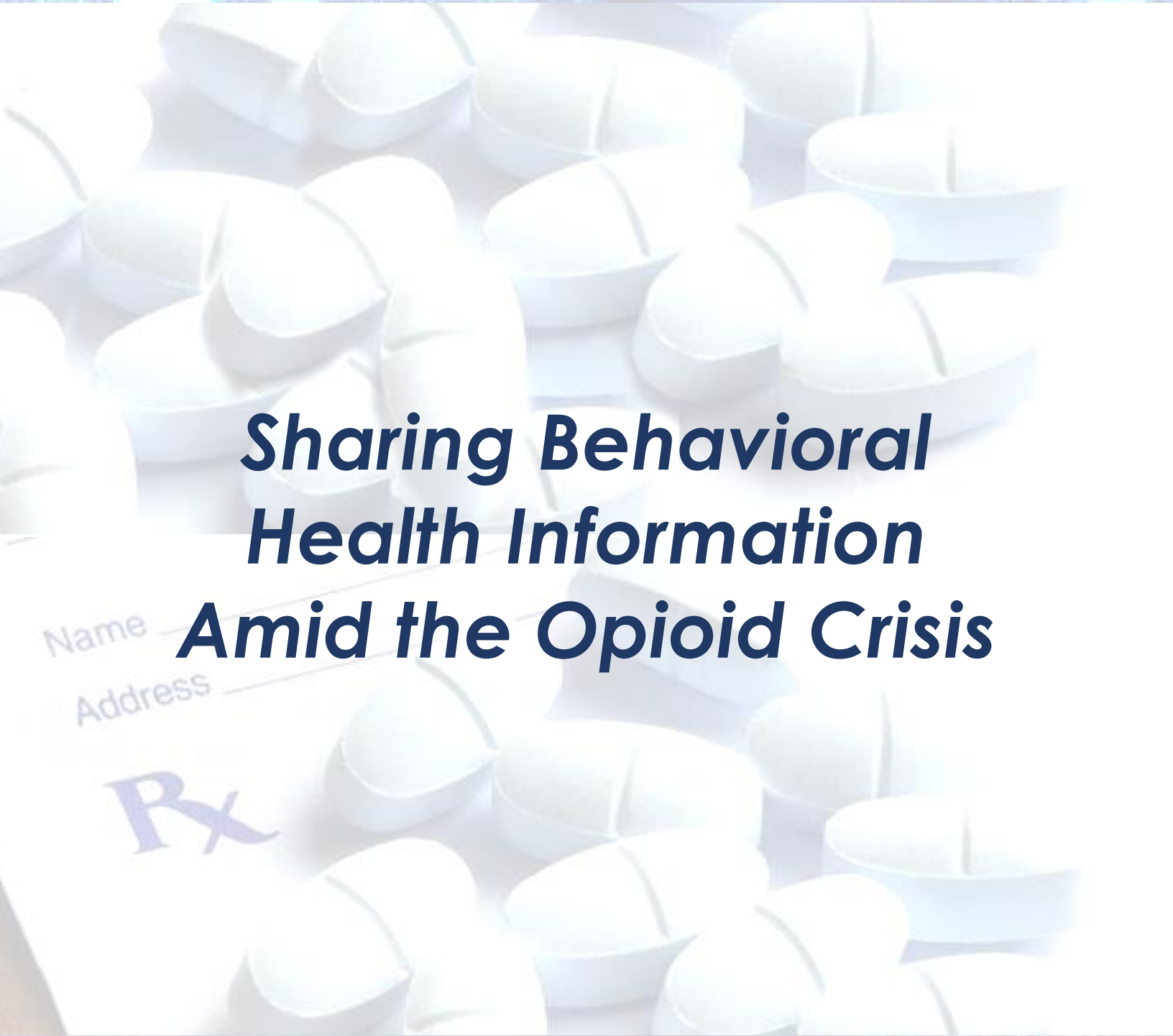
ISSUE BRIEF • JUNE 2018

Sharing Behavioral Health Information Amid the Opioid Crisis



manatt

eHealth Initiative Foundation
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Sharing Behavioral Health Information Amid the Opioid Crisis

