Protecting Sensitive Patient Information in a New Information Era: Progress and Best Practices

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Introduction

Stakeholders increasingly recognize the role of integrated care in delivering high value healthcare services. Poorly integrated or uncoordinated care across healthcare systems can adversely impact patients' health because of missed opportunities for prevention, early treatment, or avoidable health consequences.

Coordinated care for individuals with substance use disorder (SUD) is especially critical as they are at high risk for developing one or more chronic conditions, such as cardiovascular disease, stroke, certain cancers, viral hepatitis, and HIV/AIDS.[1,2,3] For SUD patients, uncoordinated care could result in severe or even fatal consequences. One prominent example is Jessie Grubb, a recovering heroin addict, who died from an opioid overdose following a hip surgery. Although Jessie's family notified the hospital staff of her SUD history, the message never reached her discharging doctor who prescribed her oxycodone and sent her home.[4]

Jessie's story, along with others, has captured federal and state policymakers' attention around the need to balance patient data sharing and confidentiality. Multiple federal laws exist to protect patient information. Recently, federal regulators have sought to align federal laws with modern needs and encourage mechanisms for data sharing in a new information era, while Congress considers potential improvements to existing laws. However, some stakeholders have requested additional changes to balance patient protections with appropriate access to SUD patient data to help identify at-risk patients and manage care more effectively.

Evolving health information technology makes it possible for providers to better coordinate care, with a focus on treating the "whole person," including a person's physical and mental health as well as social support needs. In particular, health information exchanges (HIEs) integrate care by giving providers access to patient information from various electronic health record (EHR) systems within the state where the patient receives care. Through this electronic system, HIEs can be used to improve quality of care and reduce costs, for example, by lowering hospitalizations and duplicate tests.[5]

Many states have their own confidentiality-related laws, including with respect to how patient information is used and disclosed in a HIE. Through the Center for Integrated Health Solutions,[6]

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[1] Substance use disorder (SUD) is a condition in which recurrent use of substances, such as alcohol and drugs, cause a clinically significant impairment or distress.

[2] SAMHSA. Common Comorbidities. Accessed November 20, 2017. Available at: https://www.samhsa.gov/medication-assisted-treatment/treatment/common-comorbidities

[3] SAMHSA. Behavioral Health Trends in the United States: Results from the 2014 National Survey on Drug Use and Health. Available at: https://www.samhsa.gov/data/sites/default/files/NSDUH-FRR1-2014/NSDUH-FRR1-2014.pdf

[4] David Gutman, "Jessie Grubb, whose addiction story affected Obama, dies." Charleston Gazette-Mail (Mar. 5, 2016), https://www.wvgazettemail.com/news/jessie-grubb-whose-addiction-story-affected-obama-dies/article_dc307c91-e8f5-50fe-a3b7-161e3ca7bd36.html.

[5] Jung, Hye-Young et al. Use of Health Information Exchange and Repeat Imaging Costs. December 2015. Journal of the American College of Radiology, Volume 12 , Issue 12 , 1364 – 1370.; Lammers, Eric J., Julia Adler-Milstein, and Keith E. Kocher. 2014. Does health information exchange reduce redundant imaging? evidence from emergency departments. Medical Care 52 (3): 227-34.

[6] The SAMHSA-HRSA Center for Integrated Health Solutions supports integration of primary care and behavioral health services to address the needs of individuals with mental health and substance use disorders through training, technical assistance, and grant funding.

five states (Rhode Island, Kentucky, Maine, Oklahoma, and Illinois) have taken the initiative to identify technology barriers and policy solutions for the inclusion of behavioral health information within state HIEs since 2012. Several other states have also begun to share mental health information through state HIEs. However, due to federal requirements, sharing SUD information still presents challenges.

This white paper provides an overview of federal laws to protect SUD patient data, shares lessons learned from Rhode Island's HIE, and evaluates key factors for consideration as efforts to coordinate care continue.

Policy Background

Origin and Evolution of Part 2

Congress has long recognized that SUD patients' personal health information is especially sensitive, as a breach of privacy can adversely affect these patients' health, employment, and social relationships. In 1970, Congress passed the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act (CAAAPTRA).[7] This Act provided funding to establish federal programs to assist in the prevention and treatment of SUDs and specifically noted concerns around the confidentiality of SUD records.[8] Congress subsequently made amendments in 1974, mainly for purposes for extending program funding.[9] In addition, the amendments included a provision requiring written patient consent for disclosure of SUD records in a federally assisted program.[10]

Based on this legislation, in 1975, the Substance Abuse and Mental Health Services Administration (SAMHSA) first promulgated 42 C.F.R. Part 2 (hereafter "Part 2"), which limits the permitted disclosure or use of information about individuals in federally assisted alcohol or drug abuse treatment programs ("Part 2 programs").[11] Figure 1 shows the timeline of the evolution of Part 2 rule.

