unsure what "train wreck" might come in next. He also takes advantage of the generally hectic nature of the ER by calling in oral orders for patients who do not need any pain medication. Pharmacists assume this is appropriate and the ER doctors are so swamped that they often sign off on all the orders at the end of their shift without checking the patient record.

When he is particularly jonesing for pain medication, Randy will divert intravenous (IV) narcotics and inject the drugs in hospital

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times a year); *See infra* note 23 (defining drug diversion in a healthcare setting as an "employee stealing [opioids] for their own use.").

bathrooms and storage closets. His favorite is Dilaudid, which comes in bulk vials, often containing ten times as much medication as any reasonable physician would order.[5] He can divert huge amounts of Dilaudid without anyone raising an eyebrow. He uses similar processes for IV diversion as he does diverting tablets: he calls in an oral order, pulls more than he needs, persuades another nurse to sign off that he got rid of the medication without actually witnessing, and banks on the physician not reviewing the orders before signing.

Over the course of a ten-week contract, Randy can divert thousands of pills and countless amounts of IV opioids without anyone noticing. In all his years as a traveler he has never been the subject of an investigation or even raised red flags. He simply steals what he can and moves on to the next hospital. Nobody knew the scope of his diversion and addiction until he was found dead from overdose in a hospital storage closet.

Stories like this are increasingly common in the hospital setting and are a significant contributor to the current opioid epidemic. Despite the severity of potential consequences, the scope of the issue is largely hidden. Nobody wants to think that our healers struggle with substance abuse and are often working while impaired. Unfortunately, it does

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[5] *DILAUDID and DILAUDID-HP INJECTION*, U.S. FOOD & DRUG ADMIN., https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/019034s018lbl.pdf (last visited Jan. 31, 2020); *See also* Lydia Wells, et al., *Fentanyl is Superior to Morphine Fact or Myth. . . Revisited*, U. HEALTH SYS. (Nov. 2004), https://www.universityhealthsystem.com/~/media/files/clinical-pathways/01-comparison-of-fentanyl-with-morphine.pdf?la=en (stating Dilaudid is the "Goldilocks" of IV opiates: it is more powerful than Morphine, less powerful than Fentanyl, and carries fewer potential side effects than Fentanyl… "Morphine and hydromorphone [Dilaudid] are the safest and most efficacious opioids. . . [and] Fentanyl is the least safe of the opioids. . . .").

happen. A lot.[6] Unsurprisingly, nothing major is being done on a national scale to identify and prevent clinician drug diversion in hospitals.

To address this issue, Congress and the Department of Health and Human Services (HHS) should implement a two-pronged approach aimed at prescribing and administering practitioners. First, Congress should pass legislation establishing a federal Medication Order Monitoring Program (MOMP) for prescribing practitioners to effectively track all medication orders for controlled substances and identify any providers who are diverting drugs by overprescribing. Second, the HHS should add a section to the Conditions of Participation (CoP) regarding the preparation and administration of controlled substances, update the regulatory definition of an emergency situation, and add a section to the CoP governing pharmacy review and reconciliation requirements.

Part II of this Article will provide an overview of the epidemic and then discuss current oversight and efforts to combat the epidemic. Part III presents a two-pronged approach to prevent clinician drug diversion. The first prong targets prescribing practitioners by implementing a monitoring program that tracks every single medication order written in every facility they practice in. The second prong provides regulatory updates that close common loopholes administering practitioners exploit to divert drugs. It then applies the proposed regulations to a traveling nurse to demonstrate how the regulations work together to curb drug diversion.

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[6] *See, e.g.*, *infra* note 55 (stating that 10–15% of clinicians struggle with substance abuse); *see also infra* note 36 at 172 (stating that two nurses were responsible for diverting 16,000 pills).

II. The Opioid Epidemic and How it Applies to Clinician Diverters

The opioid epidemic is one of the most universally acknowledged health crises facing the United States today.[7] Substance abuse and death statistics are staggering.[8] An estimated 10.3 million people abused opioids in 2018 and approximately 130 people die per day due to opioid overdose.[9] This section will briefly cover the history of the epidemic, discuss oversight agencies, and detail current efforts to combat the epidemic.

A. How Do Clinician Diverters Fit into the Broader Scope of the Opioid Epidemic?

The opioid epidemic can be divided into three distinct phases.[10] Opioids were introduced in the 1990s when pharmaceutical companies marketed opioids as a non-addictive pain medication, leading to high rates of prescriptions and subsequent addiction.[11] This initial push corresponded with an increase in opioid overdose deaths starting in 1999 and continuing into the early 2000s.[12] The second wave began in

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[7] Nat'l Inst. on Drug Abuse, *Opioid Overdose Crisis*, *supra* note 1.

[8] *Id.*

[9] *Id.*; s*ee also* U.S. Department of Health and Hum. Serv., *What is the U.S. Opioid Epidemic?*, HHS.GOV, https://www.hhs.gov/opioids/about-the-epidemic/index.html (last reviewed Sept. 4, 2019); *see also* Ctr. for Disease Control and Prevention, *Understanding the Epidemic*, CDC.GOV, https://www.cdc.gov/drugoverdose/epidemic/index.html (last visited Jan. 31, 2020) [hereinafter CDC, *Understanding the Epidemic*].

[10] CDC, *Understanding the Epidemic, supra* note 8.

[11] *Id.*

[12] *Id.*; Ctr. for Disease Control and Prevention, *Opioid Overdose: Prescription Opioids*, CDC.GOV, https://www.cdc.gov/drugoverdose/opioids/prescribed.html (stating one of

2010, when the country saw an increase in heroin related deaths.[13] Heroin and opioid abuse are strongly tied together.[14] An estimated 4–6% of people who abuse opioids will transition to heroin (typically when they lose access to prescription opioids), and approximately 80% of heroin abusers misused prescription opioids first.[15]

The third phase of the opioid epidemic, starting in 2013, saw a drastic increase in synthetic opioid overdoses.[16] Synthetic opioids are "a class of drugs. . . designed to provide pain relief. . . [mimicking the effects of drugs like] codeine and morphine. They tend to be highly potent. . . [requiring] only a small amount of the drug. . . to produce a given effect."[17] One of the most common synthetic opioids is Fentanyl, a powerful pain reliever (50 to 100 times as powerful as morphine) that was originally intended to help with cancer patients.[18] However, it is

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the most abused drugs during this time was OxyContin, produced by Purdue Pharma); *see also* OFFICE OF THE INSPECTOR GEN., DEP'T OF JUST., REVIEW OF THE DRUG ENFORCEMENT ADMINISTRATION'S REGULATORY AND ENFORCEMENT EFFORTS TO CONTROL THE DIVERSION OF OPIOIDS, i, 3 (2019) [hereinafter OIG Report].

[13] Ctr. for Disease Control and Prevention, *supra* note 6.

[14] See Andrew Kolodny et al., The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction, 36 ANNUAL REVIEW OF PUB. HEALTH 559, 560–61 (2015).

[15] Nat'l Inst. On Drug Abuse, *supra* note 7.

[16] Ctr. for Disease Control and Prevention, *supra* note 6.

[17] *What are Synthetic Opioids?*, FL. CTR. FOR RECOVERY, https://www.floridacenterforrecovery.com/blog/what-are-synthetic-opioids (last visited Sept. 28, 2020).

[18] *Id.*

increasingly a drug of choice for addicts across the country.[19] Fentanyl "is sold through illegal drug markets for its heroin-like effect. . . [and] is often mixed with heroin and/or cocaine as a combination product—with or without the user's knowledge—to increase its euphoric effects."[20] In 2018 alone, the United States reported over 31,000 synthetic opioid-related deaths.[21]

Opioid abuse is not a problem with an easily identifiable victim; it is present across the entire country.[22] It impacts everyone from small town blue collar workers to wealthy celebrities.[23] Travis Scott rapped about the epidemic saying "opioid addiction, pharmacy's the real trap"

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[19] *Id.*

[20] *Id.*

[21] Ctr. for Disease Control and Prevention, *Fentanyl*, CDC.GOV, https://www.cdc.gov/drugoverdose/opioids/fentanyl.html (last updated Mar. 19, 2020) [hereinafter CDC, *Fentanyl*].

[22] Nat'l Inst. on Drug Abuse, *Opioid Summaries by State*, DRUGABUSE.GOV, https://www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state (last updated Apr. 16, 2020) [hereinafter Nat'l Inst. on Drug Abuse, *Opioid Summaries by State*].

[23] *See* Joel Achenbach, *A Remote Virginia Valley Has Been Flooded by Prescription Opioids*, WASH. POST (Jul. 18, 2019), https://www.washingtonpost.com/national/a-remote-virginia-valley-has-been-flooded-by-prescription-opioids/2019/07/18/387bb074-a8ca-11e9-9214-246e594de5d5_story.html (discussing the millions of pills sent to a small town in Virginia); *see also* AnnaMarya Saccia, *How Oxycodone Gets Laced with Fentanyl*, ROLLING STONE (Aug. 14, 2018), https://www.rollingstone.com/culture/culture-news/oxycodone-laced-fentanyl-demi-lovato-711045/ (discussing singer Demi Lovato's opioid related overdose).

and Kanye West admitted to battling opioid addiction.[24] Hospital clinicians are an important but often ignored contributor to the overwhelming number of Americans who abuse opioids.[25]

1. Drug Diversion & Available Data

A significant contributor to the opioid epidemic is drug diversion. Drug diversion is simply a polite way of saying stolen drugs.[26] While anyone can divert drugs (patients, family members, staff, etc.), this Article will focus on diversion for personal use by clinicians in a hospital setting.[27] Methods of diversion are variable based on setting, type of clinician, and type of drug.[28] The primary settings for diversion discussed in this Article are emergency rooms,

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[24] TRAVIS SCOTT, *Watch* (Epic Records 2018); *see also* Thomas N. Palermo, *The Opioid Crisis*, 33 CRIM. JUST. 4, 5 (2019).

[25] *See* Tina Reed, *Drug Diversion is a Big Problem for Healthcare. A New Database is Aimed at Figuring Out Just How Big*, FIERCE HEALTHCARE (May 21, 2019, 9:25 AM), fiercehealthcare.com/hospitals-health-systems/drug-diversion-a-big-problem-for-health-facilities.

[26] *Drug Diversion*, PREMIER SAFETY INSTITUTE, https://www.premiersafetyinstitute.org/safety-topics-az/opioids/drug-diversion/ (last visited Jan. 31, 2020).

[27] *Do You Know About Drug Diversion?*, CTRS. FOR MEDICARE & MEDICAID SERV., https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Downloads/infograph-Do-You-Know-About-Drug-Diversion-[April-2016].pdf (last visited Jan. 31, 2020).

[28] *ASHP Guidelines on Preventing Diversion of Controlled Substances*, AM. SOC'Y OF HEALTH-SYSTEM PHARMACISTS, 78 https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/preventing-diversion-of-controlled-substances.ashx (last visited Jan. 31, 2020).

procedural areas, and inpatient units. Each of these settings provides unique opportunities to divert.[29]

For example, a nurse in an emergency room can call in several oral prescriptions for controlled substances for patients who don't need them or don't exist, keep the medication, and the ER physician will likely sign off on all orders at the end of the shift without realizing their mistake.[30] The ER can be an ideal place for diversion because opioids are available in every format and it is easy to use the "emergency" excuse as a cover for multiple means of diversion.[31]

Anesthesia areas such as the Post-Anesthesia Care Unit (PACU) and the Operating Room (OR) provide the biggest opportunities to divert some of the most dangerous drugs in the hospital.[32] Intravenous (IV) Fentanyl, Dilaudid, and Morphine are all commonly used in these settings.[33] Clinicians have ample access to these drugs and can divert

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[29] *Id.* at 81.

[30] Interview with Clifton Wilkerson, Bd. Certified Ob/Gyn (October 22, 2019) (notes on file with Author) [hereinafter Dr. Wilkerson Interview]. Dr. Wilkerson is a Fellow of the American College of Obstetrics and Gynecology, currently serves on the Board of Directors for Paris Regional Medical Center in Paris, Texas, and is the former Chief of Staff and Department Chair for the Surgical Department. Physicians often have so many orders to sign at the end of their shift that they do not closely review orders called in by nurses and other staff that they trust.

[31] *See* 21 C.F.R. § 290.10 (2020) (defining an Emergency Situation, which allows for an oral prescription of a Schedule II narcotic); *see generally* Dr. Wilkerson Interview.

[32] *ASHP Guidelines on Preventing Diversion of Controlled Substances*, *supra* note 27 at 83.

[33] *See* Huy Vo et al., *Opioid and Non-Opioid Analgesia During Surgery*, AM. NURSE TODAY (May 9, 2018), https://www.americannursetoday.com/opioid-non-opioid-analgesia-surgery/.

in a variety of ways.[34] Typically, they divert these drugs by keeping excess medication that should be wasted.[35] Other forms of diversion are outright theft of whole doses and direct injection of the medication.[36] The latter is one of the most dangerous forms of diversion.[37] Clinicians will inject themselves with their patient's medication, refill the syringe with saline or other solutions, and then inject their patient using the same needle.[38]

Drugs in tablet form are commonly diverted on inpatient units (telemetry, intensive care, medical/surgical, etc.).[39] Detection of tablet diversion is theoretically easier (via a simple count reconciliation

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[34] Jamie A. Pena & Peter A. McNeilly, Investigating and Prosecuting Opioid Diversion and Tampering Cases Involving Medical Professionals and Institutional Healthcare Providers, 64 U.S. ATT'YS' BULL. 115, 117–18 (2016).

[35] *ASHP Guidelines on Preventing Diversion of Controlled Substances, supra* note 27, at 82 (defining wasting as the common term for returning excess medication to the appropriate disposal container, which should be verified by an independent observer (usually a nurse) every time a controlled substance is wasted).

[36] *Id.* at 83-88.

[37] *Id.*; *See*, *e.g.*, Lovering, *infra* note 80 (detailing the number of patients infected by one clinician who diverted by direct injection).

[38] *See, e.g.*, Gabrielle Masson, *Ex-Utah Nurse Pleads Guilty to Infecting 7 Patients with Hepatitis C*, BECKER'S HOSP. REV. (Sept. 26, 2019), https://www.beckershospitalreview.com/quality/ex-utah-nurse-pleads-guilty-to-infecting-7-patients-with-hepatitis-c.html (explaining that this is a huge concern for hospitals because it leaves patients in a lot of pain and exposes them to all kinds of infections).

[39] *See*, *e.g.*, Andrew E. Lelling, *Corporate Accountability for the Opioid Epidemic*, 66 U.S. ATT'YS' BULL. 159, 171 (2018).

system), but clinicians have been able to divert tens of thousands of tablets without detection.[40] There are several ways savvy clinicians can accomplish this. Tablets can be swapped for "look-alikes," medication orders can be written for patients who do not need pain medication, and excess tablets can be diverted instead of returned per hospital policy.[41] Anecdotally, excess tablets can be diverted by pulling the medication, pocketing it, and documenting a legitimate reason for why it wasn't given.[42]

In addition to the means of diversion described above, prescribing practitioners can use their credentials to divert from all units of the hospital. Diversion by over-prescription occurs when a prescribing practitioner writes a medication order for a patient that is outside their scope of practice or "without a legitimate medical purpose."[43] Most relevant to this Article are medication orders written without a legitimate medical purpose. Common indicators of this type of diversion are unusually high dosages and amounts per patient, identical amounts and dosages for every single patient, two prescriptions for the same patient at the same time, and increase in dosages "long after anything in the patient's medical records would support such an increase."[44]

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[40] *See id.*

[41] Beth Hawkes, *Drug Diversion in Nursing*, BSN TO MSN (Nov. 29, 2015), https://bsntomsn.org/2015/drug-diversion-in-nursing/.

[42] *Id.*

[43] K. Tate Chambers, A Primer on Investigating Doctors Who Illegally Prescribe Opioids, 66 U.S. ATT'YS' BULL. 19, 23 (2018).

[44] *Id.* at 30.

Data regarding clinician diversion is significantly underreported, making it difficult to grasp the true scope of the issue.[45] Even industry experts are unable to ascertain the actual magnitude of the issue.[46] Available data is often published by artificial intelligence companies who have a vested interest in establishing the severity of hospital diversion because the data helps sell products. For example, a recent study conducted by Protenus, an artificial intelligence company whose products allow hospitals to effectively track movement of controlled substances,[47] found that over 90% of clinician diversion is unreported.[48] Of the reported cases, 34% of clinician diversion is from a hospital setting.[49] Additionally, Thomas Knight (founder and CEO of another healthcare analytics company) recently created HealthcareDiversion.org, a 501(c)(3) nonprofit solely devoted to identifying and combatting clinician diversion in a hospital setting.[50]

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[45] *2019 Drug Diversion Digest*, PROTENUS, INC. 1, 18 (2019) [hereinafter *2019 Drug Diversion Digest*].

[46] Reed*, supra* note 24.

[47] Drug Diversion Surveillance: Detect theft and misuse of controlled substances in your organization, PROTENUS, INC., https://www.protenus.com/features/detect-clinical-drug-diversion (last visited Jan. 31, 2020).

[48] *2019 Drug Diversion Digest*, *supra* note 44.

[49] *Id.* at 6.

[50] *Stop Drug Diversion*, HEALTHCAREDIVERSION, https://healthcarediversion.org/about-us/ (last visited Jan. 31, 2020) (Detailing a mechanism to report clinician diversion, and separates diversion into four categories: pharmacy, physician, nursing, and anesthesiology); *Find Incidents in Your Area*, HEALTHCAREDIVERSION, https://healthcarediversion.org/incidents/ (last visited Jan. 31, 2020).