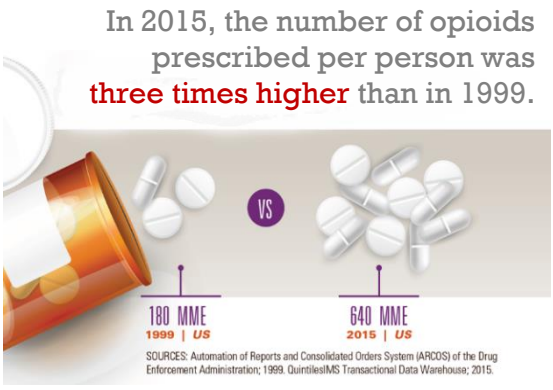
As the old model of patient care silos—where behavioral health providers treat patients separately from the rest of the healthcare system—breaks down, participants from across healthcare are attempting to access patient-specific behavioral health data to create integrated care models. Primary care providers are taking on a greater role in treating those with addictions, as are new players (teletherapy companies), and traditional entities (providers, health plans, pharmaceutical companies). The opioid epidemic has increased the need for behavioral health services and for healthcare stakeholders to seek a more active role in managing behavioral health.

On May 1, eHealth Initiative Foundation and Manatt, Phelps & Phillips hosted an executive advisory board on the role of health information technology in protecting and sharing behavioral health data amid the opioid crisis. The roundtable meeting, *Sharing Behavioral Health Information in Light of the Opioid Epidemic,* explored the role of privacy and security in the context of the crisis. Much of the discussion focused on the impact of policies and regulations that hinder the sharing of sensitive patient data and affects health outcomes. Experts and industry leaders from Walgreens, Surescripts, CRISP, OhioHealth, Senator Shelley Moore Capito's office, and the Substance Abuse and Mental Health Services Administration (SAMHSA) provided information on the policies and technologies that affect the use of behavioral health information in patient care and discussed ways to address challenges.

This brief addresses the role of electronic prescribing of controlled substances (EPCS), regulatory and legislative obstacles, including 42 Code of Federal Regulations Part 2 (42 CFR Part 2), the Health Insurance Portability and Accountability Act (HIPAA), and the Prescription Drug Monitoring Program (PDMP), and aims to provide potential solutions for tackling the opioid crisis.

THE EVOLVING OPIOID EPIDEMIC

In the late 1990s healthcare providers began prescribing opioids at greater rates. Providers were trying to treat chronic pain and pharmaceutical companies were able to allay fears about the addictive nature of the drugs.[1] However, even in low doses, using opioids for more than three months increases the risk of addiction by 15 times.[2] By 2015, the number of opioids prescribed was enough to have every American medicated around the clock for three weeks. By 2016, 116 people were dying every day from opioid-related overdoses, while 11.5 million misused prescription opioids.[3] Widespread misuse of prescription and non-prescription opioids officially reached epidemic levels and a public health emergency was declared in 2017.



The Prescription Problem

Opioids are still being prescribed too frequently, for time periods that are too long, and in doses that are too high. Although the amount of opioids prescribed per person in the U.S. peaked in 2010, and decreased each year through 2015, prescribing had been occurring at an incredibly high rate. The Center for Disease Control (CDC) asserts that prescribing remains too high and varies widely throughout U.S. counties.[4] Opioid doses of

90 morphine milligram equivalents (MME) increase overdose risk ten times, while doses of 50 MME[i] doubles overdose risk. The CDC recommends lower opioid doses, 20 MME or less per day, and prescription lengths of three days or less, as more than seven days of opioid use is rarely needed.[5] By 2016, drug overdose and opioid-involved deaths continued to increase, with 40% of deaths attributed to **prescribed** opioids. The epidemic cuts across race, gender, age, and class stratifications. Overdose deaths have risen among men and women, all races, and adults of nearly all ages.[6]

Surescripts, the nation's largest Health Information Network (HIN), transmits nearly 4.8 million e-prescriptions daily and is connected to virtually all electronic health records (EHRs), pharmacy benefit managers, pharmacies, clinicians, and health plans. According to data presented by Surescripts, 13% of all prescriptions filled in the U.S. are for controlled substances. Prior to 2010, federal law prohibited e-prescribing for controlled substances and many states required special prescription pads and record keeping. Prescription pad forgery remains a concern. The dual work associated with multiple systems is also a reality for providers that are otherwise e-prescribing, but still using paper prescriptions for controlled substances.