SAMHSA made substantive updates to Part 2 in 1987. Following those updates, significant changes in the healthcare system and technology occurred, including the emergence of integrated care models, the development of electronic health records (EHRs), and a new focus on value-based care. In light of these developments, SAMHSA implemented various programs to encourage the use of health information technology for SUD information by providers in HIEs.[12] Despite these efforts, many stakeholders considered the 1987 iteration of the Part 2 rule

[7] Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970, Pub. L. No. 91-616, 84 Stat. 1848, 1853 (1970) (codified as amended at 42 U.S.C. § 290dd-2).
[8] *Id*. at § 331, 84 Stat. at 1853.
[9] Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act Amendments of 1974, Pub. L. No. 93-282, 88 Stat. 125 (1974) (codified as amended at 42 U.S.C. § 290dd-2).
[10] *Id*. at § 333(b), 88 Stat. at 87.
[11] 42 C.F.R. § 2.12(a) (2017).
[12] For example, SAMHSA implemented a one-year pilot project with five state HIEs that provided training and technical assistance on integrating mental health and SUD information, as well as the Data Segmentation for Privacy initiative that convened federal and private industry groups to develop patient data sharing standards.

to pose a barrier to the integration of SUD treatment and physical healthcare. In particular, stakeholders expressed concern about data sharing and information exchange for patients who seek care in multiple settings.[13] SAMHSA made additional updates to Part 2 in 2017, discussed further below.

In 1996, Congress passed related, but much broader, legislation, the Health Insurance Portability and Accountability Act (HIPAA), addressing how to protect individually identifiable health information and set minimum federal standards for patient confidentiality. Despite passage of HIPAA and concerns around the 1987 Part 2 rule, SAMHSA left the Part 2 rule unchanged until 2017. In 2017, SAMHSA promulgated substantive revisions[14] to Part 2 and proposed additional clarification in a supplemental proposed rule.[15,16] These revisions included changes or clarification around patient consent requirements, re-disclosure (i.e., disclosing the same patient information two or more times), and the security of electronic records, among others.

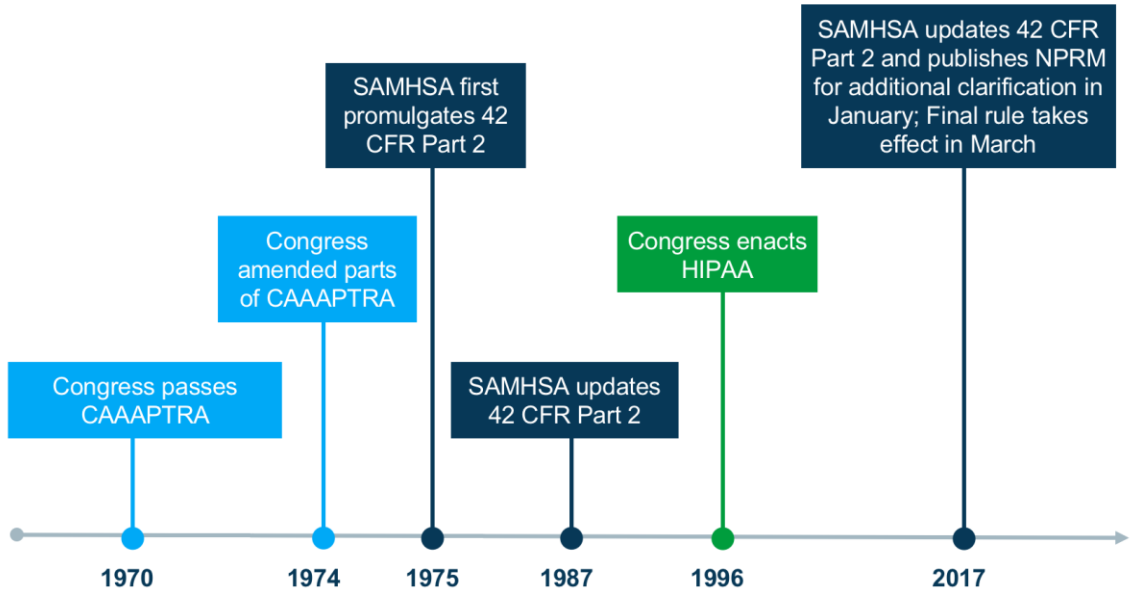
Avalere reviewed published comments on the 2017 Part 2 rule revisions. The revisions have been met with some stakeholder opposition. Opponents' main concern is that the rule inhibits facilitation of patient data exchange, due to previous and newly created barriers that impede information sharing.[17] Overall, commenters asserted that the final rule does not go far enough to align HIPAA and Part 2. However, some stakeholders appreciated the rule's additional clarity for states regarding HIEs.

