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October 24, 2025

By email: Zachary.garceau@health.ri.gov

Zachary Garceau
Rhode Island Department of Health
3 Capitol Hill
Room 403
Providence, RI 02908

Re: Notice of Proposed Rulemaking for the Regional Health Information Organization and Health Information Exchange, 216 RICR-10-10-6

Dear Mr. Garceau

Please accept the following comments made in response to the Department's Notice of Proposed Rulemaking for the state regulations governing the Regional Health Information Organization and the Health Information Exchange.

We appreciate your attention to our views, and trust that you will give them your careful consideration. If the suggestions we have made are not adopted, we request, pursuant to R.I.G.L. § 42-35-2.6(1), a statement of the reasons for not accepting the arguments we have made.

Sincerely,

Madalyn McGunagle
Policy Associate

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COMMENTS ON PROPOSED RULES AND REGULATIONS PERTAINING TO THE REGIONAL HEALTH INFORMATION ORGANIZATION AND HEALTH INFORMATION EXCHANGE [216-RICR-10-10-6]
October 24, 2025

The American Civil Liberties Union of Rhode Island (ACLU) urges the Department of Health (DOH) to withdraw these proposed regulations and terminate the current rule-making proceedings, and to instead return with a revised list of amendments that do not raise the numerous concerns highlighted in our testimony below.

The ACLU has had a long-standing interest and involvement in the Health Information Exchange (HIE) in light of the critical privacy, autonomy, and confidentiality issues it raises. While we appreciate the effort to update and clarify the regulations, we are concerned about a number of issues that these draft regulations provoke. To start, some historical background is necessary to at least partially explain our reasons for seeking a fresh start on revising these regulations.

When the DOH first proposed regulations in 2009 to implement in our state what was then a new centralized database of patient health care records – and which by design included mental health and other sensitive medical information – our organization objected that the proposed regulations provided virtually no details as to how the system would actually work, or how it would protect the privacy, confidentiality, and informed consent interests of patients.

In light of the important privacy and confidentiality issues raised by an electronic health records system, the legislature clearly envisioned the adoption of detailed regulations by the DOH. Indeed, the HIE statute contains no fewer than *seven* provisions requiring implementing details about the system to be fleshed out by DOH through a public rule-making process. However, those issues were only minimally addressed, if at all, in the regulations the Department first proposed after passage of the HIE statute. The DOH justified this approach at the time by stating that the issues could be better handled through internal "policies" that were not subject to the public notice and comment requirement that formal agency regulations must undergo.

Not satisfied with that explanation, our organization sued the Department under the Administrative Procedures Act (APA), challenging the inadequacy of the rules the agency had adopted and asking the court to require DOH to promulgate "regulations that completely fulfill its obligation" under the HIE statute. The lawsuit ultimately led to the filing of a consent decree in 2014, in which the Department acknowledged it would cease relying on "unofficially promulgated policies" to implement the HIE law, and that it had "prepared for promulgation, regulations agreed to by the Plaintiff which completely fulfill [its] duties and obligations" under the HIE statute. Those revised regulations were adopted shortly thereafter. Yet this current proposal seeks to repeal

many of those provisions that were specifically adopted to "fulfill" the Department's duties under the HIE statute and the APA. In short, in numerous instances, this proposal acts as if the litigation and consent decree never existed. We find this regression extremely problematic.

Also of concern is that many of the questionable revisions appear to be done in the name of "flexibility" and "convenience," but that flexibility is often for the convenience of the providers, the Department, and the RHIO (Regional Health Information Organization) rather than the patients whose sensitive medical records are at issue.

In light of the numerous revisions being proposed by the Department, the commentary below is not meant to be exhaustive, but we hope it is sufficient to encourage the Department to return to the drawing board.

Our comments are offered in the order of the proposed rule:

§ 6.2 Definitions. The proposed rule deletes the current rule's inclusion of more than a dozen definitions found in R.I.G.L. § 5-37.7-3. While this makes for a leaner set of regulations, we believe the inclusion of the definitions is extremely helpful to patients and other members of the public reviewing the rules. Finding an appropriate statutory section can be time-consuming or difficult for a layperson, and requiring readers to access a second source eliminates the convenience of having a self-contained document. Removing the definitions might make sense if they were likely to regularly revisited and amended by the General Assembly, but there is no reason to believe that to be the case. We therefore urge reinstatement of those definitions.

§ 6.2(A)(28). The current definition of "Public Health Authorities" in the regulations includes federal, other state, and tribal public health authorities. However, the breadth of that definition is inconsistent with statutory provisions limiting access to confidential health care information for public health purposes to "state agencies." See R.I.G.L. § 5-37.7-4 (e) and § 5-37.7-7(b)(2). Moreover, due to the recent understandable loss of public confidence in the federal government's willingness to safeguard legally protected confidential information – and particularly confidential health care information[1] – the regulation's inclusion of federal agencies is especially distressing. It is no exaggeration to say that sensitive medical records are at great risk of being misused by those agencies. We believe it is imperative to revise this provision to authorize access to HIE records for public health purposes to state agencies only.