The rest of the industry's knowledge regarding diversion is purely anecdotal.[51]

There are several reasons why there is a lack of good data. First, it is really difficult to catch drug diversion.[52] There are many access points throughout the hospital that provide opportunities to divert.[53] Hospitals and systems who make substantive efforts to identify diversion are typically reliant on lagging data, which can take months (if not years) to identify diversion.[54]

Additionally, there is a strong culture of non-reporting in the healthcare field in general.[55] The industry has traditionally been punitive.[56] Any adverse outcomes of non-reporting can subject

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[51] Interview with Clifton Wilkerson, *supra* note 29.

[52] *See Drug Diversion and Impaired Health Care Workers*, JOINT COMMISSION (Apr. 2019), https://www.jointcommission.org/assets/1/23/Quick_Safety_Drug_diversion_FINAL2.PDF ("Experts believe that only a fraction of those who are diverting drugs are ever caught[.]").

[53] *ASHP Guidelines on Preventing Diversion of Controlled Substances*, *supra* note 27.

[54] Jessica K. Cohen, *Analytics Speeds Drug-Diversion Discovery from Weeks to Hours*, MOD. HEALTHCARE (May 4, 2019), https://www.modernhealthcare.com/operations/analytics-speeds-drug-diversion-discovery-weeks-hours.

[55] *See generally* Mark A. Abramson, Jared R. Green & Lindsey B. Gray, Exposing the "Dirty Little Secret:" Random Drug Testing of Health Care Workers in the Wake of the Hepatitis C Outbreak, 54 N.H. B.J. 10, 12 (2014).

[56] *Interview with Dr. Wilkerson, supra* note 30.

hospitals and clinicians to criminal liability including jail time, or civil liability including loss of license and/or fines.[57]

There is also a historical expectation that clinicians take care of their own.[58] Anecdotally, clinicians value loyalty and are less likely to report on each other.[59] This so-called "'conspiracy of silence'. . . shrouds the medical community. . . [and clinicians] are notoriously reluctant to 'turn in' coworkers."[60] This culture of silence begins as early as medical and nursing school, and is amplified by the pervasive "us versus them" view clinicians have towards hospital compliance, quality, and administrative officers.[61]

Finally, smart diverters know how to exploit the reality of a hospital environment and flow.[62] The hospital is typically the busiest

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[57] *See, e.g.*, Associated Press, *California Alleges Doctor Killed 4 Patients with Opioids*, L.A. TIMES (Aug. 14, 2019), https://www.latimes.com/california/story/2019-08-14/california-alleges-doctor-killed-4-patients-with-opioids [hereinafter *California Alleges Doctor Killed 4 Patients with Opioids*].

[58] Abramson et al., *supra* note 54, at 12.

[59] *Id.*

[60] *Id.*

[61] *See, e.g.*, Diane W. Shannon, *Bridging the Divide for Leaders and Physicians,* PHYSICIANLEADERS.ORG (Sept. 6, 2017), https://www.physicianleaders.org/news/bridging-the-divide-for-leaders-and-physicians (describing the importance of good communication and eliminating the "us versus them" mentality).

[62] *See generally What is Patient Flow?,* NEW ENG. J. OF MED. CATALYST (Jan. 1, 2018), https://catalyst.nejm.org/what-is-patient-flow/ (providing detailed description of hospital patient flow).

during the day shift when the hospital has the most patient movement.[63] Because staffing ratios are becoming tighter (more patients per clinician), it is possible for diversion of small amounts of controlled substances to completely escape notice of even the most vigilant employees.[64]

Diversion is equally likely to be missed on the night shift due to typically decreased staff.[65] Fewer people are around with eyes on what each individual is doing, making it less likely for the diverting clinician to get caught.[66] A diverting clinician understands patterns of staffing and movement and can create a plan of diversion that exploits the holes in security present at different hours of the day.[67]

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[63] *See id.*

[64] *Interview with Dr. Wilkerson*, *supra* note 29 ("[A] floor nurse. . . [who] was saving very small amounts of powerful narcotics when they were administered to patients. . . would have enough by the end of the shift to use for herself [and] was [only] discovered accidentally when a coworker saw a syringe in her purse.").

[65] *See* Hannah J. Wong & Dante Morra, *Excellent Hospital Care for All: Open and Operating 24/7*, J. GEN. INTERNAL MED. 26(9):1050–2 (2011).

[66] *See* Pamela B. de Cordova et al., *Night and Day in the VA: Associations between Night Shift Staffing, Nurse Workforce Characteristics, and Length of Stay*, NAT'L INST. OF HEALTH (Apr. 1, 2019), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3959218/pdf/nihms-552094.pdf (showing difference in staffing levels of day shift versus night shift).

[67] *See id.*

2. Clinician Substance Abuse: Prevalence & Impact

The lack of reporting casts a veil over the true scope of the issue.[68] Like other professions (for example, the legal field),[69] clinicians are adept at hiding the signs of diversion and substance abuse.[70] To gain a complete sense of the issue, available data must be evaluated in light of the prevalence of substance abuse among the healthcare professions.

Approximately 10–15% of clinicians are estimated to have an issue with substance abuse at some point in their career.[71] Studies show that 17.6% of physicians will misuse opioids.[72] These substance abuse issues don't spring up out of nowhere; opioid addiction typically stems

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[68] Kurt Eichenwald, *When Drug Addicts Work in Hospitals, No One is Safe*, NEWSWEEK (June 18, 2015, 6:07 AM), https://www.newsweek.com/2015/06/26/traveler-one-junkies-harrowing-journey-across-america-344125.html (providing first-hand account of how a traveling healthcare worker exploited gaps in policy to divert drugs over many years).

[69] Elaine Zimmerman, *The Lawyer, the Addict*, N.Y. TIMES (Jul. 15, 2017), https://www.nytimes.com/2017/07/15/business/lawyers-addiction-mental-health.html ("In recent years. . . 'we're seeing a significant rate of increase specifically among attorneys using prescription medications. . . [like] Xanax, Adderall, [and] opiates'").

[70] Pena, *supra* note 33, at 119 ("most diverters are only detected after several months of diversion because they become experts at concealing their addiction.").

[71] Abramson, *supra* note 54, at 10.

[72] Angelica Halat, An Anesthesiologist, a Brain Surgeon, and a Nurse Walk into a Bar: A Call for Change in How America Handles Health Care Worker Substance Abuse, 46 SETON HALL L. REV. 939, 951 (2016).

from valid use of the drugs as pain management following an injury.[73] When the valid prescription runs out, clinicians begin to divert small amounts from the hospital.[74] As their tolerance and addiction grow, they begin diverting increasing quantities of some of the most powerful opioids.[75]

Despite well documented concerns regarding addiction in the medical community, drug testing is incredibly unpopular.[76] Several articles have been written advocating for increased drug testing but to date there have been no major policy changes.[77] Practically this means clinicians can continue to abuse substances undetected and provide patient care while impaired.[78]

Clinician substance abuse and diversion impact more than the clinicians themselves.[79] Hospitals can face significant liability.[80] First, impaired clinicians have the potential to significantly harm their

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[73] *See, e.g.*, Hawkes *supra* note 40.

[74] *See*, *e.g.*, *id.*

[75] *See*, *e.g.*, *id.*

[76] *See generally* Abramson*, supra* note 54, at 13.

[77] *See, e.g.*, Halat, *supra* note 71, at 943 ("Despite the logic behind drug testing medical professionals, calls to implement such testing, especially on a random basis, repeatedly fail in the political arena").

[78] *See generally* Abramson, *supra* note 54, at 10.

[79] *See, e.g.*, Lelling, *supra* note 38.

[80] Pena, *supra* note 33, at 122 ("Hospitals are often reluctant to report diversion because of the potential exposure that such a potentially public exposure may present").

patients.[81] Additionally, diverted drugs pose a huge financial concern.[82] Protenus estimates that 47 million doses were lost in 2018 alone, causing $474 million in losses to healthcare organizations.[83] Finally, hospitals can face investigation if they have "significant" diversion.[84] The meaning of significant has recently been called into question—because there is no precise definition, hospitals lack guidance on what needs to be reported and when.[85] When a failure to report is discovered, hospitals can face serious consequences.[86]

3. Key Terminology

This Article will address two primary sources of diversion within a hospital: prescribing practitioners and administering

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[81] Daniel Lovering, *U.S. Hospital Worker Sentenced to 39 Years for Spreading Hepatitis*, REUTERS (Dec. 2, 2013), https://www.reuters.com/article/us-usa-crimt-hepatitus/u-s-hospital-worker-sentenced-to-39-years-for-spreading-hepatitis-idUSBRE9B10RN20131202.

[82] *2019 Drug Diversion Digest*, *supra* note 44, at 3.

[83] *Id.*

[84] 21 C.F.R. § 1301.76(b) (2020) ("The registrant shall notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft").

[85] *See* Sue Ambrose & Holly K. Hacker, *When Opioids go Missing, Hospitals are Supposed to Alert the DEA. That Didn't Happen at UT Southwestern*, DALL. MORNING NEWS (Sept. 8, 2019), https://www.dallasnews.com/news/investigations/2019/09/08/when-opioids-go-missing-hospitals-are-supposed-to-alert-the-dea-that-didn-t-happen-at-ut-southwestern/ (discussing ambiguity of reporting requirements).

[86] *See, e.g.*, Lelling, *supra* note 38, at 171.

practitioners.[87] Prescribing practitioners include any practitioner who has approval from the Drug Enforcement Agency (DEA) to prescribe controlled substances.[88] This grouping will vary by state.[89] For example, some states allow mid-level practitioners like Advanced Practice Nurses to prescribe, while others are more limited.[90]

The administering practitioner is most often a nurse, but a physician or mid-level provider may also be permitted.[91] This Article will refer to prescribing and administering practitioners collectively as clinicians.

Controlled substances include Schedule II–V drugs as defined in the Controlled Substances Act.[92] Notable examples relevant to this Article are OxyContin, Dilaudid, and Fentanyl.[93] These are some of

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[87] *Do You Know About Drug Diversion?*, *supra* note 26 (Stating other sources of diversion are pharmacy staff, patients, and family members).

[88] *Practitioner's Manual – SECTION II*, DRUG ENFORCEMENT AGENCY DIVERSION CONTROL DIVISION, https://www.deadiversion.usdoj.gov/pubs/manuals/pract/section2.htm (last visited Jan. 31, 2020). This report is currently being updated by the DEA. *Id.*

[89] *State Practice Environment*, AM. ASS'N OF NURSE PRACTITIONERS, https://www.aanp.org/advocacy/state/state-practice-environment (last updated Dec. 20, 2018).

[90] *Id.* (Using examples like the state of Washington which allows full practice (allowed to prescribe controlled substances), Utah which has reduced practice (some limits on practice), and California which has restricted practice (always have to be supervised)).

[91] *See* 42 C.F.R. § 482.23(c) (2019).

[92] 21 U.S.C.A. § 812(a).

[93] *Controlled Substances Schedules*, DRUG ENFORCEMENT AGENCY DIVERSION CONTROL DIVISION,

the most dangerous drugs available at a hospital and are heavy contributors to the opioid epidemic.[94] They are referred to collectively because proposed changes will be applicable to all controlled substances.

Additionally, a crucial distinction relevant to this Article is between prescription and medication order. Prescription refers to any order written by a prescribing practitioner that is filled by a pharmacy for a patient who will not receive the medication while admitted in an acute care setting.[95]

In contrast, a medication order refers to any prescribing practitioner order for a controlled substance that is written and filled for use of an in-house patient.[96] Though the DEA does not specifically

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https://www.deadiversion.usdoj.gov/schedules/#:~:text=Schedule%20II%2FIIN%20Controlled%20Substances%20(2%2F2N)&text=Examples%20of%20Schedule%20II%20narcotics,opium%2C%20codeine%2C%20and%20hydrocodone (last visited Sept. 30, 2020).

[94] *See generally* Nat'l Inst. on Drug Abuse, Opioid Overdose Crisis, *supra* note 1.

[95] Drug Enf't Admin., *Section V – Valid Prescription Requirements*, U.S. DRUG ENF'T ADMIN. DIVERSION CONTROL DIV., (Nov. 8, 2012), http://fapmmed.net/OFFICE_OF_DIVERSION_CONTROL.PDF.PDF.

[96] *BDS Medication Administration Curriculum Section III*, DEP'T OF HEALTH & HUM. SERV., 2, (2011), https://www.dhhs.nh.gov/dcbcs/bds/nurses/documents/sectionIII.pdf ("A medication order is written directions provided by a prescribing practitioner for a specific medication to be administered to an individual. The prescribing practitioner may also give a medication order verbally to a licensed person such as a pharmacist or a nurse.").

define medication order, it does say that "[a] prescription is not an order for medication which is dispensed for immediate administration to the ultimate user (for example, an order to dispense a drug to an inpatient for immediate administration in a hospital is not a prescription)."[97]

Medication administration route is a major factor in methods of diversion.[98] Administration route refers to the physical format of medication when it is given to the patient.[99] Controlled substances are typically administered orally via tablet form or as a liquid administered intravenously (IV).[100] Route is usually different based on setting. For example, a patient in the PACU is more likely to receive IV Dilaudid than a floor patient.[101] Conversely, a floor patient is more likely to receive OxyContin in tablet form.[102] Methods of diversion vary by

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[97] *Id.*

[98] *See generally ASHP Guidelines on Preventing Diversion of Controlled Substances, supra* note 27, at 78 (discussing methods of diversion).

[99] *See generally Medication Administration: Why it's Important to Take Drugs the Right Way*, HEALTHLINE, https://www.healthline.com/health/administration-of-medication#training (last visited Nov. 27, 2019).

[100] *Id.* There are additional routes, such as transdermal patches, but this Article will focus on oral and IV medications. Additionally, this Article does not address PCA Pumps because administration is controlled by the patient rather than the clinician.

[101] Jie Luo & Su Min, *Postoperative Pain Management in the Postanesthesia Care Unit: An Update*, J. Pain Res., 2687, 2690 (2017) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5695271/pdf/jpr-10-2687.pdf (Describing pain management in PACU with IV opioids, including Dilaudid).

[102] *See, e.g.*, Mayo Clinic Staff, *Pain Medications After Surgery*, MAYO CLINIC (Feb. 22, 2020), https://www.mayoclinic.org/pain-medications/art-

setting and medication type. Diverters are constantly adapting to circumvent hospital diversion prevention processes and procedures.[103]

IV medications typically come in either multidose vials (MDVs) or single dose vials (SDVs). A MDV is a bottle of medication approved for multiple separate administrations.[104] A new sterile needle and syringe must be used with each administration of medication from the MDV.[105] The use of MDVs is strongly discouraged by the government and healthcare industry because it provides significant opportunities for contamination, infection, and diversion.[106]

A SDV is "a vial of liquid medication intended for. . . injection. . . for use in a single patient for a single case, procedure, injection."[107] SDV vials can come in varying dosage amounts. Smaller dosages—ampules—are preferable because they eliminate the need for wasting

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20046452 ("Examples of opioids prescribed in pill form after surgery include oxycodone[.]").

[103] *See generally ASHP Guidelines on Preventing Diversion of Controlled Substances*, *supra* note 27 (discussing methods of diversion).

[104] *Questions about Multi-Dose* Vials, CENTERS FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/injectionsafety/providers/provider_faqs_multivials.html (last visited Sept. 26, 2020).

[105] *Id.*

[106] *Multi-Dose Vials: What's the Point?*, BECKER'S HOSP. REV. (Jul. 30, 2014), https://www.beckershospitalreview.com/quality/multi-dose-vials-what-s-the-point.html.

[107] *Questions About Single-Dose/Single Use Vials*, CENTERS FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/injectionsafety/providers/provider_faqs_singlevials.html (last visited Jun. 20, 2019).

excess medication thereby removing an opportunity for diversion.[108] They can also come in bulk SDVs containing more than any prescribing practitioner would order for a single dose.[109] Practically, when an administering practitioner pulls a bulk SDV there will be a large amount of medication that will not be given to the patient.[110] This extra medication is supposed to be wasted, but a diverting practitioner will often keep it.[111] This is not as significant an issue with ampules because they come in much smaller doses.[112] Even if the administering practitioner pulls a larger ampule than ordered by the prescribing practitioner, the wasted amount will be much less than if they had pulled a bulk SDV.[113]

For example, a common post-op pain medication is Dilaudid.[114] Dilaudid is sold in the following dosages: 1mL ampule, 5mL ampule,

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[108] *Ampoule*, LEXICO.COM (POWERED BY OXFORD), https://www.lexico.com/en/definition/ampoule (last visited Aug. 22, 2020) (An ampule "is a small sealed glass capsule containing a liquid, especially a measured quantity ready for injecting." Ampule can also be spelled ampoule.).

[109] *DILAUDID® and DILAUDID-HP® INJECTION*, *supra* note 4.

[110] *See ASHP Guidelines on Preventing Diversion of Controlled Substances, supra* note 27 (recommending that controlled substances be stocked in "lowest commercially available units" to avoid diversion of wasted product).

[111] *See id.*

[112] *See id.*

[113] *See id.*

[114] *See* Wells, *supra* note 4.

50mL SDV[115], and 250mg SDV (powder form).[116] Despite fact that a 50mL SDV has 10 to 50 times the amount of medication as the two available ampule sizes, it is still proffered as a cost-effective single-dose option.[117] This could incentivize hospitals to purchase the bulk option as a cost saving measure.[118] Because the bulk medication is sold and marketed as a single dose, approximately 45 to 49mL of medication will be wasted on every administration.[119] This is a gross waste of a scarce resource and a frightening opportunity for diversion.[120]

Most medications are stored in Automated Dispensing Cabinets (ADCs).[121] ADCs are typically located throughout the hospital and are only accessible by credentialed clinicians.[122] The medication pull and

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[115] *Questions About Single-Dose/Single Use Vials*, *supra* note 106 (This can be used as a SDV or can be divided "into multiple single-use vehicles (e.g., syringes) [and] is considered repackaging." Repackaging is a way hospitals can maximize the use of bulk SDVs.).

