## STATE OF RHODE ISLAND RHODE ISLAND DEPARTMENT OF HEALTH CONCISE STATEMENT OF PROPOSED NON-TEHCNICAL AMENDMENTS (AMENDMENTS TO EXISTING REGULATIONS)

In accordance with the Administrative Procedures Act, R.I. Gen. Laws § 42-35-2.7(b)(8), the following is a concise statement of proposed non-technical amendments *Regional Health Information Organization and Health Information Exchange (216-RICR-10-10-6)* 

	Information Exchange (216-RICR-10-10-6)
Section	Rationale/Summary of Change
Throughout	<ul> <li>Changed "confidential health information" to "confidential healthcare information"</li> <li>Changed "his/her" to "their"</li> <li>Changed "patient participant" to "patient"</li> </ul>
	Changed the following definitions to signpost to the statutory definition:
6.2(A)	<ul> <li>Authorized representative</li> <li>Business associate</li> <li>Confidential healthcare information</li> <li>Data-submitting partner</li> <li>Disclosure report</li> <li>Electronic mobilization</li> <li>Emergency</li> <li>Healthcare provider</li> <li>Healthcare services</li> <li>Health plan</li> <li>HIE Advisory Commission</li> <li>Patient</li> <li>Provider participant</li> <li>Regional health information organization or RHIO</li> </ul>
	Removed the following definitions:      Participant     Participation     Unanticipated event
6.2(A)(12)	Revised the definition of "Gender marker" to remove "sex or" and add "including sex or sex assigned at birth where a medical record does not separately distinguish these values."
6.2(A)(21)	Added definition of "Must."
6.2(A)(22)	Added definition of "Opt out"
6.2(A)(23)	Revised definition of "Opt out form" to:  • Change "patient participant" to "patient"  • Removes "permission for the RHIO to allow"  • Added "except as provided in § 6.3.1(A)(3)
6.2(A)(24)	Removed "at the RHIO" from the definition of "Patient matching"
6.2(A)(28)	Revised definition of "Public health authorities" to remove "a territory, a political subdivision of a state or territory"
6.2(A)(30)	Added definition of "Research" and defined it as "means as defined by HIPAA and its implementing Regulations (45 C.F.R. § 164.501)."
6.2(A)(31)	Changed "security event" to "security incident"
6.3.1(A)(1)	Changed "HIE" to "RHIO" and "signing" to "submitting"

6.3.1(A)(2)	<ul> <li>Revised as follows:         <ul> <li>Added "Data-submitting partners shall inform patients with whom they have an active direct treatment relationship, as defined by 45 C.F.R. § 164.501"</li> <li>Removed "Individuals shall be informed" and "through provider participants and other publicly available means"</li> </ul> </li> </ul>
6.3.1(A)(2)(a)	Added "Data-submitting partners are not required to inform patients of the opportunity to opt out with whom they have an indirect treatment relationship as defined by 45 C.F.R. § 164.501."
6.3.1(A)(3)(c)	Change "where" to "to the extent"
6.3.1(A)(4)	Added "Each provider participant shall maintain with the RHIO a current copy of its Notice of Privacy Practices and, if separate, the above-referenced opt out notice."
6.3.1(A)(4)	Removed section
6.3.1(A)(5)	Changed "RHIO's" to "HIE's" and "completed" to "validly submitted"
6.3.1(A)(6)	Removed "If there are remaining concerns or complaints after contacting the RHIO, individuals can contact the Department of Health "Health Information Line.""
6.3.1(A)(7)	<ul> <li>Added "and to the HIE," and changed "resolving" to "addressing their"</li> <li>Changed "will" to "must"</li> <li>Changed "RI HIE" to "RHIO and/or HIE"</li> <li>Added "any such" and "they receive"</li> <li>Added "any"</li> <li>Changed "will" to "shall"</li> <li>Removed sections (d), (e), (f), (g), (j), and (k)</li> </ul>
6.3.1(A)(7)(d)	Removed "written"
6.3.1(A)(7)(e)	Added "and the patient shall be informed of the current status and disposition of the complaint."
6.3.2(A)	Added "and RIDOH"
6.3.2(A)(1)	Changed "Participant" to "Patient" and removed "healthcare provider, health plan, and individual"
6.3.2(A)(4) and (6)	Sections removed
6.3.2(A)(7)	Changed "a person" to "individuals"
6.3.2(A)(9)(a)	<ul> <li>Removed "staff"</li> <li>Changed "review" to "ensure that"</li> <li>Changed "completed" to "submitted"</li> <li>Added "is reviewed"</li> </ul>
6.3.2(A)(11)	Added "and"
6.3.2(B)	Remove "utilize a committee structure that"
6.3.2(C)	<ul> <li>Changed "access" to "request and obtain from"</li> <li>Added "copies of"</li> <li>Added "from data-submitting partners, and, if separate, their data-submitting partners' opt out notices"</li> <li>Removed "which will be posted on the RHIO's websites. The Notice of Privacy Practices will be written in plain language and will contain applicable information such as: the uses and disclosures of PHI through the HIE, patient participants' individual rights, the RHIO's responsibilities regarding the privacy of patient participants' information and the complaint process."</li> </ul>
6.3.2(D) and (E)	Removed sections