§ 6.3.1(A)(2). Limiting the requirement to inform a patient of the opportunity to opt out to only those "provider participants" with "an active direct treatment relationship" as defined by 45 C.F.R. § 164.501, as this provision does, is inconsistent with R.I.G.L. § 5-37.7-7(c). That section of the statute requires all provider participants (defined by R.I.G.L. § 5-37.7-3(18) to also include pharmacies, labs, or health plans) to notify their patients of their opt-out ability. Similarly, data-submitting partners who meet the statutory definition of provider participant are also subject to the same requirement to inform patients of the opportunity to opt out, even if they have an "indirect treatment relationship" with the patient. While "indirect" providers may find this obligation

[1] See, e.g., "Trump Officials Demanded Confidential Data About Transgender Children Seeking Care," by Chris Cameron, New York Times, August 20, 2025.

burdensome or unwarranted, it serves a meaningful purpose and is required by statute, and therefore cannot be eliminated by regulation.

§ 6.3.1(A)(5). This provision changes the specification that an opt-out form must be "completed" to "validly submitted." But it does not mention procedures to inform a patient that their form was invalidly submitted, nor what to do if that happens. As a result, a patient could believe they have opted out of data sharing, when in reality their data remains in the HIE after an unacknowledged submission error. The DOH cost-benefit analysis justifies this change by stating "the RHIO would have no practicable way of knowing if someone has signed a paper form somewhere, and therefore submission of the form is a more reasonable requirement." While that is a legitimate concern as far as it goes, it fails to address situations when a form *has* been received but is deemed "invalid" for some reason. This should be addressed.

§ 6.3.1(A)(7)(d). Following our lawsuit concerning the 2009 regulations, DOH promulgated various rules designed to address the significant privacy issues raised by the creation of the HIE system. Under R.I.G.L. § 5-37.7-4(g), both the HIE and the RHIO are required to "maintain, and abide by the terms of, HIPAA-compliant business associate agreements." However, proposed regulation § 6.3.1(A)(7)(d) removes the 2014 regulatory requirement that the RHIO contractually require provider participants to comply with HIPAA, including establishing and implementing HIPAA-compliant policies and procedures. The DOH cost-benefit analysis does not address why this provision was removed, and we believe it should be restored.

§ 6.3.1 A(6) and A(7). A number of changes being made in these two subsections erode vital complaint procedures. Almost all of the provisions being repealed were adopted in response to the ACLU litigation and designed to comply with the regulatory obligations imposed by the HIE statute. Eliminating a patient's ability to complain to the Department about the RHIO or HIE and giving the Department the discretion whether to review complaints received by the RHIO is an inadequate oversight process for a system that is responsible for safeguarding the confidential healthcare information of the overwhelming majority of Rhode Islanders. These deleted sections should remain. To provide some specifics:

- **§ 6.3.1(A)(6) -** Removes the 2014 rule that designates the DOH "Health Information Line" as a resource for individuals who have remaining concerns or complaints after contacting the RHIO. The DOH cost-benefit analysis of these proposed regulations does not address why this resource was deleted from the regulation.
- **§ 6.3.1(A)(7)(former e) -** Deletes the 2014 provision that complaints may be filed with the provider participant directly, with the RHIO, or with the DOH. The DOH cost-benefit analysis of these proposed regulations does not address why this process was deleted from the regulation.
- **§ 6.3.1(A)(7)(former f) -** Removes the 2014 requirement that if a patient is filing a complaint directly with the RHIO, they fill out a patient complaint form. The DOH cost-benefit analysis of these proposed regulations does not address why this process was deleted from the regulation.
- **§ 6.3.1(A)(7)(former g) -** Deletes the 2014 requirement that if a complaint concerns breach of security, it may invoke the response to breach procedures by the RHIO.

The DOH cost-benefit analysis of these proposed regulations does not address why this process was deleted from the regulation.

- **§ 6.3.1(A)(7)(former j) -** Removes the 2014 protocol for complaints filed directly with DOH. The DOH cost-benefit analysis of these proposed regulations does not address why this process was deleted from the regulation.
- **§ 6.3.1(A)(7)(former k) -** Deletes the 2014 requirement that any complaint filed with the provider participant, RHIO, or DOH be resolved within 30 days of submission. The RIDOH cost-benefit analysis notes that this provision was deleted and language was added to § 6.3.1(A)(7)(e) to reflect that a patient who files a complaint "shall be informed of the current status and disposition of the complaint." The cost-benefit analysis further notes that the original requirement that a complaint be resolved within 30 days of submission "was not feasible in many cases" and that one of the considered alternatives was to retain the 30-day requirement, but that "it would be difficult for the RHIO to resolve complaints within 30 days." We would argue that it is vital that any complaint filed about the HIE should continue to be resolved during this timeframe, as these complaints are related to the possession and distribution of confidential health information, and a timely response or correction is not only warranted, but essential.

All of these provisions were adopted in 2014 to comport with the Department's rulemaking obligations set out in the HIE statute as acknowledged by the consent decree. Their deletion, and deletion without good cause, is alarming and should be reversed.

§ 6.3.2(A)(4). The DOH proposes to delete this provision, which requires the RHIO to develop and maintain a process for patients to obtain copies of their healthcare information held by the HIE. But specifying a process helps to effectuate the statutory right of a patient to obtain a copy of their healthcare information from the HIE, R.I.G.L. § 5-37.7-10(1), and the rule allows some discretion by leaving the exact process in the RHIO's hands. Yet the DOH cost-analysis refers to the rule's "administrative burden" and the need for flexibility. This is yet another example of the DOH removing a regulatory standard that helps implement the HIE statute's obligations, and doing so in a way that transfers a burden to the patient instead. We urge reinstatement of this provision.