[116] *DILAUDID® and DILAUDID-HP® INJECTION, supra* note 4.

[117] *See generally id.*

[118] For the purposes of this Article, bulk will refer to any amount of medication stored and marketed as a single dose medication that exceeds normal dosing protocols.

[119] *See DILAUDID® and DILAUDID-HP® INJECTION, supra* note 4 (detailing standard drug dosage and administration).

[120] *See generally Recent Trends in Hospital Spending and Manufacturer Shortages*, AM. HOSP. ASS'N (Jan. 15, 2019), https://www.aha.org/system/files/2019-01/aha-drug-pricing-study-report-01152019.pdf (describing the impact of rising drug costs and drug shortages on hospital budgets and operations).

[121] Matthew Grissinger, Safeguards for Using and Designing Automated Dispensing Cabinets, 37 PHARMACY & THERAPEUTICS 490 (2012).

[122] *See id.* at 491 (discussing ADC placement considerations).

administration process is fairly simple. The administering practitioner will sign into the ADC with hospital credentials, pull the appropriate medication, administer the medication to the patient (often using a barcode scanning procedure), waste or return any excess medication at the ADC, and then document what was administered to the patient.[123]

Each ADC is filled with stocked and profiled medications.[124] Stocked medications are drugs that are stored in bulk and are not assigned to any specific patient.[125] Profiled medications are drugs that have been assigned to specific patients.[126] The typical process for profiled medications is a prescriber puts in a medication order, a licensed pharmacist reviews the order and checks for any issues, and then the pharmacist assigns the exact medication order to the patient.[127]

ADC records are a key tool in detecting diversion.[128] Tablet counts are the easiest method of detecting diversion.[129] It is simple math: A amount was stocked, B amount was pulled, C amount was administered, and D amount (if any) was returned to the ADC.[130] IV

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[123] *See generally Guidance on the Interdisciplinary Safe Use of Automated Dispensing Cabinets*, INST. FOR SAFE MEDICATION PRACTICES (2009), https://www.ismp.org/sites/default/files/attachments/2018-03/ISMP02B-ADC%20Guidelines-0706%20_6_.pdf (A two-employee sign off is required for on-site destruction of controlled substances.); 21 C.F.R. § 1317.95(d).

[124] Grissinger, *supra* note 120, at 490.

[125] *Id.*

[126] *Id.*

[127] *Id.*

[128] Pena, *supra* note 34, at 120.

[129] *Id.*

[130] *See generally* Mark Fan et al., Diversion of Controlled Drugs in Hospitals: A Scoping Review of Contributors and Safeguards, 14 J. HOSP. MED. 419, 421–22 (2019).

reconciliation is slightly more difficult.[131] The processes for pull, administration, and waste are similar, but determining the amount wasted once it is in a waste container is much more difficult.[132]

Administering clinicians are explicitly allowed to deviate from normal ADC processes in an emergency situation.[133] The definition of an emergency situation is open to the interpretation and clinical judgment of the provider.[134] Pain management is not explicitly included in any definition of emergency situation but administering practitioners continue to use it as a justification for bypass of required processes.[135]

Any hospital that uses ADCs to store medication has the capability of doing the reconciliations described above.[136] It is a manual process, but when done timely, it reveals discrepancies that indicate potential diversion.[137] In addition to the manual checks, several vendors provide artificial intelligence that "monitor the movement of controlled substances throughout [healthcare] organization[s]."[138] Costs of these

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[131] *See id.*

[132] *See id.*

[133] 21 C.F.R. § 290.10 (2020).

[134] *Id.*

[135] *Id.* (defining "emergency situation"); Fan, *supra* note 129, at 423 (discussing "critical override" as a means for diversion).

[136] *See generally* Fan, *supra* note 129, at 421–22.

[137] Pena, *supra* note 33, at 120.

[138] *E.g.*, *Solutions*, PROTENUS, INC., https://www.protenus.com/solutions/ (last visited Oct. 1, 2020) [hereinafter PROTENUS, INC.]; *Controlled Substances*, INVISTICS, https://invistics.com/flowlytics-overview/for-dea-compliance/ (last visited Jan. 30, 2020) [hereinafter *Controlled Substances*, INVISTICS].

programs are not available to the general public but are presumably significant given the touted capabilities.[139]

B. The Epidemic Continues Despite Monitoring of Controlled Substances at Every Stage in the Value Stream

Agencies exist at federal, facility, and state levels to monitor and regulate the entire controlled substance value stream. The controlled substance value stream includes every step from manufacture to consumption of the drugs.[140] This Article discusses the most relevant agencies to clinician diversion in a hospital setting.

1. Federal Governance

The Drug Enforcement (DEA) is major player in battling the opioid epidemic. The DEA was created to enforce Titles II and III of the Controlled Substances Act.[141] The DEA has broad powers to monitor and regulate the flow of controlled substances from production to administration.[142] The Diversion Control Division (DCD) of the DEA was created specifically to address drug diversion.[143] The DCD is

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[139] *E.g.*, PROTENUS, INC., *supra* note 137; *Controlled Substances*, INVISTICS, *supra* note 137 (offering demonstrations but no pricing options).

[140] *See* Dwyer, *infra* note 236 (describing all the actors involved in the opioid value stream and the National Prescription Opiate Litigation).

[141] *See* BRIAN T. YEH, CONG. RESEARCH SERV., R45164, LEGAL AUTHORITIES UNDER THE CONTROLLED SUBSTANCES ACT TO COMBAT THE OPIOID CRISIS (2018).

[142] *See id.*

[143] *Program Description*, DRUG ENFORCEMENT ADMINISTRATION DIVERSION CONTROL DIVISION, https://www.deadiversion.usdoj.gov/prog_dscrpt/index.html (last visited Jan. 31, 2020).

divided into local field offices spread across the country.[144] These offices work to crack down on illegal activity surrounding controlled substances.[145] Recently, they have been working at identifying and shutting down pill mills.[146]

Any practitioner who wants to prescribe controlled substances has to apply and obtain a registration number from the DEA.[147] Once a practitioner obtains a DEA registration number, the DCD has specific mandates for prescriptions for controlled substances, which include: "[a] prescription. . . must include. . . [d]ate of issue; Patient's name and address; Practitioner's name, address, and DEA registration number; Drug name; Drug strength; Dosage form; Quantity prescribed; Directions for use; Number of refills (if any) authorized; and Manual

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[144] *Diversion Field Office Contact Information Search*, DRUG ENFORCEMENT ADMINISTRATION DIVERSION CONTROL DIVISION, https://apps2.deadiversion.usdoj.gov/contactDea/spring/main?execution=e2s1 (last visited Jan. 31, 2020).

[145] *Program Description*, DRUG ENFORCEMENT ADMINISTRATION DIVERSION CONTROL DIVISION, *supra* note 142.

[146] Pia Malbran, *What's a Pill Mill?*, CBS NEWS (May 31, 2007, 6:01 PM), https://www.cbsnews.com/news/whats-a-pill-mill/ ("'Pill mill' is a term used primarily by local and state investigators to describe a doctor, clinic or pharmacy that is prescribing or dispensing powerful narcotics inappropriately or for non-medical reasons."). *See*, *e.g.*, Brendan O'Brien, *U.S. Charges 58 in Texas with Healthcare Fraud, Illegal Opioid Distribution*, REUTERS (Sept. 18, 2019 11:57 AM), https://www.reuters.com/article/us-usa-opioids-texas/u-s-charges-58-in-texas-with-healthcare-fraud-illegal-opioid-distribution-idUSKBN1W32BX.

[147] Practitioner's Manual – SECTION II, supra note 87.

signature of prescriber."[148] Medication orders written in a hospital have comparable requirements.[149] A key difference is that prescribing practitioners can write medication orders using the hospital's registration number in lieu of their personal registration number.[150]

Medication orders are increasingly entered via electronic ordering. This provides an additional layer of security because electronic orders must be entered by the prescribing practitioner via their electronic medical record credentials.[151] Some facilities still allow written prescriptions and oral orders under limited circumstances.[152] Both of these methods of ordering are inherently at risk for diversion.[153]

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[148] 21 C.F.R. 1306.22.

[149] BDS Medication Administration Curriculum Section III, supra note 95 at 2.

[150] 21 C.F.R. § 1301.22(c) (2020).

[151] *Practitioner's Manual – SECTION II, supra* note 87 (allowing a prescribing practitioner to use the hospital's DEA number so long as it is tied to an individual hospital code number).

[152] Oral orders in hospital setting are usually called in by the nurse who fills out a telephone order form that the prescribing practitioner will sign at a later time. *See* Fan, *supra* note 129, at 423 (describing unverified telephone orders as a source of diversion).

[153] *See* Lelling, *supra* note 38, at 172 (describing a case where a medical assistant stole a prescription pad from the hospital and wrote 244 prescriptions for controlled substances); Dr. Wilkerson Interview, *supra* note 29 (Anecdotally, a "nurse. . . in the ED[] took advantage of the typical chaos as well as work load and entered bogus physician orders for narcotics for her patients. The patients never received the medications. The 'ordering physician' typically has hundreds of what we call '[oral] orders' to sign of[f] on at the end on an ED shift. They do not typically read each order for legitimacy and accuracy.").

The DEA currently maintains several databases that monitor the movement of drugs.[154] The Automated Reports and Consolidated Orders System collects data from manufacturers and distributors of Schedules I–III controlled substances.[155] The DEA Thefts and Loss Reports System stores all reports of drug theft and loss.[156] The Registrant Information Consolidated System encapsulates many of the DEA's internal systems.[157] Finally, the Suspicious Order Reporting System collects reports sent by manufacturers and distributors of any suspicious orders.[158] All of these systems are reliant on manual data entry based on self-reporting of hospitals, manufacturers, and other organizations that touch controlled substances.[159]

Hospitals are required to report any significant diversion to the DEA.[160] This is a source of concern for many hospital administrators because the word significant is ambiguous.[161] There are no precise guidelines on quantities (straight numbers or percentages) that

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[154] *See, e.g.*, 21 C.F.R. § 1304.33 (2020).

[155] 21 C.F.R. § 1304.33(d).

[156] Drug Enf't Admin., *Reports Required by 21 C.F.R.*, DRUG ENF'T ADMIN. DIVERSION CONTROL DIV., https://www.deadiversion.usdoj.gov/21cfr_reports/index.html (last visited Jan. 31, 2020).

[157] OIG Report, *supra* note 11, at 10; *See generally* Drug Enf't Admin., *Reports Required by 21 C.F.R.*.

[158] OIG Report, s*upra* note 11, at 9-10.

[159] *See, e.g.*, 21 C.F.R. § 1304.33(c) (2020).

[160] 21 C.F.R. § 1301.76(b).

[161] *See* Ambrose, *supra* note 84 (discussing the ambiguity of reporting requirements).

constitute significant diversion.[162] A lack of understanding is likely a contributing factor to low rates of reporting. Many of the hospitals that have been investigated (and subsequently disciplined) failed to report diversion.[163]

The DEA recently came under fire by the Office of the Inspector General (OIG).[164] In a report released in September 2019, the OIG evaluated all actions the DEA had taken to address the opioid epidemic from 2010–2017.[165] In this report it found, among many concerns, the DEA failed to use its robust regulatory and administrative powers to their fullest.[166] The OIG additionally pointed out that the DEA had failed to require electronic only prescriptions despite the fact that stolen prescription pads are a notorious source of significant diversion.[167] Finally, it found the DEA consistently "rarely used its strongest enforcement tool, the Immediate Suspension Order, to stop registrants from diverting prescription drugs. . . and other alleged violations."[168]

While the OIG was forceful in its criticism of the DEA, it did emphasize that the DEA already has the tools and the means to better combat the epidemic.[169] The agency doesn't require an overhaul or

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[162] 21 C.F.R. § 1301.76(b) (2020).

[163] *See, e.g.*, Lelling, *supra* note 38, at 166.

[164] OIG Report, *supra* note 11, at i.

[165] *Id.*

[166] *Id.* at 13.

[167] *See*, *e.g.*, Lelling, *supra* note 38.

[168] OIG Report, *supra* note 11, at 21. This is a directly applicable tool for the proposed MOMP in this article.

[169] *Id.* at 13, 46.

infusion of capital, just reorganization of strategy and improved coordination with local authorities.[170]

Beyond the DEA, the umbrella agency that governs all of the hospital operations discussed in this Article is the Department of Health and Human Services (HHS). The HHS serves as the "nation's principal agency for protecting the health of all Americans and providing essential human services."[171] This is one of the largest governmental agencies, with 11 Operating Divisions and 14 agencies under the Office of the Secretary.[172] Notable agencies include the OIG and the Centers for Medicare and Medicaid Services (CMS).[173]

As a federal agency, the HHS has rulemaking authority.[174] This authority allows it to "create regulations (also known as 'rules') under the authority of Congress to help government carry out public

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[170] *See id.* at 45-47 (all 9 recommendations look at utilization of existing tools or potential partnerships with local law enforcement. There is no mention of a total overhaul or more money being added to the DEA budget.).

[171] *HHS Historical Highlights*, U.S. DEP'T OF HEALTH & HUM. SERVS., https://www.hhs.gov/about/historical-highlights/index.html (last reviewed Feb. 10, 2017).

[172] *HHS Organizational Chart*, U.S. DEP'T OF HEALTH & HUM. SERVS., https://www.hhs.gov/about/agencies/orgchart/index.html (last reviewed Nov. 14, 2018) (showing the CDC, FDA, OIG, SAMHSA, and the NIH all fall under the HHS).

[173] *Id.*

[174] *See, e.g.*, *HHS Proposes New Rules to Improve Interoperability of Electronic Health Information*, U.S. DEP'T OF HEALTH & HUM. SERVS. (Feb. 11, 2019), https://www.hhs.gov/about/news/2019/02/11/hhs-proposes-new-rules-improve-interoperability-electronic-health-information.html.

policy."[175] Agencies are empowered to "propose a new regulation or modify an existing regulation" in many different situations for a variety of reasons.[176] This explicitly includes situations where the HHS identifies an issue that requires change.[177]

The OIG and CMS are both HHS agencies that play a significant role in this Article.[178] When the DEA identifies drug diversion, it is the responsibility of the OIG to prosecute the individual and organization.[179] CMS has a huge degree of control over hospital operations as described in the following section.[180] CMS is tasked with ensuring compliance with the Conditions of Participation (CoP).[181] Additionally, CMS can both grant and revoke its certification of a

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[175] *Laws and Regulations*, U.S. DEP'T OF HEALTH & HUM. SERVS., https://www.hhs.gov/regulations/index.html (last visited Nov. 12, 2019).

[176] *HHS Regulations Toolkit*, U.S. DEP'T OF HEALTH & HUM. SERVS., https://www.hhs.gov/regulations/regulations-toolkit/index.html (last reviewed Jul. 1, 2014).

[177] *Id.*

[178] *HHS Organizational Chart, supra* note 172.

[179] *Spotlight On… Drug Diversion*, OFFICE OF THE INSPECTOR GEN., U.S. DEP'T OF HEALTH & HUM. SERVS, https://oig.hhs.gov/newsroom/spotlight/2013/diversion.asp (last visited Nov. 27, 2019).

[180] *E.g.*, 42 C.F.R. § 482.1 (2020).

[181] 42 C.F.R. § 482.11 (2020). Their power is derived from Social Security Act. 42 U.S.C.A. § 1305.

hospital.[182] A hospital must be certified by CMS to receive federal funding.[183]

CMS provides oversight for variety of federal healthcare programs and most importantly to this Article, provides guidance regarding compliance with the CoP.[184] The CoP are a set of regulations for any hospital that accepts federal funding.[185] They govern a wide variety of practice areas such as nursing services, pharmacy services, and infection control.[186] Any hospital that wants to participate in federal health insurance programs must comply with these regulations.[187]

To facilitate compliance, CMS produces a Provider Manual that is available to all healthcare facilities and contains highly detailed practical guidance on how to comply with regulations.[188] This is a critical tool for hospital administration and quality departments to use

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[182] *E.g.*, *Termination Notices*, CTR. FOR MEDICARE & MEDICAID SERVS., https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Termination-Notices (last updated Jan. 28, 2020).

[183] *See generally* 42 C.F.R. § 482 (2020) (describes all of the conditions for participation in the Medicare and Medicaid programs for hospitals).

[184] *Manuals*, CTR. FOR MEDICARE & MEDICAID SERVS., https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/index?redirect=/Manuals/ (last updated May 28, 2019) [hereinafter *Manuals*, CMS].

[185] 42 C.F.R. § 482.23, § 482.25, § 482.42 (2020).

[186] 42 C.F.R. §482.42 (2020).

[187] 42 C.F.R. § 482.1 (2020).

[188] *Manuals*, CMS, *supra* note 183.

when crafting hospital policies and procedures related to controlled substances.[189]

Non-compliance with the CoP can have serious consequences.[190] The most severe consequence is that CMS can withdraw its certification of the hospital; this means that the hospital would lose all federal reimbursement.[191] In 2014, Medicare accounted for over 35% of the average hospital's payer mix.[192] A Deloitte study projected that this number would climb to 40% by 2020. Medicare, Medicaid, and Tri-Care (all federal programs) on average account for almost 60% of the average hospital's payer mix.[193] Realistically, a

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[189] *Id.* ("It offers day-to-day operating instructions, policies, and procedures based on statutes and regulations, guidelines, models, and directives.").