A Rhode Island official emphasized that the latest updates to the Part 2 rule provides a clearer framework for states to pursue and improve HIEs as well as detailed guidance for protecting Part 2 data in the process.

In addition, SAMHSA acknowledged as part of the rulemaking that many HIEs are experiencing technical barriers related to SUD data. In general, SAMHSA shared that it will continue to work with partners, like the Office of the National Coordinator, to develop consent management support and data standards for states.[18,19]

[13] 82 Fed. Reg. 6,052, 6,055 (Jan. 18, 2017).
[14] *Id.*
[15] In the supplemental proposed rule, SAMHSA proposes additional clarification to the Part 2 regulations as amended by the final rule, particularly around the disclosure of patient Part 2 data to third-parties that assist with administrative or legal tasks related to healthcare operations (e.g., payment for services).
[16] The final Part 2 rule went into effect on March 21, 2017. The regulations were initially scheduled to go into effect 30 days after publication, but the effective date was delayed until March 21 to give the Administration additional time for review. Additionally, SAMHSA issued a Supplemental Proposed Rule to gather comments on areas that require more clarifications and revisions until February 17, 2017.
[17] 42 C.F.R. § 5.2 (2017).

Figure 1: Historical Timeline of Federal Actions Related to 42 CFR Part 2



The Relationship Between HIPAA and Part 2

The Privacy Rule, promulgated under HIPAA,[20] governs the use and disclosure of protected health information[21] (PHI) by "covered entities," which include health plans, healthcare clearinghouses, and providers that transmit health information in electronic form relating to a covered transaction.[22] In general, covered entities may not use or disclose PHI, unless permitted or required.[23] Furthermore, if a covered entity engages a business associate to assist with healthcare-related functions, the business associate must also comply with HIPAA requirements.[24]

Part 2 works in tandem with HIPAA, but governs a narrower set of patient information. Part 2 diverges from HIPAA in a few notable ways, as shown in Figure 2. Part 2 generally requires patient consent, subject to specific elements in the regulations, for disclosure.[25,26] Part 2 also includes additional protections that prohibit re-disclosure after an original disclosure, meaning that patient information that has already been disclosed receives the same protections if it is disclosed again.[27]

[20] 42 U.S.C. § 1320d (2016).
[21] 45 C.F.R. § 160.103 (2017).
[22] § 160.102.
[23] Covered entities may use or disclose PHI for other purposes, if they fulfill detailed regulatory requirements for authorization. § 164.508(c). Covered entities may use or disclose PHI without written patient authorization for purposes related to treatment, payment, and healthcare operations. § 164.506(a).
[24] 45 C.F.R. §§ 164.502(a)(1)-(4) (2017).
[25] 42 C.F.R. § 2.31(a) (2017).
[26] In limited circumstances, such as medical emergencies, patient consent is not required. *See* § 2.51(a) (excepting medical emergencies); § 2.52(a) (excepting scientific research); § 2.53(a) (excepting audits and evaluations).
[27] § 2.32(a).

Figure 2: Comparison Table Between HIPAA and Updated Part 2 Rule

	HIPAA	42 CFR Part 2 (2017)
Applicability	Applies to covered entities and business associates[28]	Applies more narrowly to federally assisted drug abuse programs[29]
Confidentiality Restrictions	Permits business associates to use and disclose PHI, subject to an agreement with a covered entity[30]	Permits communications between a Part 2 program and a qualified service organization (QSO)[31]
Consent Requirements	Merely permits, but does not require, patient consent for disclosure to covered entities or business associates[32]	Includes specific requirements for disclosure or use of information to Part 2 programs or QSOs[33]
Re-Disclosure	Authorization must include a statement to explain that the information may be subject to re-disclosure[34]	Prohibits re-disclosure of patient SUD records, unless there is a written consent which explicitly permits the disclosure[35]

