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:

The Department is amending this rule to include the following:

- Introduce flexibility in RHIO processes for reviewing opt-out consent decisions.
- Establish requirements for research and analytics uses of HIE data.
- Amend requirements for membership on the HIE Advisory Committee.

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

TESTIMONY AND COMMENTS:

Due to the substantial volume of comments received related to the sections listed below, RIDOH has decided to only move forward with a subset of changes previously proposed for public comment. Please be informed that the comments received on the sections not addressed in the final regulation will be re-noticed and addressed at a later date as RIDOH plans to propose a new amendment which may include proposed changes to these sections. At that time, the public will be able to comment on the re-noticed proposed rule. For more information, see "Changes to the Text of the Rule" below for a list of the sections that are still being amended.

Sections with comments received but not addressed in this Concise Explanatory Statement due to the reasons noted above:

§ 6.2
§ 6.2(A)(23)
§ 6.2(A)(28)
§ 6.3.1(A)
§ 6.3.1(A)(2)
§ 6.3.1(A)(5)

§ 6.3.1(A)(6)
§ 6.3.1(A)(7)
§ 6.3.1(A)(7)(d)
§ 6.3.2(A)
§ 6.3.2(A)(3)
§ 6.3.2(A)(4)
§ 6.3.2(A)(9)
§ 6.3.2(A)(10)
§ 6.3.2(C)
§ 6.3.2(D)
§ 6.3.3(B)
§ 6.3.3(D)
§ 6.4
§ 6.4(D)
§ 6.4(F)
§ 6.4(G)
§ 6.5
§ 6.5.1(A)(1)
§ 6.5.1(A)(8)
§ 6.5.3
§ 6.5.3(B)
§ 6.5.3(C)
§ 6.5.6
§ 6.6
§§ 6.6.2 – 6.6.7

Note: The above listed sections are given as the section number used in the original proposed regulations. The section numbers used below reflect the section number in the final proposed regulations.

Research and Analytic Uses

Comment Received: Concerns about creating a dual-approval process for data requests involving facilities licensed by BHDDH.
Section involved: § 6.5.6(B)(1)
Response: RIDOH notes that in most cases research should be conducted under legal agreements with the data-submitting partners (DSPs), so this will not apply. In the rare cases that there is research conducted under state authority (i.e., without explicit approval from the DSPs who own that data) that includes BHDDH licensed providers, it is necessary and appropriate to create a dual approval process. See R.I. Gen. Laws § 40.1-1-13(4) which establishes as one of the powers of BHDDH: "Ensure the collection, analysis, and dissemination of information for planning and evaluation of substance abuse services." BHDDH does have a process for external data request reviews and addressing it is beyond the scope of this regulation.

Comment Received: Requiring data requests to demonstrate a near-term benefit is overly restrictive, or "near-term benefit" should be more broadly defined.
Section involved: § 6.5.6(D)
Response: RIDOH disagrees that there should be a broader pathway for state-authorized research uses of HIE data. The HIE was not established under state authority to create a pathway for research; therefore, utilization of state authority for research is deliberately restricted in this regulation to exceptional circumstances that demonstrate near-term benefit. The determination of what constitutes near-term benefit is explicitly left up to the Director of Health in consultation with the HIE Advisory Commission in § 6.5.4(D)(1) of the regulations. As stated, "In all other cases, access or disclosure specifically permitted by legal agreement with the data-submitting partner(s) should be utilized."

Comment Received: State oversight is not appropriate for reviewing outputs regarding internal quality improvement (QI) analyses that rely on HIE data.
Section involved: § 6.5.6(E)(3)
Response: *RIDOH agrees that this was not the intent and added "healthcare operations" to the list of allowable purposes in § 6.5.4(A)(1).*

Comment Received: Expedite review for requests supporting federally or state-funded public health research programs (e.g., IDeA-CTR, ECHO, NIH RADx) that already operate under strict IRB oversight and align with public health priorities.
Section involved: § 6.5.6
Response: RIDOH disagrees with establishing in regulation any preferential handling of requests for use of HIE data under state authority. Although the RHIO may establish such policies and procedures under consultation with the HIE Advisory Commission, it is unnecessary to feature them in regulation.