[190] *See* Pena, *supra* note 33, at 122.

[191] *See, e.g.*, *Notice of Termination, Effective July 9, 2018*, CTR. FOR MEDICARE & MEDICAID SERVS. (Jun. 25, 2018), https://www.dshs.wa.gov/sites/default/files/BHSIA/WSH/SIA/Western%20State%20Hospital%20Termination%20Letter%206_25_18jb.pdf (stating that funding was withdrawn because of noncompliance with the Conditions of Participation, including 42 CFR §482.23 Nursing Services).

[192] Allyson Gorman et al., *The Uncertain Road Ahead: Could Technology Offer Hospitals Relief from Increasing Margin Pressures?*, DELOITTE, https://www2.deloitte.com/content/dam/Deloitte/us/Documents/life-sciences-health-care/us-lshc-hospital-financial-performance-emerging-technologies.pdf (last visited Jan. 31, 2020) (explaining that payer mix is the percent revenue attributable to different types of payers such as commercial, government (Medicare, Medicaid, Tricare), and self-pay).

[193] *Id.* Of course, this is highly subject to change with many Democratic Nominees for the 2020 presidential election running on a platform advocating for increased Medicare Coverage. *See* Joseph Ax, *Where the Top Democratic U.S. Presidential Candidates Stand on 'Medicare for All'*, REUTERS (Sept. 10, 2019), https://www.reuters.com/article/us-usa-election-healthcare-

hospital cannot function without 60% of its expected reimbursement.[194] Even if the hospital did manage to keep its doors open after losing certification, once CMS withdraws federal funds, many commercial insurers are likely to follow suit, making it impossible for the hospital to get paid for the care they provide.[195] Therefore, loss of certification is almost certain to cause the hospital to shut down completely.[196]

Both prescribing and administering practitioners are governed by the CoP.[197] The most robust rules are housed within 42 C.F.R.§ 482.23, which sets forth requirements for Nursing Services.[198] This section holds rules and restrictions governing the preparation and administration of controlled substances.[199] Preparation and

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factbox/where-the-top-democratic-us-presidential-candidates-stand-on-medicare-for-all-idUSKCN1VV13A (asserting that any variation of the proposed plans will increase Medicare coverage across the country, making the CoP even more critical).

[194] *See, e.g.*, Joseph Ax, *Where the Top Democratic U.S. Presidential Candidates Stand on 'Medicare for All'*, REUTERS (Sept. 10, 2019), https://www.reuters.com/article/us-usa-election-healthcare-factbox/where-the-top-democratic-us-presidential-candidates-stand-on-medicare-for-all-idUSKCN1VV13A; *See also* Mike Hixenbaugh & Charles Ornstein, *At St. Luke's, Friday's Federal Termination Could Affect More than Heart Transplants*, HOUS. CHRON. & PROPUBLICA (Aug. 17, 2018), https://www.houstonchronicle.com/news/investigations/article/St-Luke-s-heart-transplant-program-to-lose-13161833.php (analyzing the potential downstream impact of losing Medicare certification).

[195] *See*, *e.g.*, *id.*

[196] *See*, *e.g.*, *id.*

[197] 42 C.F.R. § 482 (2020).

[198] 42 C.F.R. § 482.23 (2019).

[199] *Id.*

administration rules are tied to definitions included in the Controlled Substances Act.[200] Section 812(b) provides a complete definition of each class of the controlled substances.[201]

The Code of Federal Regulations additionally provides a definition of emergency situations, which allows exceptions for when a medication can be administered based an oral order.[202] The text of this section does not explicitly define a window of time and instead leaves it to the practitioner's subjective judgment that immediate treatment is necessary.[203]

Additionally, 42 C.F.R. § 482.25 includes minimum requirements for pharmaceutical services.[204] The language regarding required documentation and reconciliation processes is sparse, providing little guidance to hospitals looking to enhance their drug diversion detection processes.[205]

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[200] 21 U.S.C.S. ch. 13.

[201] 21 U.S.C.S. § 812(b).

[202] 21 C.F.R. § 290.10 (2012).

[203] *Id.*

[204] 42 C.F.R. § 482.25(a)(3) (2011).

[205] *Id.* ("Current and accurate records must be kept of the receipt and disposition of all scheduled drugs.").

2. Facility Governance

In addition to the CoP, CMS requires accreditation by an independent agency.[206] CMS has a published list of acceptable accreditation agencies for various healthcare settings.[207] The Joint Commission (TJC) is the most common agency, accrediting over 4,000 hospitals across the country.[208] Independent agencies have their own requirements and guidelines, which are in alignment with CMS requirements.[209] Approved agencies conduct whole system, facility, and individual unit surveys, which thoroughly investigate for any deviations from required policy.[210] If the agency finds serious fallouts that surpass a certain threshold, they have the ability to remove their certification, again putting the hospital's Medicare certification in jeopardy.[211]

While CMS and other accreditation agencies set the minimum standards that hospitals must follow,[212] hospitals have the freedom to

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[206] *Hospitals*, CTRS. FOR MEDICARE & MEDICAID SERV., https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/Hospitals (last modified Jul. 25, 2019).

[207] *CMS Approved Accrediting Organizations Contacts for Prospective Clients*, CTRS. FOR MEDICARE & MEDICAID SERV. (Aug. 10, 2020), https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Accrediting-Organization-Contacts-for-Prospective-Clients-.pdf.

[208] *Facts About Joint Commission Accreditation and Certification*, Joint Commission, https://www.jointcommission.org/-/media/deprecated-unorganized/imported-assets/tjc/system-folders/topics-library/accreditation_and_certification_10_09pdf.pdf?db=web&hash=D69C362F1F50C042F4C77C9F129322D6#:~:text=Today%2C%20it%20accredits

implement any additional restrictions and processes they deem necessary to prevent diversion in their facilities.[213] They have control over the entire value stream, from the moment the controlled substance comes into the hospital all the way until it is administered to the patient.[214]

Actual hospital policies to address the opioid epidemic are highly variable.[215] For example, the Mayo Clinic has a robust program in place to detect and prevent future diversion.[216] It instituted system wide changes that included hiring a Medication Diversion Prevention Coordinator, deploying multidisciplinary Drug Diversion Response Teams, and enhanced control systems specifically tailored to the

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%20approximately%204%2C500,accredited%20by%20The%20Joint%20Commission. (last visited Oct. 1, 2020) (stating about 82% of the nation's hospitals are accredited by the Joint Commission).

[209] Hospitals, *supra* note 205.

[210] *E.g.*, *Snapshot of Survey Day*, JOINT COMMISSION, https://www.jointcommission.org/accreditation-and-certification/health-care-settings/hospital/prepare/snapshot-of-survey-day/ (last visited Jan. 31, 2020).

[211] *E.g.*, Stephanie Armour, *Hospital Watchdog Gives Seal of Approval, Even After Problems Emerge*, WALL STREET J. (Sept. 8, 2017), https://www.wsj.com/articles/watchdog-awards-hospitals-seal-of-approval-even-after-problems-emerge-1504889146.

[212] *See generally* 42 C.F.R. pt. 482 (2020).

[213] *See* 41 C.F.R. § 482.23(c) (2019); Keith H. Berge et al., Diversion of Drugs within Health Care Facilities, a Multiple-Victim Crime: Patterns of Diversion, Scope, Consequences, Detection, and Prevention, 87 MAYO CLINIC PROC. 674, 679-81 (2012) (example of a hospital designing their own program).

[214] *See, e.g.*, *id.* at 678–679.

[215] *See*, *e.g.*, *id.*

[216] *Id.*

Department of Anesthesiology.[217] On the other end of the spectrum, there are small hospitals with minimal focus or restrictions in place.[218] Most hospitals fall somewhere between these two extremes and have had varying levels of success in combatting clinician diversion.[219] Programs are likely dependent on a variety of factors like size, financial health, and history of diversion.[220]

3. State Governance

The practices of medicine and nursing are heavily governed by state law.[221] Each state has the authority to create its own board examinations and practice requirements.[222] States control all clinician licensures, to include processes and procedures for obtaining a license in their state for an out of state licensed clinician.[223]

Additionally, states have the power to discipline any clinician who is noncompliant with their rules.[224] After a complaint is filed, the

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[217] *Id.* at 679.

[218] For example, a small hospital has almost no controls in place in their PACU. All medications, including controlled substances, are pulled from stocked medication. Nurses describe the unit as the "Wild Wild West" where they are free "to pull whatever [they] want." *See* Interview with Anonymous PACU Nurse (Sept. 17, 2019) (notes on file with Author).

[219] *See generally* Fan, *supra* note 129.

[220] *See generally id.*

[221] *See* Drew Carlson & James N. Thompson, *The Role of State Medical Boards*, AMA J. OF ETHICS (Apr. 2005), https://journalofethics.ama-assn.org/article/role-state-medical-boards/2005-04.

[222] *See id.*

[223] *See id.*

[224] *E.g.*, *Enforcement*, TEX. MED. BOARD, http://www.tmb.state.tx.us/page/enforcement (last visited Jan. 31, 2020).

state board will conduct its own independent investigation to determine what punishment, if any, is appropriate.[225] In cases of clinicians addicted to controlled substances, state boards can immediately revoke a clinician's license or can provide rehabilitation programs.[226] Existing programs, such as the California Board of Nursing Intervention Program, allow nurses with a substance abuse disorders to maintain their licenses if they comply with all elements of the program.[227] Common elements in rehabilitation programs include medical and psychological examinations, drug testing, twelve-step groups, and other treatment plans required to help nurses overcome their substance abuse disorder.[228]

Beyond boards of nursing and medicine, states have the power to pursue criminal charges against clinicians who have committed criminal acts in the course of patient care.[229] Criminal prosecutions

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[225] *E.g.*, *id.*

[226] *See*, *e.g.*, *id.* ("[C]ases that deal solely with issues of physical or mental impairment may be referred to the Texas Physician Health Program for evaluation and resolution.").

[227] *Compare Alternative to Discipline*, ARIZ. STATE BOARD OF NURSING, https://www.azbn.gov/discipline-and-complaints/alternative-to-discipline (last visited Jan. 31, 2020), *with Program Requirements*, CAL. BOARD OF NURSING, https://www.rn.ca.gov/intervention/intreq.shtml (last visited Jan. 31, 2020) (Arizona explicitly excludes known diverters from their rehabilitation program, but California does not).

[228] *Program Requirements, supra* note 226.

[229] *E.g.*, Duntsch v. State, 568 S.W.3d 193 (Tex. App.—Dallas 2018, pet. ref'd); Matt Goodman, *Dr. Death*, D MAGAZINE (Nov. 2016), https://www.dmagazine.com/publications/d-magazine/2016/november/christopher-duntsch-dr-death/ ("Plano surgeon Christopher Duntsch left a trail of bodies. The shocking story of a madman with a scalpel.").

regarding the practice of medicine are rare but do exist.[230] For example, a landmark case in Texas found an impaired surgeon—popularly known as Dr. Death—guilty of elderly abuse.[231] Potential criminal charges loom over any impaired clinician.

Finally, states have the ability to place restrictions on the ways in which providers are able to prescribe controlled substances.[232] State Prescription Drug Monitoring Programs, discussed more fully below, have a variety of rules governing prescribing behaviors.[233] Despite this control, it is critical to remember that all state rules trace back to the federally granted permission to prescribe controlled substances.[234] If the DEA did not grant a prescribing practitioner a license to prescribe controlled substances, states could not regulate their subsequent orders.[235]

C. Local, State, and Federal Government Actors are Using a Piecemeal Approach to Combat the Epidemic

Government actors are currently struggling to find the best way to tackle the opioid epidemic but have yet to figure out a comprehensive

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[230] *E.g.*, Goodman, *supra* note 228.

[231] *Id.*

[232] *E.g.*, State Practice Environment, *supra* note 88.

[233] Brandeis University, *History of Prescription Drug Monitoring Programs*, PRESCRIPTION DRUG MONITORING PROGRAM TRAINING AND TECH. ASSISTANCE CTR. (Oct. 2018), http://www.pdmpassist.org/pdf/PDMP_admin/TAG_History_PDMPs_final_20180314.pdf [hereinafter *History of Prescription Drug Monitoring Programs*].

[234] 21 C.F.R. § 1301.11 (2020).

[235] *See id.*

solution.[236] The two most common responses are litigation, which is a punitive back-end measure, and state level prescription drug monitoring programs, which are semi-preventive measures primarily targeting patient abusers.[237]

1. Litigation

Litigation is certainly the most visible action to combat the epidemic.[238] There are numerous cases, spread across the entire country, against pharmaceutical companies, hospitals, pharmacies, and physicians individually.[239] Most relevant to this Article are cases against hospitals and pharmaceutical companies.

Although clinician diversion is rarely caught and reported, there have been a few highly publicized settlements in the past twenty years.[240] For example, Massachusetts General Hospital (Mass Gen) was fined following a DEA investigation that showed two nurses had diverted "16,000 pills—mostly oxycodone—from the hospital."[241] The audit also showed an additional 20,000 plus pills were missing and unaccounted for.[242] The investigation found numerous other violations of the Controlled Substances Act, including a pediatric nurse injecting herself with Dilaudid while on the clock, a physician writing controlled

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[236] *E.g.*, CDC, *Understanding the Epidemic, supra* note 8 (describing current efforts by the CDC).

[237] *See, e.g.*, Colin Dwyer, *Your Guide to the Massive (and Massively Complex) Opioid Litigation*, NPR (Oct. 15, 2019), https://www.npr.org/sections/health-shots/2019/10/15/761537367/your-guide-to-the-massive-and-massively-complex-opioid-litigation.

[238] See, e.g., *id.*

[239] *See, e.g.*, Lelling, *supra* note 38.

[240] See, e.g., id.

[241] *Id.* at 171.

[242] *Id.*

substance orders for patients he had never seen, and a pattern of nurses diverting drugs without detection or punishment.[243] The hospital agreed to a settlement involving a fine of $2.3 million and a three-year corrective plan to "implement diversion controls[]" including revamped annual training and an outside auditor to audit all Mass Gen facilities.[244]

Effingham Health System (EHS) dealt with a similar issue.[245] The DEA found that the Georgia health system had "tens of thousands of oxycodone 30 mg tablets. . . unaccounted for and likely diverted[.]"[246] Unlike Mass Gen, EHS failed to notify the DEA of any suspected diversion.[247] EHS settled for $4.1M, the largest ever civil penalty for drug diversion.[248] As part of the settlement, EHS entered into a corrective plan to "avoid diversions in the future."[249]

Dignity Health, the fifth largest health system in the country, settled with the U.S. for $1.55M for poor handling and accounting of controlled substances in their facilities.[250] The agreement required implementation of an improved reconciliation process for controlled substances.[251] Finally, Utah based Intermountain Healthcare was investigated by the DEA when a former medical assistant stole a

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[243] *Id.*

[244] *Id.* at 171–72.

[245] *Id.* at 170.

[246] *See, e.g.*, Lelling, *supra* note 38, at 170.

[247] *Id.* at 171.

[248] *Id.*

[249] *Id.*; Press Release, U.S. Dep't of Justice, Southern District of Georgia Announces Largest Drug Diversion Civil Penalty Settlement in U.S. History (May 16, 2018).

[250] Lelling, *supra* note 38, at 172.

[251] *Id.*

physician's prescription pad and wrote 244 prescriptions for controlled substances for herself and her family.[252] The system paid the U.S. $1M to resolve claims of lax policies and controls.[253]

Local and state actors are also pursuing cases to hold pharmaceutical companies, manufacturers, and pharmacies responsible.[254] A judicial panel recently consolidated over 2,500 individual suits into a single suit, aptly named the National Prescription Opiate Litigation, which was filed in the Northern District of Ohio.[255] The suit "involv[es] thousands of plaintiffs at nearly every level of government and defendants from every link in the chain of opioid drug production."[256] Multiple companies have settled rather than going to the bellwether trial,[257] including Amerisource Bergen, Cardinal Health, McKesson Corporation, and Teva Pharmaceutical Industries, who collectively agreed to pay $260 million on October 19, 2019 (a mere two days before the bellwether trial was set to start).[258]

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[252] *Id.* at 171.

[253] *Id.*

[254] *See, e.g.*, Dwyer, *supra* note 236.

[255] *Id.*

[256] *Id.*

[257] Paul Cannon, *What is a Bellwether Trial?*, SIMMONS & FLETCHER, https://www.simmonsandfletcher.com/product-liability/bellwether-trials/ (last visited Jan. 31, 2020) ("A *bellwether trial* is a test trial involving a case that derives from a large pool of lawsuits filed against the same party. . . [and is] used as [a] test case[] in attempt to foresee how future litigation may turn out.").

[258] Sara Randazzo, *Last-Minute Opioid Deal Could Open Door to Bigger Settlement*, WALL STREET J. (Oct. 21, 2019), https://www.wsj.com/articles/four-drug-companies-reach-last-minute-settlement-in-opioid-litigation-11571658212; Dwyer, *supra* note 236 (explaining other notable companies who have settled include Johnson &

The closest comparable case to the National Prescription Opiate Litigation is the Master Settlement Agreement made between 48 states and four major tobacco companies in 1998.[259] Terms of the Master Settlement Agreement are remarkably similar to existing settlement agreements with pharmaceutical companies.[260] A key criticism of the $206B Master Settlement Agreement is that it had little to no impact on American health.[261] This was likely because states failed to devote

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Johnson, Endo Pharmaceuticals, Mallinckrodt, Endo International, and Allergan).

[259] *See The ABCs of the Tobacco Master Settlement Agreement*, NAT'L ASS'N OF ATT'YS' GEN., https://www.naag.org/publications/naagazette/volume_1_number_2/the_abcs_of_the_tobacco_master_settlement_agreement.php (last visited Jan. 31, 2020).