[28] 45 C.F.R. §§ 164.502(a)(1)-(4) (2017).
[29] 42 C.F.R. § 2.12(a)(ii) (2017).
[30] 45 C.F.R. § 164.502(a)(3) (2017).
[31] 42 C.F.R. § 2.12(c)(4) (2017); *see* § 2.11 (defining a "qualified service organization" as "an individual or entity who provides services to a part 2 program, such as data processing, bill collecting, dosage preparation, laboratory analyses, or legal, accounting, population health management, medical staffing, or other professional services, or services to prevent or treat child abuse or neglect, including training on nutrition and child care and individual and group therapy" and "has entered into a written agreement with a part 2 program", subject to specific requirements in that section). Note that the Rhode Island Health Information Exchange Act of 2008 makes no reference to QSOs and its patient opt-in consent options suggest that QSOs would not be included in the consent process.
[32] 45 C.F.R. § 164.506(a) (2017).
[33] 42 C.F.R. § 2.31(a) (2017).
[34] 45 C.F.R. § 164.508(c)(vi)(2)(iii)(2017.
[35] 42 C.F.R. § 2.32(a) (2017).

CASE STUDY: RHODE ISLAND'S HIE, CURRENTCARE

Many states have their own confidentiality-related laws that govern how patient information is used and disclosed in a HIE. However, federal requirements still present challenges for states with respect to SUD information sharing. As a state that has been able to overcome some of these challenges, Avalere evaluated Rhode Island's HIE, CurrentCare, as a case study for addressing consent management and data segmentation for SUD patient information.

Avalere conducted interviews with 2 federal- and 3 state-level experts involved in either the updates to Part 2 or the implementation and operationalization of Part 2 requirements within a state HIE. Interviewees included current and former officials at SAMHSA, Rhode Island's CurrentCare, and New York's HIE, Statewide Health Information Network for New York (SHIN-NY). The interviewees represented a mix of federal and state perspectives on the successes and challenges related to Part 2 in the context of HIEs.

Background: Coordinated Health Information Sharing

HIEs can play an important role in facilitating integrated care through coordinated information sharing among diverse providers and treatment settings. To establish safeguards and confidentiality protections for CurrentCare, Rhode Island passed The Rhode Island Health Information Exchange Act of 2008[36] (the "Act"). The Act mandates that confidential healthcare information may only be accessed from the statewide HIE with an authorization form signed by the patient participant or the patient's authorized representative.[37] Since the passage of the Act, Rhode Island has used CurrentCare to aggregate fragmented health data in an information hub, with the goal of enhancing care coordination.[38]

[36] The Rhode Island Health Information Exchange Act of 2008. Available at http://webserver.rilin.state.ri.us/billtext08/senatetext08/s2679aaa.htm.
[37] *Id*.
[38] Rhode Island Quality Institute. Rhode Island Health Information Exchange Strategic and Operational Plans. http://www.riqi.org/matriarch/documents/ri_hie_strategic_and_operational_plan_2010.pdf. September 24, 2010. Accessed October 23, 2017.

As a centralized platform for patient information, CurrentCare can enable providers to better coordinate and integrate care based on patient's physical and behavioral health conditions, particularly through the inclusion of its separate Part 2 tab in the CurrentCare Viewer, as discussed below. Providers also get a sense of related services that a patient might need to support the treatment of these conditions (e.g., social services). Rhode Island's HIE design is unique in that it enables care coordination and integration for patients, especially at-risk patients with SUD, through its broad patient consent model that enables patients to allow all providers access to their health information when needed.

In a survey, nearly all (95%) respondents indicated that they believe there is value in giving their providers access to more complete medical information through a service like CurrentCare. Additionally, almost all (95%) respondents believe that a service like CurrentCare provides benefits to their overall health.

Source: CurrentCare. CurrentCare by the Numbers. CurrentCare Website.

The Rhode Island Quality Institute (RIQI), a state-designated regional health information organization, operates CurrentCare. Through RIQI, CurrentCare provides a variety of data services for both providers and patients, including[39]:

CurrentCare Alerts	CurrentCare Viewer	Statewide Provider Directory	CurrentCare For Me
Notifies providers in real-time about patient hospital encounters	Enables providers to view patient data through a patient-specific "dashboard," which can assist in reporting quality and cost metrics	Serves as the single source to gather provider information for users	Allows consumers to access and manage their data in a portal

[39] CurrentCare Website. CurrentCare Services. http://www.currentcareri.org/HealthcareProviders/CurrentCareServices.aspx. Accessed November 8, 2017.