§ 6.3.2(C). This proposed revision of § 6.3.2(C) undoes the 2014 requirement that the RHIO's notice of privacy practices be posted on its website, written in plain language, and contain certain applicable information. Instead, the patient would be given the burden of requesting the notices if they so choose. The DOH cost-benefit analysis reasons that this amendment would "ensure that patients have access to copies of the agreements under which their data was submitted to the HIE, and the proposed amendments remove the burden on the RHIO to maintain online database of those documents." But eliminating these requirements moves that burden to the patient. It reduces the accessibility of this information that is critical to ensuring patients understand how their health data is being used and their rights as patients.

The cost-benefit analysis also notes that DOH considered retaining these requirements but concluded that the plain language requirement was unnecessary because "the RHIO's notice of privacy practices is not actually relevant to the patient because the notice they were actually

provided about their HIE participation was from their provider, and that notice is what governs their data usage." However, because of the RHIO's critical and relevant role in this entire process, we believe that the requirement that the RHIO's notice of privacy practices be posted online in plain language is a reasonable one and should be reinstated.

§ 6.3.2 (former D)– The proposed regulation, without any explanation, removes important language adopted in 2014 holding the RHIO responsible for failing to comply with any provisions of federal law or the HIE statute or regulations, and authorizing various remedies to address such violations, including suspending actions of the RHIO pending compliance. The cost-benefit analysis does not address why this process was removed, but it clearly does not warrant excision. Its absence suggests there will be little deterrence against RHIO for violations of patients' rights.

§ 6.3.3(B). These proposed regulations attempt to erode patients' rights by removing important processes that are not addressed in the governing statute. Under R.I.G.L. §5-37.7-10(4), "a patient who has his or her confidential healthcare information included in the HIE shall have the following rights… (5) To request to amend his or her own information through the provider participant…" Proposed regulation § 6.3.3(B) targets for elimination a multitude of patient protections that were first included in the 2009 regulations. Specifically, the draft regulations delete the process governing a patient requesting an amendment to their protected health information, a 60-day response requirement to tell the patient why the request to amend has been denied, a 30-day requirement that the patient be notified in writing that their request to amend has been processed, and a 30-day notice requirement to tell a patient if their requested change to their information was a result of an internal error and that the correction has been made. Also removed from this draft is the requirement that the RHIO have data-sharing agreements in place with provider participants who submit data to the HIE.

While the DOH cost-benefit analysis notes that amendment requests from patients have been rare in the ten years the HIE has been operating, it does not mean that having these procedures in place is any less important. In considering alternative options, DOH considered retaining certain provisions but ultimately decided that removing the entire section "would alleviate this burden" on RHIO to "maintain full policies and procedures." As with many other changes we have cited, the DOH explanation inappropriately gives undue deference to system participants and shifts burdens onto the patient instead. The DOH should maintain and keep in place this process of requesting record amendments through their provider to safeguard and promote the statutory right to amend records found in the statute.

§ 6.3.3 (current D). This section describes the information that should be included in an annual report from the RHIO to the HIE Advisory Commission. We believe it should also include a summary of any complaints received by the RHIO, see § 6.3.1(A)(7)(e), as well as the resolution of those complaints.

§ 6.4(A). By statute, the HIE Advisory Commission is to provide "community input" as well as policy recommendations for the RHIO and HIE operations. R.I.G.L. § 5-37.7-3(14). Community representation is essential to providing community input. The statute also requires the Commission to provide recommendations on use of, and appropriate confidentiality protections for, healthcare information. R.I.G.L. § 5-37.7-5(c). Rhode Island residents with information held

by the HIE have a significant stake in ensuring the confidentiality of their information and should be included members of the HIE Advisory Commission. We therefore believe the proposed Commission membership as laid out in the regulation needs to include community members without conflicts.

§ 6.4(G). The proposal makes significant and troubling changes to this section of the regulations. First, the draft regulation removes language requiring the HIE Advisory Commission to "actively obtain and consider public input on all recommendations prior to submitting them to the Director." In deciding to eliminate this provision, the DOH cost-analysis claims that "it was determined . . . that the existing requirements were not specific in regard to how this input would be obtained." But public bodies of all sizes, missions and responsibilities routinely and ably seek and welcome public input. There is no compelling reason for an advisory commission like this, examining important issues affecting the privacy rights of hundreds of thousands of Rhode Islanders, to eliminate public comment before making recommendations to the DOH director. The regulations can easily lay out the ways that public input would be accepted, and that is the path that the regulations should take, if this deficiency is a concern, rather than eliminating the requirement for public input altogether.

Additionally, this revised section removes language that currently states that meetings of the HIE Advisory Commission are subject to the state's Open Meetings Act (OMA). There is no reason to eliminate this command from the rules. In recent years, some advisory committees have attempted to argue that they are exempt from the OMA, notwithstanding the clear definitional inclusion of public bodies with advisory power in the statute. The HIE Advisory Commission should not be provided any opportunity to make a similar claim. Although the cost-benefit analysis asserts that the Commission "already falls under" the OMA, the absence of explicit language to that effect may create confusion and reduce public engagement. Retaining this language will avert any such uncertainty.

