

Subcommittee: HIE Policy

Chair: Mr. Justin Palmer

Date: April 18, 2024

Status: Final



District of Columbia Health Information Exchange Policy Board

Recommendation on Operationalizing DC HIE Compliance with the Federal Substance Use Disorder Confidentiality Regulation

I. SUMMARY

The recommendation on *Operationalizing DC HIE Compliance with the Federal Substance Use Disorder (SUD) Confidentiality Regulation* proposes an effective date of January 1, 2025, for the DC HIE to comply with the final rule, issued by the US Department of Health and Human Services in February 2024, that implements a modification to the Confidentiality of Substance Use Disorder Patient Records regulations under 42 CFR Part 2.

These changes are intended to improve care coordination for patients seeking or undergoing SUD treatment, ease patient privacy concerns, and break down barriers to information sharing by easing compliance complexities.

This recommendation also proposes a collaborative, four-phased approach – including outreach and education, updating consent forms and privacy practices, commencing collection of new consents, and culminating with consent and exchange in full effect – to operationalize the DC HIE’s compliance with the new final rule.

II. PROBLEM STATEMENT

Earlier this year, the US Department of Health and Human Services (HHS) released a final rule to implement a modification to the federal substance use disorder (SUD) privacy statute. This final rule more closely aligns the Confidentiality of Substance Use Disorder Patient Records regulations under 42 CFR Part 2 with the regulatory requirements under the Health Insurance Portability and Accountability Act (HIPAA) privacy rule.

This final rule has implications for the HIE, its users, and participating organizations. Each US jurisdiction and affected organizations have two years to comply with the new final rule. The Policy Subcommittee considered whether the Board needs to issue District-specific guidance to this end.

Subcommittee: HIE Policy

Chair: Mr. Justin Palmer

Date: April 18, 2024

Status: Final

III. SUBCOMMITTEE GOAL AND ACTIVITY

This activity can be added under Goal #2 under the subcommittee's workplan – *Review and inform development of policy guidance or other policy recommendations for new HIE initiatives.*

IV. DISCUSSION

In early February 2024, the US HHS released a final rule to implement a modification to the federal SUD privacy statute. This final rule more closely aligns the Confidentiality of Substance Use Disorder Patient Records regulations under 42 CFR Part 2 with the regulatory requirements under the Health Insurance Portability and Accountability Act (HIPAA) privacy rule. These changes are intended to improve care coordination for patients seeking or undergoing SUD treatment, ease patient privacy concerns, and break down barriers to information sharing by easing compliance complexities.

In response to the new final rule, the HIE Policy Subcommittee convened to review: 1) how the regulations may apply to the HIE, to its users, and participating organizations; and 2) whether the Board needs to consider issuing District-specific guidance or not. The Policy Subcommittee met twice following the issuance of the new final rule.

The new final rule leaves in place the requirement that Part 2 programs must obtain patient consent prior to disclosing Part 2 information for purposes of treatment, payment, and health care operations. However, it makes substantial changes to ***how such consent may be obtained*** and ***how information may be re-disclosed***.

The new final rule has implications for: 1) SUD providers, called Part 2 programs; 2) electronic health records (EHR) vendors and Health Information Exchanges (HIEs); 3) recipients of Part 2 information; and 4) patients seeking, undergoing, or have undergone SUD treatment.

HIEs are tasked with the lawful exchange of patient health information and will benefit from streamlined consent provisions in the final rule. The updated rules permit the use of a single form under which a patient can consent to future disclosures of Part 2 information for the purposes of treatment, payment, and health care operations – or TPO – as defined under HIPAA.

Under the final rule, consent forms may:

Subcommittee: HIE Policy

Chair: Mr. Justin Palmer

Date: April 18, 2024

Status: Final

- Use a description of a class of persons who may receive information, rather than requiring the name of every potential recipient on the form who is not a treating provider
- Permit a patient to consent to disclosures of TPO using a single form, with an allowed expiration date of “none.”

Furthermore, the rule limitations on intermediaries will not apply to HIEs or EHR vendors because the rule redefines the term “intermediary” to exclude business associates and covered entities.

The final rule and HHS guidance has given organizations up to two years (April 2026) to operationalize necessary changes and come into compliance.

The Policy Subcommittee discussed the steps that would be necessary for the Designated HIE, CRISP DC, to come into compliance with the new final rule. This was then used to inform the decision to recommend an appropriate compliance and effective date for TPO-based consents and data exchange. The Subcommittee further recommended that any effective date should coincide with the start of the District’s Fiscal Year.

Operationalizing changes to the new rule will require four major phases:

1. Provider and patient outreach and education – Summer 2024
2. Updated privacy practices/consent forms – October 2024
3. Commence collection of new Treatment, Payment, Operations (TPO) consents – November 2024
4. TPO consents effective/TPO-based exchange in full effect – January 1, 2025

V. RECOMMENDATION(S) FOR BOARD ACTION:

The Policy Subcommittee proposes that the DC HIE Policy Board approve January 1, 2025, as the effective date for the DC HIE to comply with the final rule that implements a modification to the Confidentiality of Substance Use Disorder Patient Records regulations under 42 CFR Part 2.

The Policy Subcommittee recommends that the DC HIE take steps to operationalize the four phases of work outlined in this memo to enable compliance with the final rule. This will require collaboration with District agencies, effective engagement of District health system stakeholders, and partnering with on-the-ground teams through the DHCF-funded ARPA HCBS Digital Health Technical Assistance program.

Subcommittee: HIE Policy

Chair: Mr. Justin Palmer

Date: April 18, 2024

Status: Final

The Subcommittee further recommends that DHCF work collaboratively with DBH and agency partners to: 1) align final rule compliance effective dates; and 2) set and communicate aligned expectations for Part 2 providers, the DC HIE, recipients of Part 2 data, and patients.

Committee Members: Mr. Justin Palmer; Dr. James Crowe; Mr. Mark LeVota; Ms. Alice Leiter; Ms. Stephanie Brown; Ms. Adrienne Ellis; Ms. Abby Lutz; Ms. Nichole Sweeney; Mr. Jim Costello; Mr. Luigi Leblanc; Ms. Donna Ramos-Johnson; Ms. Larissa Pardo; Ms. Rachel McLaughlin; Mr. Nathaniel Curry; Ms. Eduarda Koch; Mx. Deniz Soyer.