[260] Martha Bebinger, *Purdue Pharma Agrees to $270 Million Opioid Settlement with Oklahoma*, NPR (Mar. 26, 2019), https://www.npr.org/sections/health-shots/2019/03/26/706848006/purdue-pharma-agrees-to-270-million-opioid-settlement-with-oklahoma (explaining that Purdue agreed to a $270 million settlement that allocated funds to addiction research, medication, counties and municipalities, and legal fees); *The ABCs of the Tobacco Master Settlement Agreement, supra* note 259 (The Tobacco Master Settlement Agreement included requirements "(1) to pay the states annually and in perpetuity billions of dollars; (2) to restrict permanently their advertising, promotion, and marketing of cigarettes; and (3) to contribute $1.5 billion to establish what has become the American Legacy Foundation, an entity dedicated to counter-advertising and public education against cigarette smoking.").

[261] Megan J. Wolff, *Opioid Settlements Have a Big Downside*, CNN (Oct. 22, 2019), https://www.cnn.com/2019/10/22/opinions/opioid-settlements-purdue-pharma-transparency-matters/index.html.

adequate resources from the settlement to preventative measures.[262] Efficient allocation of resources from the National Prescription Opiate Litigation is a crucial determination.[263] Parties involved want to ensure that the settlement money works to help those already affected *and* prevent future abuse.[264]

One of the biggest players in opioid litigation overall is Purdue Pharma (Purdue).[265] Purdue is the maker of OxyContin, one of the largest contributors to the opioid epidemic.[266] To date, forty-eight states have joined the lawsuit against Purdue, claiming that the company downplayed the risks and oversold the benefits of their product.[267]

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[262] *A State-by-State Look at the 1998 Tobacco Settlement 20 Years Later*, TOBACCOFREEKIDS.ORG, https://www.tobaccofreekids.org/what-we-do/us/statereport/ (last visited Jan. 31, 2020) (showing that states have only budgeted 20% of what the CDC recommends for prevention efforts as of 2018).

[263] *See, e.g.*, Bryan Mann et al., *Not Just Purdue: Big Drug Companies Considering Settlements to Resolve Opioid Suits*, NPR (Aug. 28, 2019), https://www.npr.org/2019/08/28/755007841/several-big-drug-companies-considering-massive-settlements-to-resolve-opioid-sui.

[264] *See generally id.*

[265] Erica Orden, *Purdue Pharma Sought Secret Plan to Become 'End-to-End Pain Provider,' Lawsuit Alleges*, CNN (Jan. 31, 2019), https://www.cnn.com/2019/01/31/health/purdue-pharma-unredacted-lawsuit/index.html.

[266] *See id.* (discussing Purdue's desire to sell both the OxyContin and Narcan ("Project Tango"), a strategy that allows them to create the problem, provide the solution, and profit on both ends); *Better Understanding the Opioid Addiction Crisis*, PURDUE PHARMA, purdueopioidinfo.com (last visited Jan. 31, 2020).

[267] Berkeley Lovelace, *Nearly Every US State is Now Suing OxyContin Maker Purdue Pharma*, CNBC (Jun. 4, 2019),

"Prosecutors say the company's marketing practices encouraged doctors to push higher doses of the narcotic and contributed to a public health crisis that has caused thousands of overdoses in the U.S. each year."[268]

Purdue was originally named as a defendant in the National Prescription Opiate Litigation but managed to remove itself by filing for Chapter 11 Bankruptcy on September 15, 2019, following a tentative settlement agreement.[269] Filing for bankruptcy enabled Purdue to change the momentum of its case; a judge approved an immediate freeze on the thousands of outstanding lawsuits against the company.[270] As part of the bankruptcy proceedings, attorneys are working to create a final settlement plan that is estimated to be somewhere between ten and twelve billion dollars.[271]

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https://www.cnbc.com/2019/06/04/nearly-every-us-state-is-now-suing-oxycontin-maker-purdue-pharma.html.

[268] *Id.*

[269] Jan Hoffman & Mary W. Walsh, *Purdue Pharma, Maker of OxyContin, Files for Bankruptcy*, N.Y. TIMES (Sept. 17, 2019), https://www.nytimes.com/2019/09/15/health/purdue-pharma-bankruptcy-opioids-settlement.html; Jan Hoffman, *Purdue Pharma Tentatively Settles Thousands of Opioid Cases*, N.Y. TIMES (Sept. 11, 2019), https://www.nytimes.com/2019/09/11/health/purdue-pharma-opioids-settlement.html?module=inline.

[270] *The Purdue Pharma Bankruptcy Case: What's at Stake*, WHARTON SCH. OF THE U. OF PA. (Sept. 23, 2019), https://knowledge.wharton.upenn.edu/article/purdue-pharma-bankruptcy/.

[271] Steven Church, *Purdue's Bankruptcy Case Should be Done by February, Judge Says*, BLOOMBERG L. (Jul. 23, 2020), https://news.bloomberglaw.com/bankruptcy-law/purdues-bankruptcy-case-

The only major case against big pharma to make it to trial was In an Oklahoma district court.[272] In August 2019, Judge Thad Balkman found Johnson & Johnson liable and entered a $572 million judgment against the company.[273] Because this is a judicially imposed fine it is likely to be appealed, with the eventual settlement amount decreased.[274] Despite the likely appeal, it is a significant indicator of the way judgments against pharmaceutical companies are likely to come

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should-be-done-by-february-judge-says; Laura Strickley, *Purdue Pharma Offers $10-12 Billion to Settle Opioid Claims*, NBC NEWS (Aug. 27, 2019), https://www.nbcnews.com/news/us-news/purdue-pharma-offers-10-12-billion-settle-opioid-claims-n1046526?cid=sm_npd_nn_tw_ma&utm_source=Breakfast+with+ARTnews&utm_campaign=930897e577-EMAIL_CAMPAIGN_2019_08_27_02_24&utm_medium=email&utm_term=0_c5d7f10ceb-930897e577-293932547 (bankruptcy plan should be ready for court review by February 2021).

[272] Dwyer, *supra* note 236 (explaining that Purdue and Teva both settled pretrial for $270 million and $85 million, respectively).

[273] *Johnson & Johnson Ordered to Pay Oklahoma $572 Million in In Opioid Trial*, NPR (Aug. 26, 2019), https://www.npr.org/sections/health-shots/2019/08/26/754481268/judge-in-opioid-trial-rules-johnson-johnson-must-pay-oklahoma-572-million; Sara Randazzo, *Johnson & Johnson's Oklahoma Opioid Penalty Reduced to $465 Million*, WALL STREET J. (Nov. 15, 2019), https://www.wsj.com/articles/johnson-johnsons-oklahoma-opioid-penalty-reduced-to-465-million-11573854343 (explaining the penalty was reduced to $465 million due to a mathematical error by the court).

[274] Colin Dwyer & Jackie Fortier, *Oklahoma Judge Shaves $107 Million Off Opioid Decision Against Johnson & Johnson*, NPR (Nov. 15, 2019), https://www.npr.org/2019/11/15/779439374/oklahoma-judge-shaves-107-million-off-opioid-decision-against-johnson-johnson ("Lawyers for Johnson & Johnson say they will appeal the ruling. The case will likely head to the Oklahoma State Supreme Court.").

down.[275] Public outrage towards pharmaceuticals is a key driver and the industry does not expect this litigation to slow down any time soon.[276]

States are increasingly looking to prescribing practitioners to combat the epidemic.[277] In August 2019, the California Attorney General charged Dr. Thomas McNeese Keller with four counts of murder from overprescribing of opioids.[278] In Florida, Dr. Barry Schultz is serving 157 years in prison for over prescription of opioids, including prescribing over 1,000 pills to a pregnant woman.[279] Finally, a Virginia doctor was sentenced to forty years in prison for overprescribing opioids, which resulted in the death of a patient.[280] Despite these cases, there are no signs that criminal prosecutions of prescribing practitioners will slow down in the immediate future.[281]

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[275] *Id.*

[276] *See id.* ("U.S. District Judge Dan Polster, who is overseeing the [National Prescription Opiate Litigation], is expected to schedule new trials in the coming year.").

[277] *See*, *e.g.*, California Alleges Doctor Killed 4 Patients with Opioids, *supra* note 56.

[278] *Id.*

[279] Bill Whitaker, *Who's Responsible for the Opioid Epidemic? Doctors or Pharmaceutical Companies?*, CBS NEWS (Aug. 25, 2019), https://www.cbsnews.com/news/jailed-doctor-barry-schultz-interview-opioid-epidemic-60-minutes-2019-08-25/.

[280] Joanne Finnegan, *Virginia Doctor Sentenced to 40 Years in Prison After Conviction on More than 800 Opioid Counts*, FIERCE HEALTHCARE (Oct. 2, 2019), https://www.fiercehealthcare.com/practices/virginia-doctor-sentenced-to-40-years-prison-after-conviction-more-than-800-opioid-counts.

[281] *E.g.*, *id.*

Practically, this means that prescribing practitioners have more to fear than just losing their license.

Criminal prosecutions are not limited to prescribing practitioners.[282] There have been several notable cases regarding administering practitioners being charged in relation to drug diversion.[283] For example, a former Utah nurse pleaded guilty "to two counts of tampering with a consumer product and two counts of fraudulently obtaining a controlled substance."[284] She admitted to injecting herself with controlled substances intended for her patients and then reusing the syringe on her patients.[285] The investigation discovered that she transmitted Hepatitis C to at least sixteen patients and exposed up to 7,200 more.[286]

Another healthcare worker was sentenced to thirty-nine years in prison for stealing hospital drugs and spreading Hepatitis C.[287] " He. . . injected himself with. . . [F]entanyl stolen from [the] hospital. . . [infected the needles with his blood,]. . . and then [re]filled the syringes with saline solution. . . [and]. . . staff then injected patients with the needles, unaware they had been contaminated."[288] Although he worked at hospitals in eight different states, he only admitted to using Fentanyl syringes at least 100 times at hospitals in New Hampshire, Kansas, and Georgia.[289]

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[282] *E.g.*, Masson, *supra* note 37.
[283] *E.g.*, i*d.*
[284] *Id.*
[285] *Id.*
[286] *Id.*
[287] Lovering, *supra* note 80.
[288] *Id.*
[289] *Id.*

Absent spread of disease or overdose, nurses and nonprescribing midlevel providers are significantly less likely to face individual criminal charges.[290] This is primarily because none of the orders are tied to their names; it is up to the healthcare facility to identify and report any drug related offenses.[291] If the hospital does happen to catch an administering practitioner diverting controlled substances, the most likely outcome is termination, report to the state board, and loss of license.[292] The duty to report to the DEA is unclear given the ambiguity of the word significant in hospital reporting requirements.[293]

2. State Patient Focused Prescription Drug Monitoring Programs (PDMP)

Prescription Drug Monitoring Programs (abbreviated as PDMP or PMP depending on the state) are one of the most prevalent state actions to combat the opioid epidemic.[294] These programs electronically store prescriptions written by a prescribing practitioner

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[290] Author's inference based on lack of publicly reported nursing criminal cases without spread of disease or overdose.

[291] See *ASHP Guidelines on Preventing Diversion of Controlled Substances*, *supra* note 27, at 78.

[292] *See* Eichenwald, *supra* note 67 (detailing hospital censure processes when drug diversion identified).

[293] 21 C.F.R. § 1301.76(b) (2014).

[294] Rebecca L. Haffajee, et al., States with Overall Robust Prescription Drug Monitoring Programs Experienced Reductions in Opioids Prescribed to Commercially Insured Individuals, HEALTH AFF. (MILLWOOD) (Dec. 18, 2018), (author manuscript).

and distributed by a licensed pharmacy.[295] They primarily rely on manual submissions from prescribers and pharmacies and typically include "date dispensed, patient, prescriber, pharmacy, medication, and quantity."[296] States have the option of creating their own in-house solution, or utilizing vendors to maintain their databases.[297] These vendors have the built-in capacity to patch in electronic medical record systems (EMR) to the database.[298] These patches allow providers to view PDMP data without having to sign into a separate system; all records are visible in the EMR their facility uses.[299]

The primary intent of PDMPs is to identify "aberrant drug-related behavior," which includes any behavior indicative of substance abuse in patients.[300] There are several models with varying

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[295] Substance Abuse & Mental Health Serv. Admin., Prescription Drug Monitoring Programs: A Guide for Healthcare Providers 3 (2017), https://store.samhsa.gov/sites/default/files/d7/priv/sma16-4997.pdf.

[296] *Id.*

[297] *See generally* BRANDEIS UNIV., PRESCRIPTION DRUG MONITORING PROGRAMS ADMINISTRATORS' ORIENTATION PACKAGE (2018), 10-12 https://www.pdmpassist.org/pdf/PDMP_admin/PDMP_Administrators_Orientation_Package_final_20180314.pdf [hereinafter PRESCRIPTION DRUG MONITORING PROGRAMS ADMINISTRATORS' ORIENTATION PACKAGE].

[298] *See generally id.* at 15.

[299] *See*, *e.g.*, *NABP PMP InterConnect: The Only National Network of State-Based PMPs*, NAT'L ASS'N OF BOARDS OF PHARMACY, https://nabp.pharmacy/initiatives/pmp-interconnect/ (last visited Jan. 29, 2020).

[300] Prescription Drug Monitoring Programs Administrators' Orientation Package, *supra* note 296, at 4.

requirements for provider engagement with the programs.[301] The three most common models are (1) voluntary access, (2) proactive reporting, and (3) mandated use.[302]

Access to this information is highly protected to ensure that no patient data is released inappropriately.[303] Functionally this means that law enforcement agencies have to obtain a subpoena or a warrant to get any information on the prescriptions.[304] These legal bars necessarily slow the investigation process by adding an additional step approval before any records are reviewed.[305] Therefore, PDMPs are not an ideal

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[301] *See* Ryan S. D'Souza & Jason S. Eldridge, *Prescription Drug Monitoring Program*, STATPEARLS [INTERNET] (Feb. 19, 2019), https://www.ncbi.nlm.nih.gov/books/NBK532299/.

[302] *Id.* ("One model is operated through non-mandated use, where prescribers and dispensers access the database voluntarily. Another model involves proactive reporting, where in addition to voluntarily checking databases, prescribers and dispensers also receive unsolicited reports on patients obtaining a dangerous dose or combination of controlled substances, or if they are acquiring prescriptions from multiple providers. Finally, a mandated use model is gaining recent attention due to preliminary studies demonstrating a reduction in opioid prescribing and decline in doctor shopping.").

[303] *See* Chambers, *supra* note 42, at 26.

[304] *Id.*

[305] *E.g.*, Nathan Freed Wessler, *The Government Needs to Get a Warrant if it Wants Access to Our Private Health Information*, ACLU (May 29, 2019, 11:45 AM), https://www.aclu.org/blog/privacy-technology/medical-and-genetic-privacy/government-needs-get-warrant-if-it-wants-access#:~:text=The%20DEA%20insists%20that%2C%20because,the%20app

tool for law enforcement to identify and prosecute diverting prescribing practitioners at a local, state, or federal level.[306]

Effectiveness of the programs is highly variable by state.[307] The CDC identified Florida, Ohio, and Kentucky as some of the most effective state PDMPs.[308] Both Ohio and Kentucky required prescribers to review the PDMP data in combination with new pain clinic regulations.[309] Florida implemented multiple strategies, including a PDMP, and saw a 50% decrease in Oxycodone related deaths within two years of implementation.[310] Additional state successes were seen in New York and Tennessee.[311] Both states issued mandates requiring clinicians to check the "PDMP before prescribing opioids ," and they respectively saw 75% and 36% decreases in patients seeking drugs from multiple providers.[312]

One of the newest PDMP trends is the creation of provider report cards.[313] These report cards look at a prescribing practitioner's

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roval%20of%20a%20judge (describing the importance of obtaining a warrant, a higher legal standard, to protect personal health information).

[306] *See* Chambers, *supra* note 42, at 29 (discussing the need for more than one source of information to successfully identify & prosecute diversion.).

[307] *See generally* CTR. FOR DISEASE CONTROL & PREVENTION, STATE SUCCESS https://www.cdc.gov/drugoverdose/policy/successes.html (last reviewed Jul. 29, 2019).

[308] *Id.*

[309] *Id.*

[310] *Id.*

[311] *Id.*

[312] *Id.*

[313] *Publisher Report Cards*, BRANDEIS UNIVERSITY (February 2017) https://www.ncjrs.gov/App/Publications/abstract.aspx?ID=273337 [hereinafter *Publisher Report Cards*]; PRESCRIPTION DRUG MONITORING

prescription history in comparison "to the 'average' prescriber of the same specialty."[314] The reports can include clinically relevant information to help the prescribing practitioner understand any variation they may have from the norm.[315] Report cards can either be pushed or pulled.[316] Pushed report cards are automatically sent, while pulled report cards are specifically requested by the providers.[317]

Arizona has one of the most successful report card programs.[318] Its program was created by the Arizona Substance Abuse Partnership and utilizes each provider's National Provider Identifier, a number which is assigned to them when the DEA approves their application to be able to prescribe controlled substances.[319] Arizona's program compares prescribing practitioners to other prescribers within their specialty across the country.[320] The report card uses a heatmap-like system that categorizes the practitioners' prescriptions as normal, high (within one standard deviation from the mean), severe (within two

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PROGRAMS ADMINISTRATORS' ORIENTATION PACKAGE, *supra* note 296, at 26.

[314] Publisher Report Cards, *supra* note 312.

