	Rule Section	Feedback Received	Response	Submitted by:
1	2. Definitions	Reference the definition for each term in Section 2.0 of CDR 1-100-103 in this rule to ensure consistency among interpretations and help ensure that any future revisions are not unintentionally missed if part of the HCCD regulation is revised but another is not.	Add underlined language: The following words and terms, when used in this regulation, have the <u>same meaning as those in CDR 1-100-103 §2.0,</u> unless the context clearly indicates otherwise.	United
2		Edit definitions for consistency around the word "means." Definition uses several forms "means"; "shall mean"; "refers"; "shall refer"; and "includes". The Delaware Administrative Code Drafting and Style Manual counsels that the predicate should uniformly be "means". The DHIN may wish to edit this section to conform to the Manual.	The rule has been edited to standardize the use of the word "means."	SCPD and GACEC
3		Change definition of "Clinical Proxy Data Elements" to exclude patient identifiers, if appropriate.	Patient identifiers are needed to ensure accurate matching of records. Clinical Proxy Data Elements will be displayed in clinical applications, such as the Community Health Record or a patient's Personal Health Record, in which patient identifiers are critical to the function of the clinical application.	HM
4		Expand the definition of Collaborating State Agencies to include the DHSS/all state agencies.	No change; this definition follows the statute	OSEC
5		Revise definition of "de-identified data" as follows: "Any other unique identifying ~~numbers~~ <u>characteristic or code</u>."	Change accepted; aligns with HIPAA.	HM
6		Add definition of "Health Insurer" – "means as defined in 16 Del.C. §10312."	Added to definitions.	HM
7		Revise the definition of Mandatory Reporter to include a specific reference to Medicare Parts A and B.	No change. Delaware purchases Medicare Parts A and B data from the Centers for Medicare and Medicaid Services for the express purpose of the HCCD. State regulatory action on a federal agency is not binding. Payment data for Medicare Parts C and D are available only from commercial insurers. Therefore, the	SCPD and GACEC

	Rule Section	Feedback Received	Response	Submitted by:
			rule establishes that Medicare Advantage plans and Medicare Prescription Drug plans are mandatory reporting entities.	
8		Expand the definition of "Mandatory reporter" to include all state programs that make medical payments.	No change. "Mandatory Reporting Entity" is defined in Title 16 Chapter 103 §10312(4). The DHIN may accept voluntary data submissions upon signing of appropriate data submission and use agreements. The DHIN will consult the Division of Public Health to identify potential additional public paid data sources to learn whether the format of such data is compatible with the HCCD and to determine the benefit of including such information in the database.	SCPD and GACEC
9		Change the definition of Limited Data Set to mirror HIPAA language on geographic subdivisions.	Proposed revision inserts the full definition of Limited Data Set: Add all: "Limited Data Set" means PHI that excludes 16 categories of direct identifiers and may be used or disclosed, for purposes of research, public health, or health care operations, without obtaining either an individual's Authorization or a waiver or an alteration of Authorization for its use and disclosure, with a data use agreement. The following data elements are removed from a Limited Data Set: • Names. • Postal address information, other than town or city, state, and ZIP Code. • Telephone numbers. • Fax numbers. • Electronic mail addresses. • Social security numbers. • Medical record numbers. • Health plan beneficiary numbers. • Account numbers. • Certificate/license numbers. • Vehicle identifiers and serial numbers, including license plate numbers. • Device identifiers and serial numbers.	HM

	Rule Section	Feedback Received	Response	Submitted by:
			• Web universal resource locators (URLs). • Internet protocol (IP) address numbers. • Biometric identifiers, including fingerprints and voiceprints. • Full-face photographic images and any comparable images. A Limited Data Set may include: • city; state; ZIP Code; • elements of dates; • other numbers, characteristics, or codes not listed as direct identifiers	
10		Clarify that definition of Member includes out-of-state residents only for State Employee group members."	No change; the intent is to include all state employees and retirees Members regardless of residence. Medicaid and Marketplace plan Members are Delaware residents.	HM
11		The definition of "provider" includes a typographical error.	The typographical error has been corrected in the revised draft.	SCPD and GACEC
12		The definition of "provider" excludes the Veterans Administration from participating in the DHIN [*sic*].	No change. The Veterans Administration is a payer for health care services and may participate in the HCCD as a "voluntary reporting entity." If the Veterans Administration is willing to submit data to the HCCD, the VA and the DHIN may enter into a data submission and use agreement.	SCPD and GACEC
13	3. Access	Revise 3.2 to include underlined language: 3.2 The DHIN may provide HCCD data or data access at the following levels of detail, per the procedures established in this Regulation <u>and applicable sub-regulatory guidance</u>:	No change.	HM
14		3.3.2. DHIN should establish a process so Members can access their own Clinical Proxy Data Elements.	DHIN has such a process, and the language of the regulation will be revised to reflect that. 3.3.2 DHIN may make HCCD Clinical Proxy Data Elements available to the Members to whom they apply without ~~a written application or~~ Committee review. <u>Members may access their</u>	SCPD and GACEC