Finally, the proposal adds a new provision to address recommendations from the HIE Advisory Commission when a "novel" purpose for using confidential information is requested. Of course, a "novel" purpose cannot be one that is not authorized by what the HIE statute itself allows. The regulations should make that explicit.

§ 6.5.1(A)(1). This provision removes the list of methods by which a patient may obtain a copy of their confidential healthcare information. Under the 2014 regulations, patients could do so by "submitting a valid and authenticated request," calling an informational line, completing a form in person at the RHIO offices, or sending a written request by mail. In order to address transparency and equitable access, these options were also required to be publicly listed on the RHIO website. The proposed deletion of these requirements significantly reduces clarity and accessibility, particularly for patients who face language or mobility barriers or are unfamiliar with online systems and unsure of where to find these resources. Without this publicly available list of options, patients will find it much more difficult to exercise their statutory right to access their health information. The 2014 regulations on this matter were a perfect example of the DOH exercising the regulatory authority required by the statute to give meaning to some of the statute's provisions. This proposal is a perfect example of the DOH backtracking on that regulatory obligation.

DOH's cost-benefit analysis explains that this deletion is intended to allow "the HIE to develop their own process if they choose to do so," further explaining that removing the requirement for a specific policy would allow for flexibility in following industry standard practices, but in doing so it leaves the patient unprotected and subject to potentially onerous procedures to exercise this basic right. This virtually unbridled discretion is unwarranted. The statute provides patients with a right to obtain a copy of their healthcare information held by the HIE. R.I.G.L. § 5-37.7-10(1). To effectuate this statutory right, a process for obtaining the copy needs to be made public and codified in regulation. The deleted language regarding a process needs to be restored because without it, it returns to the type of "unofficial policy" that the consent decree disavowed.

§ 6.5.1(A)(6). A patient's statutory right to opt-out of having their healthcare information disclosed by the HIE becomes meaningless if, as this provision proposes, there is no restriction on the timeframe for effectuating the opt-out decision, and the patient is only told "when the opt-out becomes effective." The regulations already give provider participants up to six months to inform patients that their information has been forwarded to the HIE and that they have the right to opt out of disclosure. See § 6.3.1(A)(3). This section should be revised so that, at a minimum, the opt-out form is effective for all information about a patient within days upon receipt of the form, not at some completely unspecified time.

§ 6.5.3(B) and (C). The proposed addition of the phrase "or this Part" should be deleted, as the rule cannot expand the statutory purposes allowed for the use of healthcare information within the HIE.

§ 6.5.4. The proposed regulation includes this entirely new section that addresses requests for confidential healthcare information – including non-deidentified data – for "analytic or research purposes." This section inappropriately opens the door for use of confidential healthcare information held by the HIE that is simply beyond the scope of uses permitted by statute. DOH cannot unilaterally authorize the use of confidential information held by the HIE for such purposes. Nor can data-submitting partners authorize by "legal agreements" broader uses of this information. Further, patients who have not opted out of HIE participation have no notice that their data may be used for such purposes. DOH's cost-benefit analysis acknowledges that this section formalizes a practice already occurring, but does not explain why it has been allowed under the parameters of the HIE statute and without informed notice to affected patients.

§§ 6.6.2-6.6.7. Past iterations of these regulations contained six detailed subsections under "Security Requirements" (§§ 6.6.2- 6.6.7), mandating robust data safety and management standards. These have been removed from the current draft without explanation, leaving only the statutorily protected minimum-security requirements. We believe it is especially pertinent to retain as many safeguards for this information as possible, especially in light of the various and significant data breaches the state has suffered in the last few years.

Similarly, under R.I.G.L. § 5-37.7-8(1), "The HIE must be subject to at least the following security procedures: (1) Authenticate the recipient of any confidential healthcare information disclosed by the HIE pursuant to this chapter pursuant to rules and regulations promulgated by the department…" The current and proposed regulations do not include an authentication process for

any recipient of confidential healthcare information, but rather only consider user authentication when accessing their own data. This should be addressed.

Finally, we wish to note a few technical errors:

- **§6.3.2(A)(3 and 4) -** Sections cite to 6.3.1(A)(8) and 6.5.1(A)(42), respectively. Neither citation exists.

- **§6.5.3 -** Mistakenly listed as "6.5.34" and references 6.3.3(A)(5) which does not exist.

In sum, we believe these proposed rules fall short by failing to comply with the statutory mandates contained in the HIE statute for rulemaking, and by failing to adequately provide for the confidentiality, security, due process and informed consent protections to patients that the regulatory process is designed to protect. We urge that these issues be addressed by restarting the rulemaking process with a new set of proposed regulations that do not flout the 2014 consent decree or the goals of both the Administrative Procedures Act and the HIE statute in promoting a robust regulatory process.

We appreciate your attention to our views, and trust that you will give them your careful consideration. If the suggestions we have made are not adopted, we request, pursuant to R.I.G.L. § 42-35-2.6(1), a statement of the reasons for not accepting the arguments we have made.

