CONCISE EXPLANATORY STATEMENT

In accordance with the Administrative Procedures Act, R.I. Gen. Laws § 42-35-2.6, the following is a concise explanatory statement:

AGENCY: Rhode Island Department of Health

DIVISION: N/A

RULE IDENTIFIER: 216-RICR-10-10-6

RULE TITLE: Regional Health Information Organization and Health Information Exchange

REASON FOR RULEMAKING: This regulation is being promulgated in accordance with R.I. Gen. Laws Chapter 5-37.7 to change the health information exchange model from an opt-in to an opt-out model.

ANY FINDINGS REQUIRED BY LAW AS A PREEQUISITE TO THE EFFECTIVENESS OF THE RULE: N/A

TESTIMONY AND COMMENTS:

Public comment was received that the six months window for providers to notify patients about disclosure of their health care information in § 6.3.1(A)(3) be eliminated. Based on feedback from providers, the Department feels that eliminating the window entirely is not practicable or feasible for providers newly submitting data to the HIE. The HIE is based on a global (rather than provider-specific) opt-out decision, so individuals will not need to update their consent status if one of their existing providers chooses to participate in the HIE. Provider participants with established data submissions to the HIE are required to notify patients at the time they enter into a treating relationship, i.e., at the first professional encounter; the six-month window does not apply.

Public comment was received that the thirty days for patients to be notified of the ability to opt-out in § 6.3.1(A)(4) be changed to sixty days. The Department agrees and accepts this change.

Public comment was received that the phrase “treatment for domestic violence or sexual assault” be added to § 6.3.2(A)(14) regarding categories of sensitive or protected personal health information. The Department agrees and accepts this change.

Public comment was received that the phrase “education and outreach campaigns regarding the public’s awareness of the HIE and the opt-out policy” be added to § 6.4(F) regarding the RHIO to the annual report to the HIE Advisory Commission. The Department agrees and accepts this change.

Public comment was received that the proposed regulation should allow providers to notify patients of their opt-out rights through providers’ NPPs and Website. The

Department clarifies that the intent of § 6.3.1(A)(3) was to allow notification through any written notice, including Notices of Privacy Practices and online documentation. The section has been edited to ensure clarity.

Public comment was received that the enabling legislation does not delegate RIDOH, the HIE, or RHIO to regulate the manner of notification by a private provider and that such a requirement makes Rhode Island an outlier of other opt-out states. The Department's reading of 5-37.7-7(c) indicates that provider participants are the responsible party for notification. 5-37.7-7(c) states, "Provider participants that share data with the HIE shall notify their patients that data is being shared with the HIE to support the provision of care, and inform their patients about their ability to opt out." It further states specific requirements for that notification, which are reflected in the proposed regulation, as "notification and opt out procedures shall be developed in consultation with the HIE advisory commission and provided in regulations promulgated […]" § 6.3.1(A)(2) was revised to add clarity that the RHIO shall provide materials and technical assistance, but as the responsibility ultimately rests on provider participants by statute, the Department chooses not to require provider participants to use materials developed by the RHIO.

Public comment was received that the proposed regulation should be changed to avoid onerous and burdensome notification processes for emergency access. The comment further states that the requirement is impossible to implement and may run afoul of federal law. The Department believes that emergency access requirements are fully compliant with HIPAA and 42 CFR Part 2. Emergency access procedures have been in place since the establishment of the HIE and would not be altered by the shift to an opt out consent model. Emergency access procedures take place only in the HIE environment and are not typically facilitated through EHR interface, specifically so that no accidental emergency access disclosures occur. As temporary access to HIE records in an emergency is a rare, deliberate, and specific act, the Department does not believe notification to the patient or representative is an undue burden.

Public comment was received that the proposed regulation should be changed to allow additional simple mechanisms and forms by patients to opt-out of HIEs. The comment further states that some healthcare providers already have automated controls within its electronic medical record systems that allow its patients to opt-out from all HIEs, not just the RI RHIO. The comment also states that the enabling statute removed opt-in language to presumably allow patients to freely exercise their rights to opt-out directly with their providers. The Department's reading of 5-37.7-3(p) as follows, "'Opt out' means the ability of a patient to choose to not have their confidential health care information disclosed from the HIE in accordance with 5-37.7-7," indicates that a patient's opt out decision reflects their wishes not to have information *disclosed from* the HIE, and not to opt out of their information *submission* to the HIE. This distinction reflects an opt-out to *disclose* vs. an opt-out to *collect* consent model. The Department considered a variety of methods for collating and recording opt out consent wishes, but

believes centralizing consents with the RHIO is the only practicable way to ensure a global consent (not specific to provider organizations) is implemented uniformly across data sources. As provider participation remains voluntary, there is nothing preventing a provider from choosing not to *submit* individual patients' healthcare information based on a provider organization level consent. However, *opt out to disclose* consent status for the HIE must be recorded, stored, and updated with the RHIO, as it has been throughout the lifetime of the opt-in consent model.