[315] *Id.*

[316] *Id.*

[317] *Pull vs Push Reporting: Leading KPI Development*, KESTREL MGMT., https://kestrelmanagement.com/pull-vs-push-reporting-leading-kpi-development/ (last visited Jan. 31, 2020).

[318] Publisher Report Cards, *supra* note 312

[319] *Id.*; *Practitioner's Manual – SECTION II, supra* note 88.

[320] *Publisher Report Cards*, *supra* note 312 ("The report card identifies five (5) major drugs: carisoprodol, benzodiazepines, hydrocodone, and other pain relievers.").

standard deviations from the mean), or extreme (within three standard deviations from the mean).[321]

Engagement with the PDMP has increased after the initiation of the program (increasing 14% in one year in Pinal County) with minimal complaints (usually regarding incorrect specialty group assignment).[322] Kentucky and Ohio have similar reporting systems with mostly positive qualitative feedback from providers.[323]

The value of any monitoring system is only as good as the data.[324] There are several sources of concern with PDMP data. First, there is variation in the type and amount of data collected, and what is collected is often insufficient.[325] For example, some state PDMPs do not collect essential provider data such as "disciplinary history or

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[321] *Id.*

[322] Press Release, Pinal County Attorney's Off., Pinal County Files Suit Against Opioid Manufacturers, Distributors, Prescribers, and Dispensers, Files in State Court for Damages to Pinal County, (Sept. 30, 2019), https://pinalcountyattorney.org/pinal-county-files-suit-against-opioid-manufacturers-distributors-prescribers-and-dispensers-files-in-state-court-for-damages-to-pinal-county/.

[323] Scott Calvert, *Doctors' Individual Opiate Prescription 'Report Cards' Show* Impact, WALL STREET J. (Sept. 2, 2016), https://www.wsj.com/articles/doctors-individual-opiate-prescription-report-cards-show-impact-1472856624.

[324] *See generally* Allyson Cady, 50 Shades of Data Sharing: How a Uniform Fifty-State Prescription Drug Monitoring Program Can Restore Discretion to Opioid Prescribers and Autonomy to Chronic Pain Patients, 29 HEALTH MATRIX 463 (2019).

[325] *Id.* at 487–90.

whether a prescriber is even alive."[326] Bad or incomplete data can drastically reduce the functionality and utility of a monitoring program.[327]

Additionally, there is inconsistency in data utilization across states.[328] As previously mentioned, states have different reporting and review requirements for PDMPs.[329] Not requiring review of the database prior to prescribing and dispensing eliminates the ability to be proactive in preventing abuse of controlled substances.[330]

Finally, interstate data sharing is a key concern states have been working to address.[331] This is critical to solve given the ease of movement from state to state. In an effort to address this issue, states are increasingly moving towards interstate sharing platforms.[332] As of August 2019, all PDMPs except California, Nebraska, and St. Louis County participate in an interstate sharing platform NABP PMP InterConnect.[333]

Interstate sharing can include data from "Health Information Exchanges (HIE), Electronic Health Records (EHR), and/or Pharmacy

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[326] *Id.* at 487 (citing Joanna Shephard, Combatting the Prescription Painkiller Epidemic: A National Prescription Drug Reporting Program, 40 AM. J.L. & MED. 85, 86 (2014)).

[327] *See generally* Cady, supra note 323.

[328] *See generally* D'Souza, *supra* note 300.

[329] *Id.*

[330] *See generally id.*

[331] *See generally NABP PMP InterConnect Map*, NAT'L ASS'N OF BOARDS OF PHARMACY (Aug. 2019), https://nabp.pharmacy/wp-content/uploads/2019/04/PMP-InterConnect-Map-August-2019.pdf.

[332] *Id.*

[333] *Id.*

Dispensing Systems (PDS)."[334] States vary on what kind of information is shared, with only seventeen states and Washington D.C. sharing HIE, EHR, and PDS information.[335] The results of this data sharing are inconsistent, likely due to the variety in what is shared and with whom.[336]

There are many moving pieces that are directly and tangentially connected to identifying and preventing drug diversion by clinicians in a hospital setting. Trying to create a comprehensive solution that accounts for every minute detail is unrealistic. Instead, to effectively address the issue, a strategy with practical, feasible actions should be implemented that will immediately kick-start sustainable prevention of clinician diversion.

III. A Two-Pronged Approach is Necessary to Effectively Curb Prescribing and Administering Practitioner Drug Diversion

It is critical to acknowledge the differences in methods of diversion between prescribing and administering practitioners. A two-pronged approach accounting for these differences will effectively plug gaps in existing policies and procedures. First, Congress should pass

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[334] *Access to PDMP Data via Integration with: Health Information Exchanges (HIE), Electronic Health Records (EHR), and/or Pharmacy Dispensing Systems (PDS)*, PRESCRIPTION DRUG MONITORING PROGRAM TRAINING & TECHNICAL ASSISTANCE CTR., http://www.pdmpassist.org/pdf/PDMP_Integration_Status_20190816.pdf (last updated Jul. 2019).

[335] *Id.* (showing that Alaska, Washington, Oregon, Arizona, Texas, Colorado, New Mexico, Oklahoma, Arkansas, Louisiana, Kentucky, Ohio, West Virginia, Pennsylvania, Maine, Rhode Island, North Dakota, and Washington D.C. are the only states that share HIE, EHR, and PDS information).

[336] *See generally* Cady, *supra* note 323.

legislation establishing a federally run Medication Order Monitoring Program for prescribing practitioners to effectively track all medication orders for controlled substances and identify any providers who are diverting drugs by overprescribing. Second, the Department of Health and Human Services (HHS) should add a section to the Conditions of Participation (CoP) regarding the preparation and administration of controlled substances, update the regulatory definition of an emergency situation, and add a section to the CoP governing pharmacy review and reconciliation requirements.

A. Congress Should Create a Federal Medication Order Monitoring Program

The first area of opportunity to prevent diversion in a hospital setting is to increase visibility of the habits of prescribing practitioners. To effectively identify diversion by over prescription, Congress should create a federal Medication Order Monitoring Program (MOMP).

Federal legislation is the most appropriate way to create the program because prescribing practitioners must be expressly granted the ability to write medication orders by the DEA.[337] Additionally, creation via legislation is supported by the fact that state programs were created via state legislation.[338] Finally, creation of an entirely new program is outside the rulemaking ability of CMS.[339] While getting any legislation passed through Congress is challenging, the severity of the crisis and

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[337] 21 C.F.R. § 1301.11 (2009).

[338] *E.g.,* MISS. CODE ANN. § 73-21-127 (1972).

[339] Azar v. Allina Health Services, 139 S. Ct. 1804 (2019) (describing the scope of the Medicare specific notice-and-comment regime). Author's Note: the creation of an entirely new program goes far beyond the creation of a substantive legal standard (which requires notice & comment rulemaking).

the strength of the solution should ensure that the bill makes it though the entire legislative process swiftly.

The MOMP would pull all controlled substance medication orders written by a prescribing practitioner in a hospital, deidentify the medication orders, and amalgamate all data into a single database. In order to make the database successful, it would need to include the following key elements: an algorithm that factors in prescribing practitioner specialty and patient load; federal oversight and regulation; enhanced scrutiny for practitioners moving between states; and electronic only prescriptions.

1. Key Structural Components of the MOMP

First, the MOMP would need to take specialty and patient load into account in its profiling of prescribing practitioners.[340] Types and dosages of controlled substance medication orders vary greatly by specialty type.[341] For example, orthopedic procedures have reasonably standard post-op pain management protocols, so the MOMP would search for and flag any significant deviation of an orthopedic surgeon's medication orders from published best practices.[342] The MOMP will also need to factor in the prescribing practitioner's patient load, looking at their behavior holistically. It effectively closes an opportunity for physicians to divert by spreading their over prescriptions across multiple facilities in the same market, or across state lines.[343] Strictly

[340] *E.g.*, Publisher Report Cards, *supra* note 312.

[341] *See generally*, *e.g.*, Joseph R. Hsu, et al., Clinical Practice Guidelines for Pain Management in Acute Musculoskeletal Injury, 33 J. ORTHOPAEDIC TRAUMA 158 (2019).

[342] *See id.* at 163-65.

[343] Author's inference based on experience with physicians (primarily surgeons and anesthesiologists) practicing at multiple hospitals within the same market.

looking at benchmarked volumes should make over prescription much easier to quickly identify.[344]

To account for the ease of prescribing practitioners' movement between facilities, cities, and states, the MOMP should be monitored by a federal agency.[345] The most logical entity is the DEA, which already has broad authority granted to it in the Controlled Substances Act.[346] Within the DEA, the best division to take on this project is the Diversion Control Division (DCD).[347]

DCD field offices spread throughout the country would be responsible for identifying and investigating any abnormally high prescription rates and suspected diversion.[348] Delegation to this division would likely have support from the OIG, who recently found that since 2000, the "DEA did not use its available resources, including its data systems and strongest administrative enforcement tools, to detect and regulate diversion effectively."[349]

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[344] *See generally* Hsu, *supra* note 346.

[345] *A Faster Pathway to Physician Licensure,* INTERSTATE MEDICAL LICENSURE COMPACT, https://www.imlcc.org/a-faster-pathway-to-physician-licensure/ (last visited Oct. 20, 2020) [hereinafter IMLC] (describing how a single oversight entity can streamline processes and make intra state data sharing easier).

[346] 21 U.S.C.A. §801 et seq. (1970); Review of the Drug Enforcement Administration's Regulatory and Enforcement Efforts to Control the Diversion of Opioids , *supra* note 12, at ii.

[347] *Program Description*, DRUG ENFORCEMENT ADMINISTRATION DIVERSION CONTROL DIVISION, *supra* note 142.

[348] *Id.*

[349] Review of the Drug Enforcement Administration's Regulatory and Enforcement Efforts to Control the Diversion of Opioids , *supra* note 12, at i.

Another key element is that all physicians must notify the MOMP when they are moving to a new state. The program should also have an algorithm that captures when a physician is writing medication orders in a new state in case the physician accidentally or intentionally failed to notify the MOMP. The MOMP will impose a temporarily heightened level of scrutiny for physicians moving between states.

The MOMP requires all medication orders be written electronically and be linked to all hospitals' EMRs. All medication orders will need to include the provider's unique DEA registration number.[350] The OIG specifically mentioned that the DEA should have been requiring electronic-only orders for years.[351] It ensures that all data sent to the MOMP is clean and consistent.[352] It additionally eliminates the well documented systemic issue with stolen prescription pads[353]

Electronic-only medication orders also allow for easier deidentification processes.[354] Deidentification of the medication orders

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[350] Providers will no longer be able to use the hospital's registration number under proposed MOMP. *See Practitioner's Manual – SECTION II, supra* note 88.

[351] Review of the Drug Enforcement Administration's Regulatory and Enforcement Efforts to Control the Diversion of Opioids , *supra* note 12, at 15.

[352] *Id.*

[353] *E.g.*, Lelling, *supra* note 39, at 171 (describing a medical assistant who stole a physician's prescription pad and wrote 244 prescriptions).

[354] *See* Guidance Regarding Methods for De-Identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, U.S. DEP'T OF HEALTH & HUM. SERV., https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html#rationale (last reviewed Nov. 6, 2015) ("The process of de-identification, by which identifiers are removed from the

is vital to the utility of the MOMP and is a crucial distinction from the state run PDMPs. By deidentifying all medication orders, the DEA can immediately review the information for each provider without running into any patient privacy issues.[355] This process enables immediate investigative and enforcement actions without having wait for a judge to grant a subpoena or a warrant.[356]

If the DCD does seriously suspect diversion by over prescription, the DEA should use its power to immediately suspend the practitioner's license.[357] If diversion is proven, the DEA should work with state boards of medicine and nursing to explore rehabilitation options rather than immediate revocation of the practitioner's license. This should help to shift the culture of fear and nonreporting in hospitals.

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health information, mitigates privacy risks to individuals and thereby supports the secondary use of data for comparative effectiveness studies, policy assessment, life sciences research, and other endeavors.").

[355] Chambers, *supra* note 42, at 26. Author's Note: Deidentification of information makes HIPAA protections inapplicable, thus effectively eliminating privacy concerns.

[356] *Id.* (states that law enforcement needs to get a subpoena or a warrant to view patient information.).

[357] Review of the Drug Enforcement Administration's Regulatory and Enforcement Efforts to Control the Diversion of Opioids, *supra* note 12, at 21.

2. Congress Should Outsource the Creation and Maintenance of the MOMP to a Vendor and Use Money from the National Prescription Opiate Litigation for Funding

Despite common complaints about compatibility, EMR integration with the MOMP should actually be a relatively smooth process.[358] Vendors used by state PDMPs already have the capacity to patch in different EMRs, allowing providers to view data without leaving their hospital's system.[359] There is no reason the same process should not work on a federal level, especially since there are a discrete number of EMR vendors currently operating within the US.[360]

To ensure immediate efficacy, the DEA should contract with one of the vendors currently operating a state run PDMP. Outsourcing to a vendor allows the government to begin the program almost immediately because the infrastructure is already in place.[361] Vendors have created systems allowing for data feeds from numerous sources including outpatient pharmacies, hospitals, and individual physician practices.[362] Vendors would not require significant time to build and implement a universally accessible and functional data sharing platform.[363]

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[358] *See generally* NABP PMP InterConnect: The Only National Network of State-Based PMPs, *supra* note 299.

[359] *See generally id.*

[360] *See* Mandy Roth, *In EMR Market Share Wars, Epic and Cerner Triumph Yet Again*, HEALTH LEADERS (Apr. 30, 2019), https://www.healthleadersmedia.com/innovation/emr-market-share-wars-epic-and-cerner-triumph-yet-again.

[361] *See generally* PRESCRIPTION DRUG MONITORING PROGRAMS ADMINISTRATORS' ORIENTATION PACKAGE, *supra* note 296.

[362] *See generally id.*

[363] *See generally id.*

Conversely, if the DEA elects to create its own system, the process could take years. Existing DEA databases are completely reliant on periodic manual data entry.[364] It has no foundation for a database that is fed by electronic medication orders from a variety of sources.[365] Without a template, the build of the MOMP would start from scratch.

The U.S. simply does not have the kind of time it would take to build a system. The crisis is showing no signs of slowing down and purely local efforts are unproven at best.[366] Outsourcing to an experienced vendor will provide the timely information needed to effectively identify likely diverters.[367] Any increased costs for outsourcing to a vendor are justified given the severity of the crisis.[368] Additionally, the costs will balance out in the long term given the time and human capital investment that would be required to build and maintain a "home-grown" database.

Joint federal and state funding can help make the outsourcing of the MOMP financially feasible.[369] The federal government would likely use funds allocated to the DEA. States, however, have a unique opportunity to claim some of the (highly) likely settlement money from the ongoing National Prescription Opiate Litigation.[370] The National

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[364] *See*, *e.g.*, 21 C.F.R. § 1304.3 (2016); OIG Report, *supra* note 11, at ii.

[365] *See*, *e.g.*, *id.*

[366] *See generally* Understanding the Epidemic, *supra* note 6.

[367] *See generally* PRESCRIPTION DRUG MONITORING PROGRAMS ADMINISTRATORS' ORIENTATION PACKAGE, *supra* note 296 (discussing the benefits of outsourcing to a vendor).

[368] *See* Understanding the Epidemic, *supra* note 6.

[369] Precise mechanics of funding the program are outside the scope of this Article.

[370] Dwyer, *supra* note 237.

Prescription Opiate Litigation is the consolidation of over 2,500 cases filed by "nearly every level of government" in forty-eight states against companies involved in the entire opioid value stream. The eventual settlement is estimated to be in the billions.[371]

Additionally, no company can be more appropriately held accountable than Purdue Pharma (Purdue), whose former president previously bragged about expecting a "blizzard of prescriptions" following the launch of the massively successful drug OxyContin.[372] Purdue severed itself from the National Prescription Opiate Litigation by filing for Chapter 11 Bankruptcy based on a tentative settlement agreement.[373] Attorneys are currently working to create a settlement plan that could be somewhere between ten and twelve billion dollars.[374] States have the opportunity to claim some of this settlement money before any deal is finalized.[375]

The allocation of funds to a preventive measure like the MOMP has a solid historical foundation given the obvious parallels of the National Prescription Opiate Litigation to the big tobacco Master Settlement Agreement. Using settlement money to fund the MOMP allows states to avoid the mistakes of the big tobacco Master Settlement Agreement.[376] A key failing of that multibillion-dollar settlement is that

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[371] *Id.*

[372] Alanna D. Rucher & Geoff Mulvihill, *Filing: OxyContin Maker Forecast "Blizzard of Prescriptions,"* ASSOCIATED PRESS (Jan. 15, 2019), https://apnews.com/4e2da888ede44c3db129b46d76504778.

[373] Hoffman & Walsh, *supra* note 269.

[374] Church, *supra* note 271; Strickley, *supra* note 271.

[375] *E.g. The Purdue Pharma Bankruptcy Case: What's at Stake*, *supra* note 269 (estimating the potential value of a settlement in the Purdue case).

[376] A State-by-State Look at the 1998 Tobacco Settlement 20 Years Later, supra note 262.

states did not use enough of the settlement money for preventive measures.[377] Even though the litigation is in its early stages, there are already concerns regarding the "difficulty [in] determining who would control any monies generated by these lawsuits and how they would be spent."[378] A federal program monitoring all the medication orders written by every prescribing practitioner in every hospital is a crucial preventive measure. There is also a sense of poetic justice in using money from the organizations who created the problem to prevent exacerbation of the problem in clinicians.