Prescription Problem: Potential Solutions

In 2010, the U.S. Drug Enforcement Administration (DEA) revised regulations to allow electronic prescriptions for controlled substances. Providers could legally e-prescribe opioids, at least on the federal level.[7] By 2015, all states adopted this practice. According to Surescripts data from February 2018, nationally, **77% of medications were e-prescribed but only 21% of prescriptions were for controlled substances. More than 90% of pharmacies are enabled for Electronic Prescribing for Controlled Substances (EPCS), however less than 25% of prescribers were EPCS enabled**. Although EPCS allows for the creation of *one* efficient workflow for all prescriptions, provider concerns still center around workflow impact. For instance, two-factor authentication is one of the requirements for EPCS. Organizations need the financial resources to adopt technology savvy workflow solutions, such as Single Sign On, and the skills for successful implementation. Patients with multiple doctors and pharmacies face an increased risk for fatal overdose and **siloed data does not allow for whole patient care.**

EPCS also allows for the security of electronic records, a reduction in fraud and abuse, and an improvement in patient safety and care.[8] Some states are looking to emulate a model that has been working well in New York state. With some exceptions, New York providers were *mandated* to electronically prescribe both controlled and non-controlled substances, beginning on March 27, 2016.[9] Surescripts data demonstrated that 75.7% of the state's prescribers were EPCS enabled, versus the 23.6% national average. EPCS makes it more difficult for patients to 'doctor shop,' which is seeing multiple providers for the same illness or to procure prescription medications. New York saw a drastic reduction in this practice. **EPCS positions pharmacies and providers to better share patient information by tracking the frequency, length of time, and dosages of patients using opioids.**

Regulatory & Legislative Obstacles

The Regulation Problem

The opioid regulation problem is vast and complex. The National Institutes of Health (NIH), The Drug Enforcement Administration (DEA) within the Department of Justice (DOJ); the National Institute of Standards and Technology (NIST) within the Department of Commerce; and agencies within the Department of Health and Human Services (HHS), such as the Center for Disease Control (CDC), Center for Medicare &

[i] Morphine Milligram Equivalents (MME) is a way to calculate the total amount of opioids, accounting for differences in opioid drug type and strength

Medicaid Services (CMS), the Substance Abuse and Mental Health Services Administration (SAMHSA), the Food and Drug Administration (FDA), and the Office of the National Coordinator for Health Information Technology (ONC), are involved with creating policies and guidance on controlled substances and the privacy and security of those with Substance Use Disorder (SUD). **Public health advocates, law enforcement officials, and the technology sector address the opioid epidemic from differing angles and perspectives, however stakeholders remain focused on the significant loss of life opioids are causing in the U.S.**

State-level laws and regulations are compounded by federal laws, regulations, proposed rules, public notices, executive orders, and proclamations and must be reconciled by healthcare organizations and providers. Sharing information across states lines creates additional complexities when laws in certain states require more stringent standards of information sharing than laws in other states. Providers may be reluctant to participate in information exchange when there is uncertainty around which state's laws should be followed in a given situation. **Provider confusion and apprehension around regulations does not bolster integrated care models. 42 CFR Part 2, HIPAA, and PDMP are key regulations which guide the manner in which most organizations share behavioral health related data.**

42 CFR Part 2: Confidentiality of Substance Use Disorder Records requires patient consent for most disclosures of information about substance abuse treatment. It also addresses concerns about the potential use of patient SUD information in non-treatment-based settings, such as administrative or criminal hearings, related to the patient. Part 2 was created to ensure that records for patients with SUD who are receiving treatment in the Part 2 program are not more vulnerable than those with SUD who do not seek treatment. *42 CFR Part 2 established in 1975. SAMHSA made substantive revisions in 2017 and 2018.*[10,11]