Public comment was received regarding § 6.3.1(A)(2) that it is not clear how and by whom a provider participant would be educated on HIE participation and what the discussion should include. The comment further stated that § 6.3.1(A)(3) does not specify who is responsible for creating a "distinct written document" and requests that it be revised to make the responsible party RHIO to ensure a consistent message. § 6.3.1(A)(2) was revised to add clarity that the RHIO shall provide materials and technical assistance, but as the responsibility ultimately rests on provider participants by statute in 5-37.7-7(c), the Department chooses not to require provider participants to use materials developed by the RHIO.

Public comment was received regarding § 6.3.1(A)(4) regarding notification to patients 30 days before the opt-out goes into effect. The comment further states that such requirement would be a significant undertaking for a practice and that the RHIO should be the responsible party. The Department's reading of 5-37.7-7(c) indicates that provider participants are the responsible party for notification. 5-37.7-7(c) states, "Provider participants that share data with the HIE shall notify their patients that data is being shared with the HIE to support the provision of care, and inform their patients about their ability to opt out." It further states specific requirements for that notification, which are reflected in the proposed regulation. The Department does not have discretion to make the RHIO the responsible party.

Public comment was received requesting the Department withdraw these regulations and instead initiate an advance notice of proposed rulemaking. The Department engaged in extensive outreach and communications with community partners, including in public forums, and believes this satisfies the intent of an advance notice of proposed rulemaking. The enabling statute was signed into law in July 2021 and specifically directed the Department to revise accompanying regulations, which ensured that interested parties involved in the legislative process were aware regulations would be promulgated.

Public comment was received regarding concerns that mental health records are not separated from other medical records. The HIE does not enable any new or additional disclosures of medical records, whether they originate from physical or behavioral healthcare. The HIE facilitates electronic exchange of health information in full compliance with HIPAA, 42 CFR Part 2, and other state and federal requirements. The alternative to use of the HIE is typically faxing, electronic messaging, or a patient distributing paper copies of their records. There is not an alternative that the disclosure

does not occur, including for mental health records. The HIE follows regulation by the Office of the National Coordinator for Health Information Technology substantially similar to regulations for Electronic Health Records, and accordingly has extensive auditing functions to ensure access to records is appropriate and in compliance. This is also specifically required in the regulation at § 6.6.6(A)(1). Access for providers is limited to treatment and care coordination purposes, to state agencies for public health purposes, and to health plans for quality improvement purposes.

Public comment was received expressing that patients may wish to withhold mental health records separate from physical health records. Based on research from other states that have transitioned from an opt-in to an opt-out consent model, the vast majority of patients who wish to opt out prefer a “blanket” consent that prohibits all record-sharing. Very few express a preference for a “granular” consent that allows them to pick and choose data elements and recipients for their records. Given that the technical complexity to implement a granular consent system is immense, the understanding that most patients prefer an all-or-nothing simplified approach, and the reality that many other avenues for record-sharing remain outside of the HIE, the Department did not pursue a granular consent option for mental health.

CHANGES TO THE TEXT OF THE RULE:

§ 6.3.1(A)(2) added the phrase “The RHIO shall provide examples or templates of educational materials and any needed technical assistance to provider participants on patient education about the HIE.”

§ 6.3.1(A)(3) added the phrase “of their opportunity to opt-out” and “whether paper, electronic, or web-based. The notification may be contained within a document detailing other privacy practices, but the HIE shall be specifically discussed. The notification shall include an explanation…”

§ 6.3.1(A)(4) changed thirty days to sixty days.

§ 6.3.2(A)(14) added treatment for domestic violence or sexual assault to list of sensitive information policies.

§ 6.4(F)(5) adds Education and outreach campaigns regarding public awareness of the HIE to list of reports the RHIO makes to the HIE Advisory Committee.

§ 6.51 (A) (2) adds the following wording “and 45 C.F.R. § 164.528” to the end of the the following sentence to now read - to the following sentence – “A charge for a copy of the disclosure report may be imposed if consistent with State law and 45 C.F.R. § 164.528.” It also adds - In accordance with 45 C.F.R. § 164.528 (c)(2), the first disclosure report shall be provided to a patient participant in any twelve (12) month period at no cost to the patient participant.

§ 6.52 (A) (1) adds Confidentiality protections for patient participants in the HIE are also pursuant to R.I. Gen. Laws Chapter 40.1-5-26, 45 C.F.R. § 164.528 and 42 C.F.R. Part

2.

REGULATORY ANALYSIS:

In development of this rule, consideration was given to:

1) Alternative approaches;

2) Overlap or duplication with other statutory and regulatory provisions; and

3) Significant economic impact on small business

No alternative approach, duplication or overlap was identified based on available information. RIDOH has determined that the benefits of the rule justify its costs.