Submitted by: Madalyn McGunagle, Policy Associate, and
Anne Mulready, Board Member, on behalf of the
American Civil Liberties Union of Rhode Island

Outlook

216-RICR-10-10-6 Comments

From Goulet, Morgan <Morgan.Goulet@huschblackwell.com>
Date Sat 10/25/2025 11:59 PM
To Garceau, Zachary (RIDOH) <Zachary.Garceau@health.ri.gov>

To Whom It May Concern:

The following comments are being provided personally, not on behalf of any client:

6.2 Definitions

1. Signpost Definitions. Throughout Section 6.2, definitions redundant with those set forth in R.I. Gen. Laws § 5-37.7 (the "Act") have been replaced with the following phrase, presumably meant to be a signpost to the statutory definition: "'[DEFINED TERM]' means as defined in R.I. Gen. Laws § 5-37.7-3[]." "Means as defined in" is grammatically meaningless. Other regulations that signpost to statutes or other sources use the following phrase, or approximation thereof: "'[DEFINED TERM]' has the same meaning as it is is defined in [CITED STATUTE]." The language of every signpost definition should be revised to more properly convey its intent.

2. Gender Neutral Pronouns. Well-intentioned efforts to remove gender specific pronouns from all regulations cannot be reduced to simply replacing gender specific pronouns with "they," which can and often does reduce the clarity of the regulation to avoid offense. One can avoid offense by rewriting the offending sentences in the plural or by replacing the pronouns with the noun. For example, in Section 3.1(A)(8), instead of "the Director of the Rhode Island Department of Health or their designee," which implies that the Director of health is multiple people, use "the Director of the Rhode Island Department of Health or the Director's designee," which is clear and avoids offending pronouns. Care should be taken throughout the regulations to avoid use of singular-they/their.

3. HIPAA Definitions. As mentioned above, throughout Section 6.2, definitions redundant with those set forth in the Act have been replaced with signposts. Nevertheless, Section 6.2 includes several HIPAA-defined terms for which the definitions have been reproduced, in some cases inaccurately and typically without reference to HIPAA. For example, Section 6.2(A)(26) defines "protected health information," yet does not reference HIPAA's definition at 45 CFR 160.103 and incorrectly implies, without referencing "covered entities," that employers are covered entities under HIPAA. This definition must be corrected to coincide with HIPAA. The incorrect implication relative to employers also makes clear that Section 6.2 should include a definition for "covered entity." Similarly, the definitions for "security incident" and "unsecured protected health information" should signpost to the HIPAA definitions at 45 CFR §165.304 and 45 CFR §164.402, respectively, in a similar fashion to the added definition for "research." Separately, "business associate," which is a HIPAA-defined term, has been redefined with a signpost definition that references the Act and not HIPAA. This change is that much more peculiar given that the Act itself references HIPAA. A suggested revision would be a version of the following: "'Business associate," per R.I. Gen. Laws § 5-37.7-3(2), means "business associate," as defined by HIPAA."

4. Addition of -Care. Throughout these regulations, the suffix -care has been added indiscriminately to the word "health," presumably because the Act defines "confidential healthcare information," not "confidential health information." The addition of -care to "health" in that term is proper and not disputed. On the other hand, the addition of -care to "health" in "protected health information" is incorrect. "Protected health information" is a defined term. Likewise, "unsecured protected health information" is a HIPAA-defined term to which -care cannot be added. There are other instances, too, where -care has been added to "health" within the regulations for unclear reasons. Care should be taken to review each instance for its propriety.

5. Circular Reasoning. Section 6.2(A)(21) adds a meaningless, circular definition. "Must" cannot mean "shall" and "shall" mean "must" without there being a definition of one of the two. It is believed that the intent was to convey that "must" and "shall" is meant to be read as the declaration of a legal obligation and have been used interchangeably. That is not what the new definition says, however. Moreover, "shall" and "must" have different meanings, even in the context of these regulations. For example, Section 6.3.1(A) provides, "Confidential healthcare information shall only be accessed, released or transferred from the HIE pursuant to [the Act]." In this instance, "shall" describes permitted disclosure, not mandatory disclosure. As such,

"shall" is more properly replaced with "may," but the prohibition on disclosure inconsistent with the Act is no less clear. If RIDOH finds the use of "shall" to be confusing or too vague, which is not unreasonable, RIDOH should scrub the regulations for "shall" and replace "shall" with "must" or another less confusing, more specific word, insofar as may be appropriate.

6. Missing Definitions. A definition for "covered entity," signposting to HIPAA, and a definition for "HIE vendor," should be added.

7. Opt-out form. Section 6.2(A)(23), which defines "opt-out form," must specify that the form "revokes provider participant access to, review of, and/or disclosure of the patient's confidential healthcare information **from and within the HIE** by electronic, written or other means;" the opt-out form applies only to the HIE.

8. Health systems. Section 6.2(A)(24), which defines "patient matching," references "linking of one (1) patient's data within and across health systems," but includes no definition of "health systems," limiting the value of the definition.

6.3.1(A)(1)

The first reference to "opt out" in Section 6.3.1(A)(1) has been moved to after "rescind permission." Other changes to the sentence related to that move have rendered the sentence inscrutable. The corrected sentence should read, "Patients shall be able to choose not to have their confidential healthcare information disclosed from the HIE, except as permitted or required by law or regulations, by submitting an opt-out form provided by the RHIO." This proposed revision would address the pre-existing need to correct the opt-out language while using language from the statutory definition of "opt out."

