STATE OF DELAWARE
STATE COUNCIL FOR PERSONS WITH DISABILITIES
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The Honorable John Carney
Governor

John McNeal
SCPD Director

MEMORANDUM

DATE: October 29, 2021

TO: Scott Perkins
Delaware Health Information Network

FROM: Terri Hancharick – Chairperson TH
State Council for Persons with Disabilities

RE: 25 Del. Register of Regulations 252, 257 and 259 [Proposed DHIN Regulations on Participation and Use of Clinical Data (September 1, 2021)]

The State Council for Persons with Disabilities (SCPD) has reviewed the Delaware Health Information Network's (DHIN) proposed amendments which, in part, implement changes to the DHIN's enabling statute (SB 88) signed by the Governor on September 10th. Numerous bills have been introduced since the Joint Legislative Oversight and Sunset Committee (JLOSC) issued recommendations based on its review of the DHIN, which concluded in 2020, seeking to implement those recommendations. SB 88 specifically updated provisions in the DHIN's enabling statute to more clearly allow for the sharing of certain clinical data "for appropriate analytic and public health purposes," according to the Synopsis of the bill as introduced. SCPD has the following observations.

101 Delaware Health Information Network Regulations on Participation and Use of Data

The proposed amendments to this section of the regulations strike all of the existing text, which pertains to the governance and administration of the DHIN. The new proposed

regulations relate to participation in the DHIN and permitted uses of data, which are governed by section 102 of the existing regulations.

The proposed regulations would require that "Data Sending Organizations" comply with all submission standards established by the DHIN, and that establish that such standards would be published on the DHIN's website. The proposed regulations also state that data that would be subject to legal disclosure restrictions beyond what is dictated by the Health Insurance Portability and Accountability Act ("HIPAA") should not be sent to the DHIN until an appropriate data use agreement is in place. The proposed regulations also make clear that Data Sending Organizations must authorize certain specific uses for the data shared with DHIN so that DHIN can satisfy its other obligations and requirements, including but not limited to "public health activities and reporting" and "research or analytic purposes" (see proposed regulations at 3.2). The DHIN may also use data for other purposes "if permitted by the Board and its agreements with relevant Data Sending Organizations" and "if such uses are permitted by the Act and relevant law" (see proposed regulations at 3.3).

The regulations would also require that "Data Receiving Organizations" and any users affiliated with the Data Receiving Organizations follow DHIN Data End User Agreement. The specific permitted use cases contemplated by the regulations and governed by the DHIN Data End User Agreement are "[t]reatment, payment, health care operations, and authorization-based disclosures as all of those terms are defined by HIPAA," "[p]ublic health activities and reporting," and "[t]o permit Data Receiving Organizations and their Users to fulfill their respective legal requirements" (see proposed subsection 4.2). The regulations also state that the DHIN may contract with Data Receiving Organizations for other uses of its data, "in its discretion and subject to approval of the board" (see proposed subsection 4.3), so long as such uses are otherwise legally permissible.

The proposed regulations also clarify how individual patients may access their information and direct the use of their information. The existing regulations simply state that individual patients may be provided with access to their information contained in the DHIN, subject terms and conditions established by the Board, and "shall be informed of and may choose to preclude a search of their individual health information" (see existing regulations at subsection 7.2). The proposed regulations add language to make clear that patients may authorize the disclosure of their information to third party through the DHIN subject to the requirements of HIPAA, and more specifically require that individual patients must have the choices to opt out of their information being searchable in the DHIN and to opt back in at any time, and that information regarding the procedures for and implications of opting out be published on the DHIN's website.

The proposed regulations also discuss the mechanisms for dispute resolution, including the operations of a Dispute Resolution Committee, which is already established per the existing regulations. The language of the proposed regulations for this subsection appears to be identical to the existing regulations.

The proposed regulations generally add emphasis that all provisions regarding the disclosure of data are subject to the requirements of HIPAA and Delaware law, however outside of this limitation, the proposed regulations give the DHIN and its Board a great deal of discretion to articulate the terms, conditions, and standards under which entities or individuals participate in or access the DHIN. That is consistent with the existing regulations. The procedures and standards used by the Dispute Resolution Committee are also largely left up to the DHIN Board.

The stricken provisions from the existing Section 101, which primarily covered the operations of the DHIN Board, do not appear to be replaced in another subsection. The enabling statute contains some language regarding composition of the Board but does not go into as much detail regarding the Board's operations and committees, though presumably the Board's by-laws would contain some more specific requirements.

102 Delaware Health Information Network Regulations on Use of Clinical Data for Approved Analytic Purposes

The proposed amendments to this section of the regulations also strike all existing text (many of the provisions under this section in the existing regulations would be included under Section 101 of the proposed regulations). The new proposed regulations relate to the use of DHIN's clinical data by third parties for approved research purposes, which are not covered in detail by the existing regulations.

The proposed regulations make clear that available clinical data that is part of the DHIN may be disclosed to third parties for the following approved purposes: "[f]acilitating data-driven, evidence-based improvements in access to and quality of health care;" "[i]mproving the health of Delawareans generally"; "lowering the growth in per-capita health care costs;" and "[p]roviding enhanced provider experience that promotes patient engagement" (see proposed regulations at subsection 3.0).