Health Insurance Portability and Accountability Act (HIPAA) is the United States' primary health privacy and security law. It is designed to provide privacy standards that protect patients' medical records and health information provided to health plans, doctors, hospitals and other healthcare providers. The HIPAA Privacy Rule addresses the use and disclosure of individuals' "protected health information" by "covered entities," and provides standards for individuals to understand their privacy rights, while being able to control the use of their health information. *HIPAA established in 1996.*[12]

Prescription drug monitoring programs (PDMP) are electronic databases that track controlled substance prescriptions in each state. PDMPs can provide health authorities information about prescribing and patient behaviors to facilitate nimble and targeted responses to the opioid crisis. *The establishment of PDMP varies by state. Continuous PDMP began in 1939, with paper records. New York had a program as early as 1918.*[13]

Recently ONC, in collaboration with SAMHSA, released two new fact sheets to assist the healthcare industry with implementation of Part 2.[14] Additionally, HHS provides guidance on responding to the opioid crisis from a HIPAA lens[15]. The DEA provided clarification on EPCS, which centers on the technological nuances of implementation and relies on NIST recommendations,[16,17] and NIST has a guide for implementing HIPAA's Security Rule.[18] **Despite attempts to clarify regulations, many providers remain confused. Misinterpretation of regulations between entities and individuals continues to hinder behavioral health data sharing.**

Industry Perspectives on Regulations

A Program Director at CRISP, a regional health information exchange (HIE) serving the state of Maryland, shared challenges faced when trying to engage behavioral health organizations. HIEs have specific regulations around Part 2.[19] CRISP's Encounter Notification Services (ENS) would allow behavioral health organizations to know if their patients were using facilities connected to the CRISP network, but Part 2 makes it difficult to decide who can receive data. Navigating the legality of receiving patient lists is even challenging for HIEs, and these lists are a requirement for using HIE services. There is a delicate balance for both HIEs and behavioral health organizations between sharing appropriate patient data and inappropriate disclosures.

A Senior Manager of Pharmacy Technical Standards, Development and Policy at Walgreens asserts that more actionable, current, and "real-time" PDMP data would be helpful in clinical decision-making. PDMP was initially adopted as a law enforcement tool and has transitioned to a clinical decision-making tool. Both providers and pharmacies contribute to state systems. However, reporting represents a challenge, especially for entities that deal with multiple states. There is no standardization in the way PDMP information is entered or viewed across the states. The Chief Information Security Officer Vice President at OhioHealth is working on the technology aspect of an initiative to combat stigma related to behavioral health. OhioHealth's tool helps primary care providers identify those at risk for SUD and the organization has implemented data sharing strategies, within their network, to remain compliant with Part 2, HIPAA, and PDMP.

Federal & Legislative Perspectives

SAMHSA's **5-point strategy to combat the opioid epidemic is focused on the areas of access, data, pain, overdoses, and research**.[20,21] According to Steve Daviss, MD, Senior Medical Advisor at SAMSHA, the categories were derived from the comments the agency received on the topic and should align with HIPAA regulations. Their goal is to provide better addiction prevention, treatment, and recovery services; better data; better pain management; better targeting of drugs that reverse overdose; and better research.

West Virginia Senator Shelley Moore Capito has been a key figure promoting state and federal legislation related to opioids, specifically "Jessie's Law," which aimed to flag patient records with addiction history and align Part 2 with HIPAA rules. Each year, West Virginia's drug overdose rates continue to set national records. The two senators from West Virginia, Sen. Capito and Sen. Joe Manchin, along with Michigan Representatives Tim Walberg and John Dingell, introduced Jessie's Law, a bi-partisan bill named after Jessica Grubb, the daughter of a former state senator and a recovering heroin addict. Originally from West Virginia, and living in Michigan, Grubb needed surgery for a running injury. She disclosed her status as a recovering addict during the hospitalization but was discharged with a prescription for 50 oxycodone. Authorities believe the fatal overdose Grubb suffered, one day after leaving the hospital, was caused by her liquefying the pills and placing them in her IV port.[22]