6.3.1(A)(2) and 6.3.1(A)(2)(a)

First, these sections have changed the statutory term "ability" to "opportunity," at the cost of clarity. In context, the first reference to "opportunity" should be changed to "ability." Second, Section 6.3.1(A)(2) appears to use "data-submitting partners" and "provider participants" interchangeably, at the cost of clarity to the provision; it is unclear who has an obligation to inform patients and who has an obligation to discuss with patients. It is unclear whether RIDOH intended to distinguish between the two. Third, Section 6.3.1(A)(2)(a) increases the confusion by saying the exact opposite of the first sentence of Section 6.3.1(A)(2). It is believed that Section 6.3.1(A)(2)(a) was intended to say the opposite. Even if it did, the provision would be confusing, due to the placement of the clause "with whom they have an indirect treatment relationship as defined by 45 C.F.R. § 164.501," and unnecessary. There is no need to spell out the converse of the first sentence; doing so merely fosters confusion. Fourth, the requirement to "offer the opportunity to discuss HIE participation" is overly complex in its language. It is believed that the intent is to require "provider participants" to discuss HIE participation with individuals patients who ask about it, but that is not at all clear. Fifth, the subject of "HIE participation" is rendered vague due to the deletion of the defined term "participation." It is recommended that Section 6.3.1(A)(2)(a) be deleted and that 6.3.1(A)(2) be rewritten.

6.3.1(A)(3)

First, "opportunity" should be changed to "ability." Second, 6.3.1(A)(3) states first that individuals will be clearly "informed," but then references "notification," so "('opt-out notice')," defining the term, should be added after "in a distinct written document, whether paper, electronic, or web-based." Third, 6.3.1(A)(3) has long improperly referenced "protected health information." Protected health information is not the same thing as confidential healthcare information. Protected health information is a subset of confidential healthcare information, but, relevant to these regulations, the Act concerns itself with confidential healthcare information, HIPAA concerns itself with protected health information. As such, "protected health information," here, should be changed to "confidential healthcare information." Care should be taken to review the regulations completely for potentially improper references to protected health information. Fourth, the list of topics following 6.3.1(A)(3) does not include—and, admittedly, though inexplicably never has—the fourth topic, disclosure to the RHIO, set forth in R.I. Gen. Laws 5-37.7-7(b)(3).

6.3.1(A)(5)

Change "protected" to "confidential."

6.3.1(A)(7)

First, this section references complaints pertaining to the "RHIO and/or HIE," only; no mention is made of the HIE Vendor. The original language spoke only of the HIE, which made sense because the complaint would be pertaining to the "HIE," i.e., the "technical system," in the broadest sense. A suggested revision would be: "pertaining to the HIE, generally, or the RHIO or HIE specifically." Another option would be: "pertaining to the HIE, generally, including but not limited to complaints pertaining to the RHIO and/or the HIE Vendor." Second, in 6.3.1(A)(7)(c), change "engage in a reprisal" to "engage in reprisals." Third, 6.3.1(A)(7)(e) provides that "the patient shall be informed of the current status and disposition of the complaint," but provides no indication of when the patient shall be so informed. The RHIO can only notify the patient of the disposition of the complaint following disposition of the complaint. It is suggested that this section be revised to clarify this fact and that notification will be upon patient request. As

for informing the patient of the "current status" of the complaint, to the extent required, it should be limited to whether the complaint is under investigation or that the complaint has been resolved.

6.3.2(A)

This section provides that "RHIO and RIDOH shall develop, implement, and maintain current policies and procedures," but it is unclear whether they will collaborate on a single set of policies and procedures or they will each develop, implement, and maintain their own policies and procedures.

6.3.2(A)(9)

This section speaks to the inclusion of "patient matching" among the topics covered in policies and procedures, but it is unclear what is meant by "including patients who have opted out of disclosure to health-care providers" with respect to the topic of "patient matching." There appears to be explanatory language missing.

6.3.2(A)(10)

Similar to section 6.3.2(A)(9), the topic to be covered in policies and procedures is clearly identified, "ongoing identity management." That said, it is unclear what "identity management" means. Also, it is unclear how the "simplified process" referenced within this section relates to the topic of "ongoing identity management." There appears to be explanatory language missing.

6.3.2(C)

This section includes the phrase "if separate, their data-submitting partners' opt-out notices." Based on context, it appears that "their" refers to the RHIO, which is singular, so "their" should be "its."

6.3.2(E) and 6.3.3(B)

These sections have historically referenced PHI. The amended version changes PHI to the synonymous "protected health information," but it is unclear why these Rhode Island Regulations reference either instead of the term used in the HIE Act, i.e., confidential healthcare information.

6.3.3(A)

This section has long stated that "the HIE and the RHIO have an obligation to maintain," but the HIE, by statutory definition, is the "technical system." As such, the HIE cannot have an obligation. It is the HIE vendor should be included with the RHIO.

6.3.3(D)

The reporting requirements in this section are vague. What, specifically, are the HIE Advisory Commission and the Department to receive from the RHIO relative to the "usage of the HIE," "patient matching," "data requests," and "disclosure report requests."