The Relationship of CurrentCare to Part 2

As with any HIE, CurrentCare must navigate federal and state privacy laws pertaining to patient information sharing. Rhode Island's Act aims to broaden access to patient information, while also preserving patient confidentiality protections, including those required by HIPAA and Part 2. Of note, the following unique characteristics of CurrentCare facilitate more seamless care coordination and integration for SUD patients:

CurrentCare uses a patient opt-in model to enable protection of Part 2 data.

Rhode Island requires patients to opt-in to both HIE participation and disclosure. First, patients must consent to enrollment in the HIE, then the patient must choose from three consent options related to use or disclosure of sensitive information: (1) authorize access by all physicians, including in emergency situations (broad consent); (2) authorize access only in emergency situations; or (3) authorize access only for certain physicians and emergency situations, which the patient may designate.[40,41]

Because CurrentCare uses an opt-in approach, enrollment is limited to patients who make the affirmative choice to participate. Today, 9 of 48 states and the District of Columbia with HIEs apply some form of an opt-in policy.[42,43] According to the interviews, states with similar opt-in policies report approximately half of potential enrollment in their respective HIEs, which suggests that an opt-in approach may limit an HIE's overall impact. To this end, some stakeholders in Rhode Island have advocated for a transition to an opt-out policy, but the state has not made any formal changes in response to these concerns.

CurrentCare's technical architecture incorporates additional steps to provide for federally-required protection of Part 2 information.

In addition to opting in to CurrentCare, a patient must sign a separate consent form at the facility level to enable a Part 2 facility as a data sharing partner to send Part 2 data to CurrentCare for a duration of one year. This step serves as an additional measure of protection for patient information, while providing for compliance with federal requirements.

However, the one-year expiration[44] for the consent can present an administrative burden for facilities. Currently, CurrentCare's data sharing partners (e.g., Part 2 facilities) must reactivate a patient's consent before the previous one expires to avoid disruptions in data sharing and needed treatment. Based on interviews, Rhode Island is considering changes to the one-year timeframe, so that patient consent lasts for as long as the patient is a participant in CurrentCare.

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[40] R.I. Gen. Laws § 5-37.7-4 (2017).
[41] 14 000-038 R.I. Code R. § 4.4(a)(4) (LexisNexis 2017).
[42] Clinovations. State HIE Consent Policies: Opt-In or Opt-Out. September 2016. https://www.healthit.gov/sites/default/files/State%20HIE%20Opt-In%20vs%20Opt-Out%20Policy%20Research_09-30-16_Final.pdf
[43] George Washington University's Hirsh Health Law and Policy Program and the Robert Wood Johnson Foundation. The Status of Health Information Exchanges: 50 State Comparison. 2013. http://www.healthinfolaw.org/comparative-analysis/status-health-information-exchanges-50-state-comparison
[44] In addition to the general opt-in consent form for participation in CurrentCare, a patient must also sign a separate consent form at the facility level to enable a Part 2 facility to send Part 2 data to CurrentCare for one year. After one year, the patient's consent must be reauthorized through a new form.

Part 2 data is segregated from other medical information, so providers can only see the Part 2 data if the patient has SUD information and signs the consent form.

CurrentCare segregates Part 2 information from other data in a separate tab in the system's infrastructure, which providers must confirm their need to access for treatment purposes before being granted access to the information. A provider must also acknowledge that he or she understands the Part 2 prohibition against re-disclosure. This infrastructure helps to further protect patient information from potential misuse.

CurrentCare permits disclosure of confidential health information without consent under a wider set of circumstances than Part 2.

Like Part 2, CurrentCare also permits disclosure without consent for purposes of treatment in a medical emergency.[45] Unlike Part 2, however, CurrentCare also permits disclosure without consent for situations related to control of public health hazards, certification and licensure of health professionals and facilities[46], as well as exceptions for RHIO[47,48] and a health plan[49]. Consequently, CurrentCare also allows for more seamless public health response, provider compliance and accreditation, and patient information sharing within communities of care and payer operations.

Key Considerations from CurrentCare

Overall, interviewees shared an appreciation for Rhode Island's broad consent model, which enables patients to authorize consent to a wide network of providers within a community and allows providers access to patients' information as needed. Specifically, experts interviewed emphasized the importance of a broad consent model as treatment for SUD and other mental health conditions becomes increasingly available in a primary care setting, and noted that providers would benefit from broader access to both primary and behavioral healthcare information. Once linked to a patient's primary care information, these data could be used to inform the development of quality measures related to physical and behavioral health interactions; such measures are currently sparse.