6.3.2(D)	<ul> <li>Added "or HIE"</li> <li>Changed "RHIO" or "voluntarily dissolving entity"</li> <li>Changed "will give" to "must provide notice to"</li> <li>Removed "The Department has a contractual right of first refusal to purchase only the assets comprising the HIE at the appraised value."</li> <li>Added "at least" and "prior to the voluntary dissolution"</li> </ul>
6.3.2(E)	<ul> <li>Changed "either of the above" to "dissolution, either voluntary or involuntary,"</li> <li>Added "and HIE"</li> <li>Changed "the protected health information in its" to "any protected healthcare information in their"</li> <li>Added "to the extent such transfer is required of either entity"</li> </ul>
6.3.3(A)	Added "as defined in 45 C.F.R Part 160.103"
6.3.3(A)(1)	<ul><li>Changed to 6.3.3(B)</li><li>Changed "RHIO" to "HIE vendor"</li></ul>
6.3.3(A)(2) through (4)	Removed sections
6.3.3(A)(5)	<ul> <li>Changed to 6.3.3(C)</li> <li>Removed "end user"</li> <li>Changed "end user" to "provider participant accessing the data"</li> <li>Added "including R.I. Gen. Laws § 5-37.7-10."</li> </ul>
6.3.3(D)	<ul> <li>Relocated text from 6.4(F) and removed (8).</li> </ul>
6.3.5	Removed "when the patient's health information can be obtained from other sources"
6.4(A)	Removed section and relocated § 6.4(B) and revised wording
6.4(C)	Changed HIE Advisory Commission term length from two years to three years.
6.4(D)	Added "and HIE vendor"
6.4(E)	Removed "and shall not vote on any recommendations regarding the use of confidential health information unless a quorum is present."
6.4(F)	<ul><li>Added "Director of Health shall be informed by the"</li><li>Added "or HIE vendor"</li></ul>
6.4(G)	Replaced existing wording with "The HIE Advisory Commission shall review and provide recommendations to the Director or a representative of the Director on processes for reviewing requests for the confidential healthcare information contained within the HIE, and shall provide new recommendations when a request represents a novel purpose for using the confidential healthcare information."
6.4(H)	Removed "but not limited to"
6.5.1(A)(1)	<ul> <li>Removed "from the HIE by:"</li> <li>Removed sections (a) through (e)</li> </ul>
6.5.1(A)(2)	<ul> <li>Changed "The forms along with information about where to submit the form shall be publicly available through posting on the HIE website;" to "The RHIO shall provide instructions to request a disclosure report on its website"</li> </ul>
6.5.1(A)(2)(a)	Reworded for clarity and added "within sixty (60) days of the request, in accordance with applicable law."
6.5.1(A)(2)(b)	Changed "enrollee" to "requester" and added "The requester must be notified if the RHIO requires an additional thirty (30) days."
6.5.1(A)(2)(c)	Changed "history" to report"
6.5.1(A)(3)	Revised R.I. Gen. Laws citation

6.5.1(A)(4)	Removed "to the RHIO"
6.5.1(A)(4)(a)	Changed "HIE" to "RHIO"
6.5.1(A)(4)(c)	<ul> <li>Changed "HIE" to "RHIO"</li> <li>Removed "a multitude of"</li> </ul>
6.5.1(A)(4)(d)	Changed "consent decisions of any type" to "Opt-out forms" and "recorded or indicated" to "completed."
6.5.1(A)(5)	<ul> <li>Changed "completed" to "validly submitted"</li> <li>Changed "revoked" to "reversed"</li> <li>Added "The RHIO shall make"</li> <li>Added "publicly available"</li> <li>Changed wording to require the form and methods of reversing an opt out decision to be made available through the RHIO and by phone.</li> </ul>
6.5.1(A)(6)	<ul> <li>Reworded for clarity</li> <li>Changed "will" to "shall"</li> <li>Added "will receive a notification when the opt-out form becomes effective"</li> </ul>
6.5.1(A)(6)(a)	<ul> <li>Added "or HIE"</li> <li>Added "pursuant to R.I. Gen. Laws § 5-37.7-7(b)(1)."</li> </ul>
6.5.1(A)(7)	Changed "HIE" to "RHIO"
6.5.1(A)(8)	Removed "medical"
6.5.2	Added "system"
6.5.3	Removed section
6.5.3(A)	<ul> <li>Changed "or" to "and"</li> <li>Added "shall" and "as may be"</li> </ul>
6.5.3(B)	<ul><li>Added "or this Part"</li><li>Added "and HIE vendor"</li></ul>
6.5.3(C)	<ul> <li>Added "or this Part"</li> <li>Added "and HIE vendor"</li> <li>Added "pursuant to § 6.3.3(A)(5) of this Part"</li> </ul>
6.5.3(D)	<ul> <li>Added "and HIE vendor"</li> <li>Removed "requesting"</li> <li>Changed "participant's health" to "confidential healthcare"</li> </ul>
6.5.3(E)	<ul> <li>Removed "pursuant to § 6.5.1 of this Part"</li> <li>Removed "on forms which are provided by the RHIO"</li> <li>Changed internal citation</li> <li>Removed "Requests to opt out from the HIE shall be made in accordance with § 6.5.1(A)(6) of this Part."</li> </ul>
6.5.5	Removed section
6.5.4	Added section titled "Requests for Confidential Healthcare Information for Analytic or Research Purposes"
6.6, 6.7, and 6.8	Sections deleted