6.4(A)

The provision that "[t]he membership of the HIE Advisory Commission shall include expertise in . . ." is unclear unless the intent is for every member of the commission to be an expert in each category listed. If the intent is that the commission be comprised of members that, in combination, have expertise in the listed categories, the provision needs to be rewritten.

6.4(D)

Unless the intent is to prohibit staff and board members of both the RHIO and the HIE vendor from being appointed to the commission, it needs to be written, e.g., "Neither current staff nor current board members of both the RHIO and HIE vendor may be appointed to the Commission."

6.4(F)

This section has long been unclear, obligating (apparently) the HIE to inform the Commission of "any newly introduced exchanges of confidential health[care] information from the RHIO to the Department for public health purposes." The amendments to this section change the recipient of the information to the Director, but the substance of the obligation remains unclear.

6.4(G)

The section previously obligated the HIE Advisory Commission to "actively obtain and consider public input on all recommendations prior to submitting them to the Director." As amended, this provision appears to limit the Commission's statutory role, set forth in R.I. Gen. Laws 5-37.7-5(c), "The HIE advisory commission, in consultation with the RHIO, will be responsible for recommendations relating to the department regarding the use of, and appropriate confidentiality protections for, the confidential healthcare information of the HIE." The statute is much broader. Also, particularly given the deletion of the provision relative to public input, it is critical that the regulations provide for the Commission's consultation with the RHIO.

6.5.4

There are many problems with this section, and the recommendation is that this section be rewritten in its entirety. As written, this section gives the overall impression of permitting analytic or research purposes only when the state is doing the analyzing/research or the state approves of the analysis/research. That is problematic. It would be less troubling were the state to simply prohibit analytic or research purposes. Additionally, this section imposes restrictions on the use of information that HIPAA, for example, does not. Research using de-identified information does not constitute "human research" and, thus, does not require institutional review board approval. And, HIPAA does not prohibit the use or disclosure of de-identified information. What should control is that if the BAAs permit de-identification of the data, then the de-identified data may be used.

Very truly yours,

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Advance RI-CTR Public Comment on RIDOH's Proposed Amendments to 216-RICR-10-10-6: Regional Health Information Organization and Health Information Exchange

Submitted by: Advance Rhode Island Clinical and Translational Research (Advance RI-CTR)

Date: October 24, 2025

To: Rhode Island Department of Health (RIDOH)

Advance RI-CTR is a statewide consortium of institutions - Brown University, Care New England, Brown University Health, the VA Providence Health Care System, and the University of Rhode Island - dedicated to advancing clinical and translational research that addresses the health challenges of Rhode Islanders. We appreciate the opportunity to provide comments on the proposed amendments to 216-RICR-10-10-6: Regional Health Information Organization and Health Information Exchange.

1. General Support for Modernization of the HIE Framework
Advance RI-CTR commends RIDOH for its leadership in advancing the Health Information Exchange (HIE) framework. The proposed updates to 216-RICR-10-10-6 strengthen patient protections, align with HIPAA and HITECH, and enhance data transparency and accountability. However, we have deep concerns regarding the ways in which these new regulations could negatively impact research and therefore population health outcomes. As a statewide research consortium, Advance RI-CTR strongly supports measures that enable secure, responsible data sharing that upholds the highest standards of privacy, equity, and patient engagement while still being able to conduct cutting edge research that will improve the quality of health care and health outcomes for Rhode Islanders.

2. Support for Strengthened Patient Rights and Transparency
Advance RI-CTR supports the expanded description of patient rights in Section 6.5, including the right to access, amend, and receive disclosure reports; the requirement for multilingual and accessible opt-out materials; and the establishment of a public complaint process with a dedicated hotline. These measures enhance patient autonomy and reinforce trust in the HIE.

We recommend RIDOH include clear timelines for complaint resolution and publish annual summaries of patient inquiries and complaints in aggregate form to promote transparency and accountability.

3. Recommendations Regarding Research and Analytic Use (Section 6.5.4)
To address the negative consequences recommended changes will have on research, Advance RI-CTR requests the following alterations:
a. Define "near-term benefit" (6.5.4(D)) and offer explicit examples and guidance to ensure consistent evaluation of research requests and inclusion of both applied and translational studies with public health relevance. As RIDOH well knows, it is difficult to predict the "near-term benefit" of any research. It frequently takes years for research to result in policy changes and/or other tangible health benefits. However, without the data generated by research, health policy is developed without the proper evidence base to promote best practices for patient health outcomes.

b. 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. These projects should also be exempt from the “near-term” benefit criterion.

c. Clearly identify academic and clinical research institutions as eligible collaborators under state or federal (i.e. NIH) oversight when conducting approved analytic data requests, with rigorous data use agreements and privacy protections.

d. Require annual reviews in HIE reporting to ensure that research benefits all Rhode Islanders and to mitigate data bias.

e. Standardize the time period in which data requests must be reviewed (e.g., 3 months) to streamline timely research projects.

f. Permit researchers to publish in scientific journals after a reasonable pre-defined review period from RIDOH (e.g., 2 months).