Multiple versions of Jessie's Law were introduced in the House and Senate during both the 114th Congress (which began in January 2015) and the 115th Congress (which ends January 2019). Some versions of the bills introduced were similar to other proposed legislation, such as the Overdose Prevention and Patient Safety (OPPS) Act.[23] An amended version of Jessie's Law, S.581, passed the Senate on August 3, 2017[24] and was reintroduced in the House as HR 5009.[25] This version advanced to the full House Energy and Commerce Committee on April 25, 2018. During this time, S. 2680: Opioid Crisis Response Act of 2018 (OCRA) legislation was also under consideration. It is the result of seven bipartisan hearings on the opioid crisis with the FDA, NIH, CDC, SAMHSA, governors, experts, and families. OCRA contains provisions related to Part 2[26] and several provisions from Jessie's Law are included.

While the need for additional regulation is well-established, roundtable participants acknowledged that the unintended consequences of regulations must also be considered. History has demonstrated the repercussive effects of well-meaning legislative or regulatory activities that were ultimately detrimental. If the chemical compound of fentanyl is regulated, will that prompt a drastic change to the existing compound by those trying to skirt regulations? Will Americans dealing with serious chronic illnesses, such as Sickle Cell Disorder, be able to access the opioids they may need? Will well-meaning legislation cause new barriers to care and other problems? There was general agreement among roundtable participants that lawmakers need to remain particularly mindful about unintended consequences related to opioid regulations.

MOVING FORWARD: POTENTIAL SOLUTIONS

Although the opioid epidemic presents many issues, there are also solutions to consider. Roundtable participants shared their thoughts on practical steps forward when addressing polices, regulations, and technology. Through collaboration, industry, lawmakers, and the various stakeholders involved in the opioid crisis can position themselves to better manage behavioral health.

Standardization **for systems, workflows, PDMP data, data that conveys a patient's substance use status, and enforcement histories for federal and state laws**

- Standardization will make sharing behavioral health data much easier and help address current issues caused by a lack thereof. For instance, data gaps hinder integrated care models. When data is reshared with multiple gaps, the gaps widen as the data continues to be shared, leaving "holes" in the patient record. Standardizing the manner in which records are transmitted will help.
- With increased consolidation among retailers, pharmacies, insurance companies, and hospitals, data sets become larger and harder to navigate. Standardization makes it easier to manage systems of combined data, while addressing issues around information blocking and the number of National Provider Identifier (NPI) numbers assigned to different portions of the same entity.
- Limited interoperability between EHR systems and the inability of EHRs to segregate records that are subject to privacy restrictions can also be mitigated with a level of standardization.
- A lack of standardization in the enforcement of federal and state laws makes it difficult for healthcare stakeholders to determine what types of information exchange may be problematic. When government demonstrates a standard enforcement history, it creates a precedent industry can follow.

Updated and nimble laws **that are flexible enough to keep pace with the changing healthcare industry and technologies, and attempt to protect patients from discrimination and unintended consequences**

- The laws addressed in this brief were written between 1939 and 1996, well before much of today's medical and technological advances occurred. As technology has continued to evolve, sometimes more rapidly than implementation can occur, the healthcare industry has grown tremendously. Lawmakers are trying to catch up and the rapidity of technology requires vigilance, coupled with laws that are flexible enough to keep pace with the constantly changing landscape.
- As laws are created and implemented, protecting patients from drug use history discrimination remains important. The federal Genetic Information Non-Discrimination Act (GINA) protects against genetic discrimination[27] and could provide a modern-day model for lawmakers to consider when thinking through discrimination policies related to drug use.

Transparency and better processes for communication, **which allow patients to understand their consumer rights around privacy and consent for data sharing**

- As one participant stated, the manner in which privacy and consent are addressed matters. Informing a patient that their consent to share health data will help in combatting the opioid epidemic and in formulating the patient's individual care plan yields a different result than asking for consent without providing adequate context for data sharing with multiple stakeholders. In order to make informed decisions about data sharing, patients need to understand their rights. Patients voluntarily deciding to share their information allows for greater exchange of records between behavioral health doctors and other providers.
- Other consent policies should also be considered, such as a standard opt-in process that requires patients to specifically opt-out of data sharing.

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