3. The Medication Order Monitoring Program is an Appropriate Use of Federal Authority and is Distinct from State Level Programs

The creation of this program is likely to be challenged an overextension of federal authority. Currently, the practices of medicine and nursing are primarily governed by the states, not the federal government.[379] The prescription of controlled substances, however, is different from the general practice of medicine.[380] The ability to prescribe these dangerous drugs can only be granted by the DEA—a federal agency.[381] Additionally, federal agencies are involved in many aspects relating to these drugs (such as the requirement for FDA

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[377] *Id.*

[378] Mann, *supra* note 263.

[379] *E.g.*, *Enforcement*, TEX. MED. BOARD, *supra* note 224.

[380] *Practitioner's Manual – SECTION II*, *supra* note 88.

[381] Review of the Drug Enforcement Administration's Regulatory and Enforcement Efforts to Control the Diversion of Opioids, *supra* note 12, at 15.

approval to go to market).[382] It is a natural extension of the DEA's scope of authority to monitor the habits of the practitioners they have empowered to prescribe opioids.

From a policy perspective, a federal approach is necessary because states are making it easier to practice medicine across state lines (via telemedicine and/or moving to a new state).[383] It is important to support these changes to ensure the continuing evolution of medicine and increases in quality of care.[384] Federal oversight of the MOMP facilitates that these trends continue safely while simultaneously preventing physicians who are diverting drugs from being able to move from state to state without getting caught.

It could also be argued that this program is an unnecessary duplication of state programs. This challenge is not viable for several reasons. First, the primary goal of many state PDMPs is to identify patients gaming the system; identification of inappropriate prescribing is a secondary goal.[385] By deidentifying patient data, the proposed MOMP is exclusively looking at the prescribing practitioner's behavior in its totality. Additionally, while almost every state does have their own program (Missouri is the only state without a statewide program), there is extreme variability in the success of these programs.[386] A

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[382] *See* 21 U.S.C.A § 801 et seq. (1970).

[383] *IMLC*, *supra* note 344.

[384] *E.g.*, Maryam Alvandi, *Telemedicine and its Role in Revolutionizing Healthcare Delivery*, AM. J. OF ACCOUNTABLE CARE (Mar. 10, 2017), https://www.ajmc.com/journals/ajac/2017/2017-vol5-n1/telemedicine-and-its-role-in-revolutionizing-healthcare-delivery.

[385] Rebecca L. Haffajee, Preventing Opioid Misuse with Prescription Drug Monitoring Programs: A Framework for Evaluating the Success of Public Health Laws, 67 HASTINGS L.J. 1621, 1634–35 (2016).

[386] *Id.* at 1635.

federal program that pulls best practices from the states most likely would ensure effective monitoring across the country. Finally, hospital medication orders are specifically excluded from many states' monitoring programs.[387] The proposed MOMP will look at the behaviors of a group of prescribing practitioners who, at best, are only substantively monitored at a facility level.

A final concern likely to be raised is that increased scrutiny of every medication order will cause prescribing practitioners to curb their orders of opioids in fear of investigation to detriment of their patients.[388] The MOMP was specifically designed to account for this fear. It compares prescribing practitioners based on specialty and volume so that they will not drastically cut medication orders to prevent investigation. Additionally, a decrease in opioid medication orders is not necessarily a bad thing. Many providers are working to substitute multi-modal pain management protocols for opioids.[389] This is actually

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[387] *See*, *e.g.,* MASS. GEN. LAWS ch. 94C § 24A(b) (2019) ("The requirements of this section shall not apply to the dispensing of controlled substances to inpatients in a hospital."); Ga. Code Ann., § 16-13-57 et seq. (Georgia); Ga. Code Ann., § 31-2A-4 (Georgia); KRS § 218A.202 et seq. (Kentucky); 22 M.R.S.A. § 7248 et seq. (Maine); Health - General, § 21-2A-02 et seq. (Maryland).

[388] Kelly K. Dineen, Definitions Matter: A Taxonomy of Inappropriate Prescribing to Shape Effective Opioid Policy and Reduce Patient Harm, 67 U. KAN. L. REV. 961, 975–976.

[389] *E.g.*, *Multimodal Approach to Pain Management Reduces Opioid Use, Prescriptions After Joint Replacement*, AM. SOC'Y OF ANESTHESIOLOGISTS (Mar. 1, 2018), https://www.asahq.org/about-asa/newsroom/news-releases/2018/03/multimodal-approach-to-pain-management-reduces-opioid-use.

a better pain management strategy for their patients because it eliminates the high risk of addiction presented by opioids.[390]

Ultimately, a congressionally created and federally monitored MOMP is the best way to identify diversion by over prescription. This solution, however, only addresses the more visible part of the problem: Administering practitioners are much more likely to escape notice because their names and ID numbers are not tied to any medication order.[391] Therefore, a regulatory response by HHS is necessary to curb their diversion. The next section of this Article will discuss proposed changes to the Code of Federal Regulations to curb diversion by administering practitioners.

B. The Department of Health and Human Services Should Implement New Regulations to Identify and Prevent Drug Diversion by Administering Practitioners

The second prong of the proposed solution is tailored to eliminate administering practitioners' ability to divert controlled substances. To accomplish this, the proposed solution requires regulatory changes governing every step in the preparation and administration process beginning with medication order and ending with post-administration reconciliation and review processes. The proposed regulations close many loopholes and common excuses allowed by the existing regulatory scheme.

To effectively eliminate an administering practitioner's ability to divert excess medication, HHS should propose the following additions and changes: the addition of 42 C.F.R. § 482.23(d)

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[390] *E.g.*, *id.*

[391] *See BDS Medication Administration Curriculum Section III*, *supra* note 95 at 4 (stating that a valid medication order needs to be signed by a prescribing practitioner, not the administering practitioner).

Preparation and Administration of Controlled Substances;[392] the update of 21 C.F.R § 290.10 Definition of Emergency Situation;[393] and the addition of 42 C.F.R. § 482.25(c) Reconciliation, Review, and Quality Improvement for Controlled Substances.[394]

All of these sections of the Code of Federal Regulations are enforced by agencies under the HHS umbrella.[395] Additionally, they involve updates to existing rules within the scope of the HHS' authority.[396] Therefore, the proposed additions and changes are an appropriate use HHS' rulemaking ability.[397]

The HHS is explicitly permitted to promulgate new rules provided it follows the rulemaking and comment process outlined by statute.[398] This requires the HHS to provide notice of the proposed rules, allow a period for public comment, and publish final rules with any updates from public comments deemed appropriate.[399] Virtually

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[392] *See* 42 C.F.R. § 482.23(c) (2019); OIG Report, *supra* note 11, at 15.

[393] *See*, *e.g.*, *Over-the-Top Risky: Overuse of ADC Overrides, Removal of Drugs without an Order, and Use of Non-Profiled Cabinets*, INST. FOR SAFE MEDICATION PRAC. (Oct. 24, 2019), https://www.ismp.org/resources/over-top-risky-overuse-adc-overrides-removal-drugs-without-order-and-use-non-profiled.

[394] *See* 42 C.F.R. § 482.25(a)(3) (2012).

[395] *HHS Organizational Chart*, *supra* note 172.

[396] *See id.*

[397] Azar, *supra* note 338, at 1809; Memorandum from Rachel Brand, Associate Attorney General, U.S. Department of Justice, to Heads of Civil Litigating Components United States Attorneys (Jan. 25, 2018) (on file with the U.S. Dep't of Just.).

[398] 42 U.S.C.A § 1395hh.

[399] *Id.*

every hospital in the US accepts federal funding, so using the CoP as an anchor, and updating related sections in the Code of Federal Regulations, is the most expedient way to ensure that all hospitals are compliant with the proposed processes and procedures.[400]

Proposed regulations are applicable to, and feasible for all hospitals, regardless of location, size, and financial status. The remainder of this section begins with a discussion of each proposed change. It then shows how the proposed changes work together to close out current gaps in policy and process that administering clinicians frequently exploit. The section concludes with an application of the proposed regulations to a travel nurse to demonstrate how they work together and with the MOMP to curb diversion.

1. Breaking Down Regulatory Additions and Updates to Close the Loop on Common Administering Practitioner Methods of Diversion

The second prong involves three changes to the Code of Federal Regulations that work together to curb diversion. This section breaks down each change individually, identifying key elements and strengths.

a. Addition of 42 C.F.R. § 482.23(d) Preparation and Administration of Controlled Substances

The first change HHS should make is to add a new section governing the preparation and administration of controlled substances. Existing regulations treat all medications equally, mandating the same processes for an administration of Advil as they do Fentanyl.[401] HHS

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[400] *See generally* James Whisler, *By 2025 Costs, Regs, Changing Payer Mix Will Help Drive Innovative Partnerships*, DELOITTE (Oct 27, 2017), https://blogs.deloitte.com/centerforhealthsolutions/by-2025-costs-regs-changing-payer-mix-will-drive-innovative-partnerships.

[401] 42 C.F.R. § 482.23(c) (2011).

should recognize challenges and opportunities unique to controlled substances and tailor a new section with higher standards and stricter rules. Key changes in the proposed section are requirements for electronic only orders and pulls from profiled medication. Full proposed language, with author's additions in italics, reads as follows:

> ***42 C.F.R. § 482.23(d) Preparation and Administration of Controlled Substances***[402]
>
> (1) *Controlled Substances, as defined in 21 C.F.R. § 290.1,* must be prepared and administered in accordance with Federal and State laws, the orders of the practitioner or practitioners responsible for the patient's care as specified under § 482.12(c), and accepted standards of practice.
>
> (i) *Controlled substances* may be prepared and administered on the orders of other practitioners not specified under § 482.12(c) only if such practitioners are acting in accordance with State law, including scope-of-practice laws, hospital policies, and medical staff bylaws, rules, and regulations.
>
> (ii) *Controlled substances must be* prepared and administered on *electronic*

[402] Authors proposed section addition to the already enacted 42 C.F.R. § 482.23.

> *orders*. *Orders may be* standing orders, order sets, and protocols for patient orders only if such orders meet the requirements of § 482.24(c)(3).
>
> (2) All *controlled substances* must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures.
>
> (3) Orders for *controlled substances* must be documented and signed by a practitioner who is authorized to write orders in accordance with State law and hospital policy, and who is responsible for the care of the patient as specified under § 482.12(c).
>
> (i) *Hand-written and oral orders are only acceptable in an emergency situation as defined in 21 C.F.R § 290.10.*
>
> (ii) When *oral* orders are used, they must only be accepted by persons who are authorized to do so by hospital policy and procedures consistent with Federal and State law.
>
> (iii) Orders for *controlled substances* may be documented and signed by other practitioners not specified under § 482.12(c) only if such practitioners are acting in accordance with State law,

including scope-of-practice laws, hospital policies, and medical staff bylaws, rules, and regulations.

(4) *Controlled substances* must be administered in accordance with State law and approved medical staff policies and procedures.

(i) *All controlled substances must only be pulled and administered as a profiled medication, as defined below:*

(A) *Profiled medication means those medications stored in an automated dispensing cabinet that have a valid electronic order from the prescribing practitioner, have been reviewed by a licensed pharmacist, and have been assigned to the patient.*

(ii) *In an emergency situation as defined in 21 C.F.R. § 290.10, controlled substances may be pulled and administered from stocked medication, as defined below:*

(A) *Stocked medication means those medications stored in an automated dispensing cabinet that are not connected to a valid*

electronic order from the prescribing practitioner, have not been reviewed by a licensed pharmacist, and are not assigned to any specific patient.

(B) *If the controlled substance is pulled and administered from stocked medication, any excess medication must be returned to the automated dispensing cabinet or wasted in a receptacle meeting the minimum qualifications stated in 21 C.F.R. § 1317.75(e). A second practitioner must observe and confirm that this process was followed.*

(C) *If a controlled substance is pulled and administered from stocked medication, there must be a hospital procedure for immediate reporting.*

(5) There must be a hospital procedure for reporting adverse drug reactions and errors in administration of drugs.

(6) *This section shall govern controlled substance preparation and administration for all inpatient and outpatient units within the hospital, specifically including the emergency department and surgical services areas.*

The first element of the proposed regulatory changes is that all medication orders for controlled substances must be submitted electronically.[403] This explicitly prevents administering practitioners from calling in oral medication orders for controlled substances. Requiring electronic medication orders is beneficial on a multitude of fronts. First, it is helpful in facilitating safe and efficient profiling of the medication by pharmacy staff, which is a huge safety consideration.[404] Second, it makes the workflow of the administering clinician easier; they would be able to pull exactly what the patient needs at the time they need it, instead of having to wait for the medication order to be called in and filled. Finally, it helps create an easier trail for local hospital departments to track ordering and administration habits of its clinicians.[405]

Electronic-only medication orders will work to facilitate the next key element of the proposed regulations; all controlled substances must be profiled. Hospital pharmacies are already required to keep

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[403] OIG Report, *supra* note 11, at 15.

[404] Karla Miller, et al., AGENCY FOR HEALTHCARE RESEARCH & QUALITY (US), *Evaluation of Medications Removed from Automated Dispensing Machines Using the Override Function Leading to Multiple System Changes* (Aug. 2008), https://www.ahrq.gov/sites/default/files/wysiwyg/professionals/quality-patient-safety/patient-safety-resources/resources/advances-in-patient-safety-2/vol4/Advances-Miller_93.pdf.

[405] *See*, *e.g.,* Amber Porterfield et al., *Electronic Prescribing: Improving the Efficiency and Accuracy of Prescribing in the Ambulatory Care Setting*, PERPS. IN HEALTH INFO. MGMT., 2 (Spring 2014), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3995494/pdf/phim0011-0001g.pdf.

complete medication profiles for every patient; it is not an additional burden to require profile only pulls.[406] Additionally, controlled substances are some of the most dangerous drugs available in the hospital, so it is logical to include every possible layer of protection to safeguard patients and prevent diversion.

This requirement is primarily applicable to IV controlled substances, which are stored in varying dosages in the ADC.[407] This requirement is important for two reasons. First and foremost, profiled medications are critical for patient safety.[408] Pharmacy review screens the medication order for patient allergies and potential adverse reactions with existing medications.[409] Beyond safety considerations, restricting a practitioner's ability to pull from stocked medication forces them to pull the exact amount that was ordered by the prescribing practitioner. This means that they can no longer pull bulk medications or larger dosages than ordered by the prescribing practitioner, functionally eliminating their ability to divert any excess medication that would necessarily be wasted.

b. Update 21 C.F.R. § 290.10 Definition of Emergency Situation

One of the most common excuses for bypassing normal protocol is to say that it was an emergency situation.[410] The existing statutory definition is overly-broad, making it difficult to identify as a source of

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[406] *See* Fan, *supra* note 129, at 421–22.

[407] *See generally* Grissinger, *supra* note 120, at 491.

[408] *Id.* at 490.

[409] *Id.*

[410] Fan, *supra* note 129, at 423 ("ADCs may allow users to perform a "critical override" when the pharmacy is closed, granting access to drugs normally requiring pharmacy review; if this access is not regularly reviewed the override feature can be abused.").

diversion without real-time data reconciliations.[411] Because it is so commonly used as an excuse, it can be difficult to distinguish between true emergencies, situations where the proper process is laborious and the clinician doesn't want to do it, and situations when an administering practitioner is using it as a means to cover up drug diversion.

Emergency situations are explicitly excluded from the requirements for electronic-only ordering and exclusive use of profiled medications described above. The current standard for emergency situation, as defined in 21 C.F.R. § 290.10, is ambiguous and can easily be used as an excuse for breaking with protocol.[412] To prevent exploitation of this carve out, HHS should update 21 C.F.R. § 290.10 to narrow the definition of emergency situation as applicable to administration of controlled substances, and distinguish it from time critical situations. Full proposed language, author's additions in italics, reads as follows:

> ***21 C.F.R § 290.10 Definition of Emergency Situation***
>
> (1) For the purposes of authorizing an oral prescription of a controlled substance listed in schedule II of the Federal Controlled Substances Act, *and for authorizing a controlled substance to be pulled and administered from stocked medication,* the term emergency situation means those situations in which the prescribing practitioner determines:
>
> (i) That immediate administration of the controlled substance is necessary, for proper treatment of the intended ultimate user; and

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[411] *See generally* 21 C.F.R. § 290.10 (2012); Cohen, *supra* note 53 (discussing how difficult it is to identify diversion retroactively.).

[412] 21 C.F.R. § 290.10 (2012).

> (ii) That no appropriate alternative treatment is available, including administration of a drug which is not a controlled substance under schedule II of the Act, and
>
> (iii) That it is not reasonably possible for the prescribing practitioner to provide *an electronic* prescription to be presented to the person dispensing the substance, prior to the dispensing.
>
> (2) For the purposes of authorizing an oral prescription of a *controlled substance and authorizing a controlled substance to be pulled and administered from stocked medication in an emergency situation, as set out in 21 C.F.R. § 290.10*, the term emergency situation *does not include time-critical situations.*
>
> (i) *Time-critical situations means those situations in which the prescribing practitioner determines that administration of the medication must occur within thirty-minutes.*[413] *It is not an emergency situation if the prescribing practitioner determines that the administration can be delayed for fifteen or more minutes.*
>
> (ii) *In time-critical situations, the administering practitioner must follow all steps outlined in 42 C.F.R § 482.23(d).*[414]

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[413] U.S. DEP'T OF HEALTH & HUMAN SERV., CMS MANUAL SYSTEM: REVISED APPENDIX A, INTERPRETIVE GUIDELINES FOR HOSPITALS (2011), https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R77SOMA.pdf.

[414] 21 C.F.R § 290.10 (*emphasis added*).