4. Strengthening the Role of the HIE Advisory Commission (Section 6.4)
Advance RI-CTR supports the updated structure and engagement requirements of the HIE Advisory Commission and recommends the following enhancements:

a. Include a representative from a Rhode Island academic or research institution to offer additional perspective that will support alignment of data governance with scientific innovation and public health objectives.

b. Publish meeting minutes and Commission recommendations on the RIDOH website to maintain transparency and promote public trust.

c. Institute an in-person public comment period allowing individuals sufficient time to provide meaningful feedback *before* votes are made by the committee.

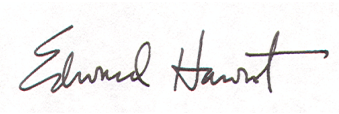
5. Promoting Data Governance, Security, and Public Accountability
Advance RI-CTR endorses the safeguards in Section 6.6, including required security assessments and breach notifications. We recommend RIDOH enhance accountability through annual public summaries of aggregate security assessments and corrective actions and by incorporating independent third-party or academic cybersecurity reviews. These steps will ensure ongoing protection, public confidence, and continual improvement in data governance.

6. Conclusion
Advance RI-CTR generally supports the modernization of the Health Information Exchange regulations. These updates will strengthen data integrity, privacy, and research utility across Rhode Island. However, without incorporation of these suggestions there is the possibility of real harm to the research environment in Rhode Island which will impact innovative and modern healthcare. We emphasize the critical importance of maintaining access to HIE data for qualified clinical and translational research. We believe it is critical to the health of Rhode Islanders to include these modifications to 216-RICR-10-10-6: Regional Health Information Organization.

We look forward to continued collaboration with RIDOH, the RHIO, and the HIE Advisory Commission to advance a secure, equitable, and research-ready health data infrastructure for the State of Rhode Island.

Sincerely,

Sharon Rounds, MD
Program Director, Advance RI-CTR
Associate Dean for Translational Science
The Warren Alpert Medical School of Brown University



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October 25, 2025

Rhode Island Department of Health
Office of Health Regulation
3 Capitol Hill
Providence, RI 02908

Re: Proposed revisions to 216-RICR-10-10-6 Part 6 – Regional Health Information Organization and Health Information Exchange

To whom it may concern:

Faculty from the Department of Pharmacy Practice and Clinical Research at the URI College of Pharmacy conduct applied health research addressing many of Rhode Island's priority public health issues using state datasets such as the All-Payer Claims Database, Medicaid data, and the Prescription Drug Monitoring Program. These efforts directly support the State's goals to improve healthcare quality, equity, and value; objectives that align with the purpose of the HIE regulation. We have reviewed the proposed revisions to 216-RICR-10-10-6, particularly Section 6.5.4 ("Requests for Confidential Healthcare Information for Analytic or Research Purposes"), and offer the following comments for your consideration.

§ 6.5.4(B)(1) (requiring BHDDH approval for data associated with providers licensed BHDDH). This establishes a dual-approval process for analytic or research use of HIE data involving facilities licensed by BHDDH, even though RIDOH already has authority over the HIE. As written, RIDOH would be unable to approve a request until BHDDH explicitly signs off, potentially delaying review without a clear added benefit. It is also unclear whether BHDDH has a defined process for external data review, or whether its criteria would align with RIDOH's. Because HIPAA, 42 CFR Part 2, and RIDOH's existing oversight already protect behavioral health data, this additional layer seems unnecessary. If the intent is to safeguard sensitive information, a consultation or notification process could achieve that goal without duplicative review.

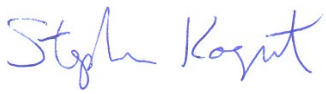
§ 6.5.D. (requiring data requests demonstrate a near-term benefit). This restriction conflicts with the statutory intent of R.I. Gen. Laws § 5-37.7, which authorizes RIDOH to use the HIE "to improve the quality, safety, and value of health care and to protect and promote the health of the people of Rhode Island," without limiting this mission to short-term objectives. The undefined term "near-term benefit" introduces ambiguity and could preclude studies that inform long-range health policy, workforce development, and prevention strategies. For example, longitudinal research on medication adherence, opioid prescribing, or chronic disease management may take several years to yield actionable findings. We recommend allowing flexibility to approve studies that advance long-term health priorities, equity objectives, or methodological innovations.

§ 6.5.4(E)(3) (Department review of any resulting outputs). This requirement could restrict the ability of provider organizations, health systems, and academic partners to conduct and disseminate internal quality-improvement (QI) analyses that rely on HIE data. While state

oversight is appropriate for external publication of research findings or public-facing reports, most QI activities are operational in nature and occur under HIPAA's definition of healthcare operations rather than research. Requiring Departmental pre-review of every report or presentation derived from HIE data may delay timely feedback loops essential to patient-safety and performance-improvement initiatives, and could discourage participation in data-driven improvement collaborations. We recommend clarifying that this provision applies only to formal research or public dissemination, and not to internal or collaborative QI work conducted under existing data-use agreements and privacy safeguards.

We appreciate the Department's commitment to protecting patient confidentiality and ensuring appropriate use of HIE data. We respectfully suggest that the final regulation balance privacy safeguards with the flexibility necessary for high-quality research, evaluation, and quality-improvement initiatives that serve Rhode Island's residents.

Sincerely,



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