However, accessing a patient's Part 2 information for comprehensive treatment remains restrictive, even in state HIEs that use a relatively broad consent model. Broad consent models can limit access to providers within a certain network, restricting other essential care providers' ability to serve patients. Overall, broad consent models can be effective in smaller states, but larger states with more complex health systems and agencies to navigate may also consider using qualified entities to open provider access to Part 2 information, given its relevance to a patient's treatment, across a healthcare system.

Despite its challenges, Rhode Island's HIE experience offers valuable considerations for other states looking to establish or refine an existing HIE that satisfies both HIPAA and Part 2

[45] 42 C.F.R. § 2.51(a) (2017); R.I. Gen. Laws § 5-37.7-7(b)(1) (2017). As noted above, Part 2 also permits disclosure without consent for purposes of conducting scientific research and performing audits and evaluations. 42 C.F.R. § 2.52(a) (2017); § 2.53(a).
[46] R.I. Gen. Laws § 5-37.7-7(b)(2) (2017).
[47] A group of organizations within a specific area that share healthcare-related information electronically.
[48] R.I. Gen. Laws § 5-37.7-7(b)(3).
[49] § 5-37.7-7(b)(4).

requirements and better integrates care, especially for vulnerable patient populations like those with SUD. CurrentCare's unique characteristics are a result of Rhode Island's initiative to ensure the protection of SUD information. According to interviewees, CurrentCare's design addresses its state-specific needs, while also providing a way for its system to protect SUD information as required under Part 2. While Rhode Island continues to consider changes to further refine its approach, CurrentCare's current attributes promote coordinated and integrated care for SUD patients enrolled in the HIE.

Conclusion

Recent Part 2 updates (as of January 3, 2018) reflect stakeholders' desire to strike a balance between information sharing to enhance care coordination and maintaining privacy protections. In particular, patients using both physical and behavioral health services have a unique need for integrated care, which benefit from coordinated information sharing. In some cases, HIEs play a role in facilitating care coordination among diverse treatment settings, as well as improving patient experience and treatment outcomes. To take full advantage of the benefits of HIEs, state and federal policymakers may evaluate future policies based on the need to protect PHI and establish appropriate levels of consent for use or disclosure, without unnecessarily inhibiting reasonable uses. Federal regulators may consider regulatory or subregulatory avenues for further harmonizing core areas of difference between HIPAA and Part 2.

More broadly, in a SAMHSA-HRSA report on behavioral health information sharing in state HIEs, stakeholders suggested that states work with SAMHSA to establish a national standard and "safe harbor" regulations related to sensitive patient information generally, which encompass the spectrum of related state laws and acknowledge state best practices in the federal guidance.[50] For example, federal policymakers and regulators may consider encouraging greater use of opt-out policies to better facilitate the use of HIEs, while also leveraging the benefits of other existing state approaches. In general, stakeholders indicated the importance of federal and state policymakers seeking broad input early and often regarding HIE-related standards and potential improvements.

Looking Ahead

In response to recent changes to Part 2, Congress has taken actions to align Part 2 with HIPAA. In July 2017, Representative Tim Murphy (R-PA) introduced the Overdose Prevention and Patient Safety Act (H.R.3545), and in September 2017, Senator Joe Manchin (D-WV) introduced the Protecting Jessica Grubb's Legacy Act (S.1850). Both bills propose to amend the current Part 2 rule by adding an exception to permit disclosure of SUD patient information for treatment, payment, and operational purposes. The latter bill would also permit the disclosure of SUD records to qualified personnel for scientific research, audit, and program evaluation purposes, regardless of the patient's written consent.

[50] SAMHSA-HRSA. The Current State of Sharing Behavioral Health Information in Health Information Exchanges. September 2014. https://www.integration.samhsa.gov/operations-administration/HIE_paper_FINAL.pdf

At an expert roundtable discussion held by the Medicaid and CHIP Payment and Access Commission (MACPAC) in January 2018, stakeholders also discussed the need to address various challenges with Part 2, many of which are discussed earlier in this paper. Overall, stakeholders cited the need for further alignment between Part 2 with HIPAA and additional guidance around who and what are subject to Part 2 provisions (e.g., clarification on who are Part 2 providers, what information should be protected, information to be included in the consent form). Stakeholders also agreed that more education is needed on the importance of data sharing while balancing appropriate consent.

Looking ahead, federal and state policymakers as well as key stakeholders will continue to examine patient information sharing amid the evolution of health information technology and information sharing to drive better coordinated care.

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