



STATE OF DELAWARE
STATE COUNCIL FOR PERSONS WITH DISABILITIES
Margaret M. O'Neill Bldg., Suite 1, Room 311
410 Federal Street
Dover, Delaware 19901
302-739-3621

The Honorable John Carney
Governor

John McNeal
SCPD Director

December 18, 2017

Dr. Jan Lee
Chief Executive Officer
Delaware Health Information Network (DHIN)
Delaware Health Information Network
107 Wolf Creek Blvd.
Suite 2
Dover, DE 19901

RE: 21 DE Reg. 463 [DHIN Proposed Health Care Claims Database Data Access Regulation
(12/1/17)]

Dear Dr. Lee:

The State Council for Persons with Disabilities (SCPD) has reviewed the Department Health Information Network (DHIN) proposal to adopt standards defining “the allowable purposes for access to claims data, the process by which a request for access to claims data will be reviewed and evaluated, and factors that will be considered in granting or denying such requests.” The proposed regulation was published as 21 DE Reg. 463 in the December 1, 2017 issue of the Register of Regulations.

The Delaware Health Information Network (DHIN) is a quasi-public entity established by 16 Del.C. Ch. 103 to maintain a community-based health information network. Its enabling statute lists twenty-one (21) powers and duties of the DHIN ranging from acquisition and compilation of data to facilitation of health research. See 16 Del.C. §§10303 and 10311. At 463.

Overall, the structure of the standards is both logical and internally consistent. The standards also generally conform to the enabling law. However, the SCPD has the following observations which may prompt consideration of some revisions.

First, §2.0. Definitions, could be improved. The predicate describing a defined term varies as follows:

“means”; “shall mean”; “refers”; “shall refer”; and “includes”. The Delaware Administrative Code Drafting and Style Manual counsels that the predicate should uniformly be “means”. See attached §4.3. The DHIN may wish to edit this section to conform to the Manual.

Second, in §2.0, the definition of “mandatory reporting entity” is generally based on 16 Del.C. §10312(4). However, unlike the statute, the proposed regulation does specifically refer to Medicare Parts C and D while omitting a reference to Medicare Parts A and B. For internal consistency, the DHIN could consider a revision to specifically refer to Medicare Parts A and B.

Third, in §2.0, the definition of “mandatory reporting entity” generally conforms to the enabling statute, 16 Del.C. §10312(4). However, it omits some programs which could logically be included. For example, it omits Division of Public Health programs such as the cancer treatment program (16 DE Admin Code 4203) which provides medical insurance coverage for cancer treatment. The DHIN may wish to consider whether the regulatory definition could be expanded.

Fourth, §2.0, the definition of “provider” is based on 16 Del.C. §10312. However, the DHIN could consider substituting “designated” for “designed”. It is possible that the statutory reference to “designed group of beneficiaries” was an inadvertent typographical error.

Fifth, as noted above, in §2.0, the definition of “provider” is based on 16 Del.C. §10312. However, the definition may literally exclude the Veterans Administration from participating in the DHIN since it is not “licensed, certified, or authorized under State law”. Perhaps this is intended. If the V.A. does participate in the DHIN, this may merit regulatory clarification and/or a revised definition of provider.

Sixth, §7.2 lists agencies which will be exempt from fees. It is based on 16 Del.C. §10314(c). Although the entire Department of Health & Social Services (DHSS) is a DHIN partner [16 Del.C. §§10311(c) and 10315(c)], only two divisions are listed as exempt from fees (DMMA and DPH). The DHIN could consider, consistent with §7.3, creating a categorical fee exemption for DSAMH, DDDS, and DSAAPD. Indeed, they could be listed in §7.3.

Seventh, §8.0 merits revision. The proposed regulation limits action on DHIN violations to the following: 1) revocation of permission to use data; and 2) civil remedies. In contrast, the statute [16 Del.C. §10307(c)] envisions mandatory reporting to the Attorney General for consideration of criminal action. A reference to the statutory reporting should be included in the regulation. In its discretion, the DHIN could also consider adding the following option:

8.1.3 Issue a referral to a licensing or accreditation body.

See 24 DE Admin Code §1700.17.13 and 24 DE Admin Code §1900.10.4.

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

Sincerely,



Jamie Wolfe, Chairperson
State Council for Persons with Disabilities

cc: The Honorable Matthew Denn, Attorney General
The Honorable Kara Odom Walker, DHSS
Mr. Brian Hartman, Esq.
Developmental Disabilities Council
Governor's Advisory Council for Exceptional Citizens
21reg463 dhin health care claims database data access 12-11-17

- Place more important provisions before less important provisions;
- Place frequently used provisions before less frequently used provisions; and
- Place permanent provisions before temporary provisions.

4.3 Definitions (See Figure 4.1)

It is recommended that definitions of terms be included in each regulation. Definitions provide clarification of terms used within a regulation, save space in the body of the regulation, and allow the regulation writer to control the meaning of a word. Define a term only when the meaning of a word is important and it is used more than once in the regulation. Do not define ordinary words that are used in their dictionary context.

Regulatory information should not be included in the definition.

Example of a Definition that is Too Substantive:

"Lockup facility" means a secure adult detention facility used to confine prisoners waiting to appear in court and sentenced prisoners for not more than 90 days. In addition to the cell, a lockup facility must include space for moderate exercise and activity, such as weight lifting, ping-pong, table games, reading, television, and cards.

This definition should end at "90 days."

Definitions should be formatted as provided in this section.

- Place definitions at the beginning of the regulation as one of the first numbered sections (following a scope, purpose, or authority section).
- The first paragraph should read, "The following words and terms, when used in this regulation, have the following meaning unless the context clearly indicates otherwise:"
- Arrange the words or specific terms being defined in alphabetical order.
- Do not number individual definitions.
- Capitalize the first letter of the first word in each definition (since it is the beginning of a sentence). All subsequent words in each definition should be lowercase, unless words are proper nouns. The word or term being defined should be placed within quotation marks and in bold font.
- Immediately after the defined word or term, insert the word "means".
- Avoid using dashes, slashes, or parentheses in a term being defined. For example, use "Individualized education plan" or "IEP" means... instead of "Individualized education plan (IEP)" means....

Figure 4.1

EXAMPLE:

2.0 Definitions

The following words and terms, when used in this regulation, have the following meaning unless the context clearly indicates otherwise:

"Adoptive parent" means a provider who gives parental care and establishes permanent family relationships for children in the provider's home for purposes of adoption.

"Adult" means an individual 18 years of age or older.

"Agency" means the local welfare or social services agency.