Comment Received: Clearly identify academic and clinical research institutions as eligible collaborators under state or federal oversight.
Section involved: § 6.5.6
Response: As there is no distinction made in the proposed rule for who is an "eligible" collaborator, there is no need to identify affirmatively eligible institutions.

Comment Received: Standardize the time period in which data requests must be reviewed by RIDOH (e.g., 3 months).
Section involved: § 6.5.6
Response: *RIDOH agrees with this suggestion and has revised the language to specify a period of 3 months.*

Comment Received: Permit researchers to publish in scientific journals after a reasonable pre-defined review period from RIDOH (e.g., 2 months).
Section involved: § 6.5.6

Response: *RIDOH agrees with this suggestion and has revised the language to specify a period of 2 months.*

Comment Received: Suggested section should be rewritten in its entirety, as it gives the impression that analytic or research uses of HIE data are permitted only when the state approves of the use. Additionally, the section was seen to introduce restrictions beyond HIPAA on such uses.
Section involved: § 6.5.6
Response: The section explicitly allows for DSPs to permit research and analysis on their data via the HIE. See § 6.5.4(C): "Nothing in this Part shall preclude data-submitting partners from utilizing the technical infrastructure of the HIE to share the data-submitting partner's own confidential healthcare information as permitted by other state and federal laws under appropriate legal agreements, including for analytic or research purposes."

It is explicitly provided for in HIPAA, therefore, any uses under HIPAA and applicable Business Associate Agreements are not governed by these provisions. Accordingly, RIDOH declines to make any changes.

Comment Received: Concerns were expressed that this section establishes permitted uses of PHI for research without patient authorization beyond what is allowable in HIPAA or Rhode Island general law, which is beyond the Department's authority.
Section involved: § 6.5.6
Response: HIPAA does allow for research uses without patient authorization provided specific conditions are met, such as ensuring that individuals cannot be reasonably re-identified as per standards set forth in 45 C.F.R. § 164.514(a). RIDOH does not find any conflict with HIPAA pertaining to this rule. Additionally, these regulations add protections beyond those provided by HIPAA by ensuring the originating provider or the state has oversight of research uses even for deidentified records.

Citations demonstrating that HIE data are covered under HIPAA are provided below.

R.I. Gen. Laws § 5-37.7-3(5): "'Data-submitting partner' means an individual, organization, or entity who or that has entered into a business associate agreement with the RHIO and submits a patient's confidential healthcare information through the HIE."

R.I. Gen. Laws § 5-37.7-4: "(f) Nothing contained herein shall have an impact on the content of, or use or disclosure of, confidential healthcare information of patients that is held in locations other than the HIE. Nothing in this chapter shall be construed to limit, change, or otherwise affect entities' rights to exchange confidential healthcare information in accordance with other applicable laws.

(g) The state hereby imposes on the HIE and the RHIO as a matter of state law, the obligation to maintain, and abide by the terms of, HIPAA-compliant business associate agreements, including, without limitation, the obligations to use appropriate safeguards to prevent use or disclosure of confidential healthcare information in accordance with HIPAA,

other state and federal laws, and this chapter; not to use or disclose confidential healthcare information other than as permitted by HIPAA and this chapter;"

HIE Advisory Commission

Comment Received: Suggested clarifying language around whether members of the commission are required to have expertise in all subjects or only one of those listed.
Section involved: § 6.4(A)
Response: *RIDOH agrees and has revised* § 6.4(A) as follows: "The membership of the HIE Advisory Commission shall include individuals with expertise in topics such as:"

Comment Received: Recommended that Commission membership should include community members without conflicts of interest.
Section involved: § 6.4(A)
Response: RIDOH finds that the requirements for Commission membership include appropriate community representation, including expertise in consumer advocacy and minority or underserved populations, and declines to make changes.

CHANGES TO THE TEXT OF THE RULE:

- Revised § 6.4(A) as follows: "The membership of the HIE Advisory Commission shall include individuals with expertise in topics such as:"
- Added "system" in § 6.5.4(A).
- Added "healthcare operations" to list of allowable purposes in § 6.5.4(A)(1).
- Changed language in § 6.5.4(B) to specify "submitted under State authority."
- Added "for a period of time not more than 3 months" to § 6.5.4(E).
- Added "for a period of time not more than 2 months" to § 6.5.4(E)(3).
- Added "if applicable" to § 6.5.4(G)(1).

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.