The regulations would create a Clinical Data Access Committee that would review requests for access to available clinical data for approved research purposes. A separate committee already exists to oversee the disclosure of data from the Health Care Claims Database specifically (see further information in the discussion of Section 104 below). Per the definition of the Clinical Data Access Committee in the proposed regulations, this new Committee could either be a separate committee or be combined with the existing Health Care Claims Database Committee. Under the proposed regulations, the Committee would consist of five to eleven members. The members "shall be representative of various stakeholder groups, including, where possible, consumers, employers, health plans, hospitals, physicians, ACO Administrators, researchers, and State government." This mirrors language in the existing regulations for the Health Care Claims Database Committee.

Requests for access to available clinical data would need to be submitted to the Committee in a written application form to be developed by the Committee. Information to be provided in the application would include the intended use of the data, justification

of the request, and an explanation of the "security and privacy measures" to be taken by the applicant to protect the data if disclosed by the DHIN. The DHIN must notify a Data Sending Organization "when an application is received for a limited data set or identified data containing Available Clinical Data that was submitted to DHIN by that Data Sending Organization," and provide ten days for the Data Sending Organization to provide written comments relating to the request.

The Committee shall consider each application and related comments from Data Sending Organizations as applicable and must approve each application by a majority vote. According to the proposed regulations the Committee has the discretion to request additional information from the applicant as needed to inform its decision. The Committee may also ask for an applicant "to acquire Institutional Review Board review" (see proposed regulations at 4.5). Information regarding applications received by the DHIN for access to clinical data as well as the Committee's decision on the application would be published on the DHIN website. According to the regulations, decisions by the Committee would not be appealable. Additionally, the DHIN may not disclose identified clinical data without written consent from the individual patient, and all re-disclosure of data must be approved by the Committee.

The proposed regulations make clear that Data Sending Organizations do not need to submit an application to access their own data previously submitted to the DHIN. Additionally, in some circumstances, de-identified data or analysis of de-identified data may be released without Board of Committee review (see proposed subsection 3.3) and the DHIN may publish its own reports based on de-identified data or analysis of de-identified data without the approval of the Committee.

The proposed regulations also contain additional provisions regarding data use for applicants who are approved for data access, including the execution of a legally binding data use agreement and steps that may be taken if an approved user violates the terms of the data use agreement. The proposed regulations also permit the DHIN to charge a reasonable fee for the use and storage of data.

As a process already exists for authorizing disclosure of data from the Health Care Claims Database, it makes sense for a similar process to exist to regulate access to other clinical data stored by the DHIN that may be requested for approved research purposes. As the process to be used by the Clinical Data Access Committee mirrors that already used by the Health Care Claims Database Committee, there would be relative consistency in how decisions are made about disclosure of other clinical data versus data from the Health Care Claims Database.

One notable difference between these proposed regulations and the existing regulations regarding the disclosure of data from the Health Care Claims Database at Section 104 is that under Section 104, more allowances are made for Collaborating State Agencies to use and re-disclose data contained in the Health Care Claims database, and the regulations are clear that data will be provided to Collaborating State Agencies at no cost. These provisions were not included in the proposed regulations for disclosure of other

clinical data under Section 102. That could be due to the broader nature of clinical data potentially available, but that difference is not explained in the summary included with the proposed regulations.

104 Delaware Health Care Claims Database Data Access Regulation

The proposed amendments to this section of the regulations contain revisions to the existing text, which describes the rules for access to data contained in the Delaware Health Care Claims Database. The proposed amendments to this section primarily consist of non-substantive wording and formatting changes. The proposed amendments do clarify that Reporting Entities must be notified of any applications to access claims data regardless of whether Committee review is required (see proposed regulations at subsection 5.1). Additionally, the proposed amendments add language that states that in circumstances where Committee review is not required by the enabling statute or regulations, DHIN staff shall consider the same information that would be considered by the Committee in making a decision about approving disclosure of data and may still ask for Institutional Review Board review (see proposed regulations at subsection 4.7).

While the relevant provisions are slightly re-worded and re-organized, the proposed amendments do not change the requirement that access to data sets from the Health Care Claims Data Base be provided to "collaborating state agencies" free of charge. As defined in the DHIN's enabling statute, "collaborating state agencies" includes the State Council for Persons with Disabilities (SCPD).

The proposed amendments to Section 104 do not appear to make any major substantive changes to the existing regulations or the prescribed procedures for requesting and authorizing access to data from the Health Care Claims Database. The one provision that may be of some concern is that depending on the volume of requests for data that do not require Committee review, imposing similar standards to be utilized by DHIN staff for those requests could lead to some inconsistent application of those standards, however it may otherwise make sense to provide a clearer framework for decisions on applications not requiring Committee review.

Thank you for your consideration and please contact SCPD if you have any questions regarding our observations on the proposed regulation.

cc: Ms. Laura Waterland, Esq.
Governor's Advisory Council for Exceptional Citizens
Developmental Disabilities Council

25 reg 252, 257, 259 DHIN 10-29-21