The redefinition of emergency situation is a critical change to existing policy. Under the new regulations, a true emergency situation is when an administering clinician, in their medical judgement, determines that the patient must have a certain medication within fifteen minutes.[415] Any medication that needs to be administered within fifteen to thirty minutes is now defined as time-critical, which will not be a permitted exception to the preparation and administration process in the proposed regulations. These measures collectively eliminate emergency situations as a convenient excuse for bypassing hospital policy and procedure.[416] Again, they close the gap that would allow diversion of excess medication that should be wasted.

Because true emergencies exist in a hospital setting, the proposed regulations allow for an alternate pathway, providing complete guidance for this exception. They explicitly define what a stocked medication is, prescribe the appropriate emergency pull and administration process, and require immediate reporting of the incident. These proposed additions are critical to actually changing behavior of administering practitioners.

A common mistake hospitals make is allowing a bypass of normal procedure without any real accountability.[417] Requiring an immediate report of the incident ensures that a supervisor is aware of the situation and can take corrective action with fresh intelligence.

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[415] Author selected fifteen minutes as a specific and measurable standard to avoid any ambiguity in interpretation.

[416] *See generally* Fan, *supra* note 129, at 426 (recommending reduction in critical overrides and frequent audits to catch discrepancies).

[417] *See ASHP Guidelines on Preventing Diversion of Controlled Substances*, *supra* note 27, at 93 (advocating for daily review of ADC reports).

Realistically, leadership has a short window to investigate given the complexity and speed of daily hospital operations.[418]

c. Addition of 42 C.F.R. § 482.25(c) Reconciliation, Review, and Quality Improvement for Controlled Substances

Proposing new rules is easy; actually making them work is much more difficult. A critical error frequently made by hospitals is not following up when a fall-out occurs.[419] If hospitals truly want to make lasting changes, they need to understand *why* a problem is occurring and design and implement changes that address the issue. Current regulations only require a hospital pharmacy to keep accurate records of their medication.[420] This loose requirement allows facilities a lot of leeway in how and when they choose to conduct reconciliations aimed at identification of drug diversion. Additionally, there is no quality improvement requirement specific to this process and section.

Therefore, a new subsection should be added that explicitly defines reconciliation and review processes, places a minimum review timeline, and requires quality improvement initiatives specifically tied to any fallouts identified during the reconciliation and review processes. Full proposed language reads as follows:

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[418] See *id.*

[419] *E.g.*, Christopher Jason, *How a Drug Diversion EHR Tool can Curb the Opioid Crisis*, EHR INTELLIGENCE (Jun. 24, 2020), https://ehrintelligence.com/news/how-a-drug-diversion-ehr-tool-can-curb-the-opioid-crisis ("[L]eaders relied on manual reviews based on very long, detailed reports that were generated by the dispensing cabinets on a monthly basis. . . [and] Two months can go by before leaders are able to interview the person who may have been involved in a potential diversion.").

[420] 42 C.F.R. § 482.25(a)(3) (2012).

42 C.F.R. § 482.25(c) Reconciliation, Review, and Quality Improvement for Controlled Substances[421]

(1) *There must be a hospital procedure for immediate review of all deviations from required preparation and administration procedures per 42 C.F.R. §482.23(d).*

(i) *There must be a hospital procedure for reconciling the amount of controlled substance that is pulled from the automated dispensing cabinet, the amount that is administered to the patient, and the amount that was returned to the automated dispensing cabinet or wasted in the appropriate receptacle.*

(ii) *Pursuant to § 482.21, there must be a hospital quality and performance improvement initiative in place to prevent future fallouts.*

(iii) ***Any*** *diversion must be immediately reported per 21 C.F.R. §§ 1301.91 & 1301.76(b).*

(2) *There must be a hospital process for regular review of all controlled substances ordered, administered, and returned or wasted.*

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[421] Authors proposed section addition to the already enacted 42 C.F.R. § 482.25.

> (i) *Regular review not to be less than weekly.*
> (ii) ***Any*** *diversion must be immediately reported per 21 C.F.R. §§ 1301.91 & 1301.76(b).*

Critical to this proposal is an acknowledgement of the cliché that what gets measured really does get done.[422] So, placing exact measurement and review requirements will ensure facility vigilance in reconciliations. Additionally, timely review of errors is crucial to identification and prevention of diversion.[423] The regulations require a weekly review as a bare minimum because the review and reconciliation requirements will likely be a manual process primarily driven by the pharmacy department. Ideally, hospitals would conduct more frequent reviews, but given the disparity in resources of hospitals across the country, weekly review is the most feasible universally applicable requirement.

The proposed regulations are applicable to all controlled substances, regardless of administration route. These requirements should be particularly effective in identification of diversion of tablets. Weekly reviews and reconciliations allow leadership to chart out

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[422] *See*, *e.g.*, Joshua Knowles & Muin J. Khoury, *What Gets Measured Gets Done: Public Health Progress in Familial Hypercholesterolemia*, CTR. FOR DISEASE CONTROL & PREVENTION (Nov. 9, 2016), https://blogs.cdc.gov/genomics/2016/11/09/what-gets-measured/.

[423] See *ASHP Guidelines on Preventing Diversion of Controlled Substances*, *supra* note 27, at 93.

patterns and trends of "dropped" and "refused" tablets, ensuring early identification of diversion.[424]

Finally, the proposed regulations now explicitly require *all* diversion, regardless of amount, be reported to the DEA. This removes previous ambiguity surrounding the meaning of significant diversion. Requiring immediate reporting of any diversion takes away any weighing of risk factors that hospital administrators might be tempted to do.

A potential tie in to the proposed regulations is to switch to exclusive use of small ampules of IV controlled substances in lieu of cheaper bulk SDVs for medications like Dilaudid.[425] Bulk SDVs are commonly used when there is not an active order and the administering practitioner has to override the ADC.[426] These SDVs are pulled from stocked medications, which are unassigned to any specific patient.[427] Administering practitioners are supposed to give the patient the prescribed amount and waste any excess medication.[428]

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[424] Artificial intelligence does exist that purports to do this automatically, but a detailed evaluation of potential programs is outside the scope of this Article. Cohen, *supra* note 53.

[425] Exact funding of this supply change is outside the scope of this Article. A follow up article could evaluate the viability of drawing from the likely settlements from the National Prescription Opiate Litigation and Purdue's Chapter 11 Bankruptcy proceedings. Relief could come in the form of cash contributions or product allocations.

[426] *See ASHP Guidelines on Preventing Diversion of Controlled Substances*, *supra* note 27, at 92.

[427] *See* Grissinger, *supra* note 120.

[428] *See ASHP Guidelines on Preventing Diversion of Controlled Substances*, *supra* note 27, at 78.

Functionally, these bulk SDVs are impractical and illogical to be stored as stocked medication in the ADC. They are packaged as a SDV—so a clinician can only pull once from the vial—but they often contain up to fifty times a normal dose.[429] This means that the majority of the medication is going to have to be thrown away every single time a bulk SDV is pulled.[430] This makes no sense from an efficiency or safety standpoint. Hospitals are literally throwing away vast quantities of an already scarce resource and providing a huge opportunity for drug diversion by the administering practitioner. If the hospital exclusively orders smaller ampules, which contain a true single dose as would be prescribed per standard dosing protocols, they easily eliminate waste and opportunity for diversion.[431]

Changing to exclusive use of smaller ampules works well with the proposed regulatory changes in this Article. Requiring all controlled substances to be profiled reduces the need for any bulk medications and the proposed redefinition of emergency situation in 21 C.F.R. § 290.10 should limit the number of times an administering practitioner can pull from stocked medication. With the switch to ampules, even when a practitioner is pulling from stock, there would be no bulk option to divert from. Collectively, the regulations and supply change close the loop on one of the biggest sources for drug diversion.

To operationalize all proposed changes, local drug diversion teams should be created and deployed.[432] Composition of these teams should include representatives from pharmacy, nursing, and

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[429] *DILAUDID® and DILAUDID-HP® INJECTION*, *supra* note 4.

[430] *Id.*

[431] *See DILAUDID® and DILAUDID-HP® INJECTION, supra* note 4 ("The usual starting dose is 1-2 mg. . . every 4 to 6 hours as necessary for pain control.").

[432] *E.g.*, Berge, *supra* note 212, at 679.

administration at a minimum.[433] Each team would be responsible for operationalizing and executing regulatory changes, auditing discrepancies, inspecting potential diversion, and reporting actual diversion to hospital administration.[434] Hospital administration should impose strict rules enforcing the regulations to ensure compliance, like a single strike policy for deviation in key steps of the process, such as failure to witness a waste or allowing a non-emergency order to be submitted orally. Finally, these teams would be responsible coordinating with state rehabilitation programs for diverting clinicians.[435] Rehabilitation programs would necessarily be a one-time opportunity to prevent abuse of the system.

2. The Proposed Regulations Close Many Commonly Exploited Loopholes and Provide a Foundation for Continuous Improvement

Like almost any other crime, there is almost no way to completely eliminate drug diversion. States such as Texas have the death penalty for murder and people still kill; the IRS can punish with hefty fines and prison time, but the Martha Stewarts of the world still get caught for insider trading. In the case of clinician drug diversion, the big hole that cannot be closed by new regulations is bedside diversion. There are many stories of practitioners—in all levels and across all units in the hospital—swapping patients' medications for saline and look-alike tablets. There are stories of practitioners injecting

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[433] *E.g.*, *id.*

[434] *E.g.*, *id.*

[435] Drug diversion teams can work with existing state boards of nursing and medicine or they can develop their own program.

themselves with their patients' drugs, reusing the needle, and spreading Hepatitis C to their patients.[436]

Unfortunately, no amount of regulation can truly eliminate this kind of criminal behavior. The kind of person who is so deep into their addiction that they would inject themselves with their patient's drugs, refill the syringe with saline, and then reuse the needle on their patient—depriving them of necessary pain medication and increasing risk of spreading disease—is not someone who is going to be deterred by a few new rules. Instead, it is crucial to maintain focus on what can be changed. This Article advocates an acknowledgement that regulatory changes are an incomplete solution and focus on the incremental improvement they can provide.

Most clinicians do not begin diverting by injecting themselves with their patients' medication.[437] Instead it usually starts with a legally prescribed opioids to treat pain related to an injury.[438] The clinician then becomes addicted to the medication.[439] When the prescription runs out, they begin diverting small amounts from the hospital.[440] If unidentified, the amounts can escalate to the bedside diversion.[441] The proposed regulations are aimed at identifying and preventing diversion in its early stages. They provide a solid foundation for continuing to limit the ways in which a practitioner can divert, helping to stop the

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[436] *See generally* Lovering, *supra* note 80.

[437] Rebecca Tyrell & Polyak, *'It Was A Living Nightmare': One Nurse's Struggle with Addiction and Her Road to Recovery*, ADVISORY BOARD (Jun. 4, 2019) (providing an example of a typical nurse's road to addiction).

[438] *Id.*

[439] *Id.*

[440] *Id.*

[441] *Id.*

escalation of diversion and providing a signal that the healthcare community will no longer overlook this kind of behavior.

Beyond bedside diversion, increased regulation of nursing practice is likely to draw complaints of overregulation. Diversion by nursing staff is a well-known issue, but not an area where there have been any meaningful preventive strategies on a state or federal level; hospitals have been merely reactive, often waiting until they have a bad outcome or federal investigation.[442] While these new restrictions represent significant barriers in nursing workflow, the severity of the crisis warrants increased regulation. Healthcare is notoriously slow to move and resistant to change—particularly with anything that comes close to "cookbook medicine." Changes like this, however, are evidence-based and have the potential to meaningfully reduce drug diversion.[443]

A final layer of concern is that even when the diversion is caught, hospitals have an incentive to keep the diversion quiet lest it draw the eyes of the DEA, CMS, TJC, or another accreditation agency.[444] Large scale investigations and surveys can significantly

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[442] *See* Ambrose & Hacker, *supra* note 84.

[443] *See*, *e.g.*, *Guide: Purpose and Use of CLABSI Tools*, AGENCY FOR HEALTHCARE RES. & QUALITY, https://www.ahrq.gov/hai/clabsi-tools/guide.html (last rev. Mar. 2018) ("When used with the Comprehensive Unit-based Safety Program (CUSP) Toolkit, the tools have nearly eliminated CLABSI [Central Line Associated Blood Stream Infections] in more than 100 participating Michigan intensive care units (ICUs) and have dramatically reduced CLABSI in more than 1,000 hospitals across the country in an AHRQ-funded initiative.").

[444] *See*, *e.g.*, Hixenbaugh & Ornstein, *supra* note 193.

disrupt hospital operations and put hospital licenses in jeopardy.[445] Additionally, guidance regarding reporting requirements is ambiguous at best.[446] Clarification to the federal regulations will help hospital administrators better understand their reporting obligations should encourage increased reporting.[447] This will enable swifter reaction from administrative and enforcement angles.

3. Practical Application of Proposed Regulations to a Travel Nurse Shows How They Can Effectively Curb Drug Diversion

Revisiting the opening hypothetical with Randy the travel nurse helps demonstrate how all the proposed regulations work together. Recall that Randy is a travel nurse who works short ten-week contracts in hospital emergency rooms. He commonly diverts both tablet and IV opiates. Randy's preferred method of diversion is pulling bulk SDVs of Dilaudid on override and keeping excess medication instead of wasting it. He frequently uses the emergency situation excuse, claiming his patient was in too much pain so he couldn't wait for the appropriate process to be completed. Under the new regulatory system and supply changes, Randy would be blocked at multiple points.

First, when he calls in the telephone order, the pharmacist receiving the phone call should be able to determine that he is describing a time-critical situation, as newly defined in 21 C.F.R. § 290.10(2)(i), and instruct him to wait for the prescribing practitioner to put in the order and for pharmacy to profile it. If he does manage to convince the

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[445] *See, e.g.*, *id.*

[446] *See* Ambrose & Hacker, *supra* note 84 (discussing ambiguity of reporting requirements).

[447] *Id.*

pharmacist that it is a true emergency, another layer of proposed regulations kick in.

His new hospital has taken the new regulations very seriously, particularly 42 C.F.R. § 482.23(d)(4)(ii)(B), and accordingly imposed a one-strike policy on any administering practitioner who signs off on wasted medication that they did not personally observe. They have also switched to exclusive use of small dose ampules. Because the bulk SDV is no longer ordered by the hospital, Randy pulls the largest ampule available on override and delivers a portion of the dose to his patient.

When he asks another nurse to sign off on his waste, she refuses to do it without personally witnessing it; she doesn't want to lose her job. This forces him to either actually waste the medication or keep it knowing he will be required to account for the discrepancy within a maximum of one week as newly required by 42 C.F.R. § 482.25(c)(2)(i). Doing this once might be explainable but doing it consistently will no longer be a viable option for him. He cannot explain away multiple overrides per shift over a ten-week contract.

Pharmacy reconciliation processes additionally quickly identify that Randy was "dropping" an abnormal amount of tablet OxyContin. He claimed he was just clumsy, but after an initial inquiry, this is no longer be a viable excuse for him. Similar to the IV Dilaudid process, he could no longer claim the medication was appropriately returned to the ADC because no nurse would sign off on something they did not witness.

Truly desperate, Randy goes back to his old faithful, and starts calling in multiple medication orders for patients who don't need pain medication, banking on the ER physician being busy and blindly signing off on all orders. Almost all of his telephone orders are blocked by well-trained pharmacy staff who quickly determine that his requests are time-

critical per 21 C.F.R. §290.10(2)(i) and not emergency situations. The remainder of his medication orders are thoroughly reviewed by the ER physician. Her DEA registration number is tied to every order, so she is not taking any risks. She refuses to sign off and turns Randy in to administration.

Armed with multiple instances of attempted drug diversion, administration calls Randy in to discuss his next steps. He can either be fired and immediately lose his nursing license, or work with the state Board of Nursing Rehabilitation Program to get treatment and keep his license. Randy elects the second option. The drug diversion team then reviews all records related to Randy's diversionary tactics and implements appropriate quality improvement projects as required by 42 C.F.R. § 482.25(c).

Randy's experience demonstrates that the proposed regulatory changes increase visibility of all controlled substances flowing through the hospital and on all the staff who touch them in the process. This increase in accountability is the first step towards shifting behavior and changing the culture of healthcare. It is critical for all staff to see that drug diversion is a continuing priority for the hospital.

The proposed regulations help work towards a hospital culture that is focused on continual improvement, increased accountability, and zero tolerance for illegal behavior that places patients at risk of significant harm. Diversion teams can work to coordinate with state rehabilitation programs to help change the punitive culture. Taken together, the proposed process changes will eliminate multiple opportunities for diversion and will help build a culture of accountability that empowers staff to report any drug diversion they witness.

IV. Conclusion

Clinician drug diversion in hospitals is a frightening issue that draws relatively little attention in the midst of the country-wide opioid epidemic. There are a multitude of opportunities for a savvy clinician to take advantage of existing hospital processes and policies to divert some of the most dangerous controlled substances on the market today.

The best way to prevent drug diversion by clinicians is to implement a two-pronged approach. First, a federally monitored Medication Order Monitoring Program tracking all medication orders for controlled substances should be created. This program will allow easy identification of diversion by over prescription.

Additionally, the Department of Health and Human Services should add a section to the Conditions of Participation (CoP) regarding the preparation and administration of controlled substances, update the regulatory definition of an emergency situation, and add a section to the CoP governing pharmacy review and reconciliation requirements. These proposed regulations include comprehensive guidelines for the entire medication administration process as well as requirements for follow up review and reconciliation processes.

Collectively, these strategies will effectively and efficiently eliminate loopholes clinicians currently exploit to divert controlled substances. They are practical, feasible solutions that can be broadly implemented across all hospitals, regardless of location, size, or financial status. They are a big first step in preventing clinician drug diversion and are crucial to establishing a pervasive culture of accountability and continuous improvement.