	Rule Section	Feedback Received	Response	Submitted by:
			health data by enrolling in DHIN's Personal Health Record on the DHIN website at www.dhin.org.	
15		Revise 3.3 as follows: 3.3 Except as otherwise specified in this Regulation, all requests for HCCD data or data access shall require ~~a~~ completion of a written Data Request Application that describes the intended purpose and use of the data, the justification for the data request, and the security and privacy measures that will be used to safeguard ~~the data~~ and prevent unauthorized access to or use of the data as well as such other acknowledgments as may be included on the Data Request Application.	Change accepted.	HM
16		In Section 3.3.1, define Community Health Record, including who may access it and for what purposes.	The following will be added to the Definitions section of the regulation: **"Community Health Record " or "CHR"** means a searchable online portal that presents authorized users with a view of a patient's aggregated clinical data from all sources that contribute health data to DHIN. Access to patient records in the Community Health Record is on the basis of an established relationship between the patient and the end user for purposes of Treatment, Payment, and Operations, as those terms are defined in the HIPAA regulations, for Public Health purposes as defined in the HIPAA Privacy Rule, or by patient consent or patient request. Patients can opt out of allowing their CHR data to be searchable by anyone who was not the ordering Provider, but may not opt out of reporting required by law or regulation, such as, but not limited to, reporting of certain conditions to the Division of Public Health.	DHA, HM
17		Section 3.3.4 should state that the interagency agreement between the DHIN and the state agency is	No change. The agreement is between organizations, not the leaders who represent and have	OSEC

	Rule Section	Feedback Received	Response	Submitted by:
		between the DHIN's Chief Executive Officer and the Collaborating State Agency's Director/Secretary.	signature authority for those organizations.	
18		Section 3.3.4.1. should require that Collaborating State agencies are bound by HIPAA and all of the DHIN's more stringent requirements.	No change; the current language references DHIN's existing confidentiality and security protocols and all applicable state and federal laws, which include HIPAA and HITECH protections.	HM
19		Section 3.4, requests from health care providers for their own data should not require committee review."	The following paragraph is added: 3.3.5 Requests from Providers for their own data, as submitted by Reporting Entities, will not require Committee review.	DHA
20	4.0 Committee	Sections 4.1., 4.2 should be more specific about the Committee membership. Generally (no specific suggestions): OSEC, DHA United: include representatives of at least two (2) mandatory reporting entities, one (1) of which is a national payer with experience submitting data to other claims databases.	DHIN will strive for broad stakeholder representation on the HCCD Committee, but since Committee members serve on a voluntary basis, there is a risk of being unable to recruit participation from every desired category. In order to ensure that the Committee can function without violating an overly prescriptive regulation, the language will be amended as follows: 4.2 The Committee shall be comprised of five (5) to eleven (11) members and shall be representative of various stakeholder groups, including, where possible, consumers, employers, health plans, hospitals, physicians, researchers, and State government	United, OSEC, DHA
21		In Section 4.3, require annual updates to the Committee's business rules rather than "periodic" as currently written.	No change; annual updates should not be required once the process is established.	HM
22		Revise Section 4.4 grammar and eliminate restated requirements.	Changed as follows: 4.4 The Committee shall consider any comments received from Reporting Entities whose Claims Data is being requested. The Committee shall approve an application by majority vote after	OSEC

	Rule Section	Feedback Received	Response	Submitted by:
			finding the following: 4.4.1 The intended use is consistent with the statutory purpose of the HCCD. 4.4.2 Access to the requested data is necessary to achieve the intended goals, including but not limited to the need for identifiable data, if requested. 4.4.3 the request complies with all applicable state and federal laws relating to the privacy and security of PHI. 4.4.4. The request complies, to the fullest extent practicable, with guidance found in Statement 6 of the Department of Justice and Federal Trade Commission Enforcement Policy regarding the exchange of price and cost information. 4.4.5 The applicant is qualified to serve as a responsible steward of the requested data.	
23		In Section 4.4, the DHIN should set a higher standard than the majority vote required in law and specify that a 2/3 majority vote is required to approve an application.	No change, the law establishes the requirement.	HM
24		In section 4.4., the Committee's decision should include any other issues deemed relevant by the Committee.	No change; the existing language covers the range of issues that should be considered.	DHA
25		In section 4.4, the Committee should document the reasons for its decisions.	The following language is added: 4.6 <u>After a decision is reached by the Committee, public notice will be posted on the DHIN website that an application for data access was received, by whom it was submitted and for what purposes, and the decision of the Committee to grant or deny the application.</u> The final determination of the Committee shall not be subject to appeal.	OSEC

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26		In Section 4.4.4, the Committee should be required to consider the substance of any comments received from Reporting Entities in deciding whether to approve an application.	Agreed. Revised language for Section 4.4 is given in line 22 above.	HM, OSEC
27		DHIN should release only de-identified data.	No change. There may be legitimate requests for identified data that are consistent with the statutory purposes of the HCCD. Paragraph 4.4 and its sub-sections and paragraph 4.5 provide for appropriate oversight when identifiable data is requested.	AHIP
28		If a provider objects to an approved data release application, then the Committee should provide a written justification and an in-person meeting with the provider. (DHA)	No change. The Committee has sole authority to determine whether an application meets established criteria for approval and achieves the HCCD's goals (section 1.2), which includes working towards the Triple Aim and supporting innovation in Delaware. The Committee will provide for transparency of decision making as described in line 25 above.	DHA, HM
29	5. Applications for Data	Post all data release applications online and allow public comment for at least 20 days (DHA)/30 days (HM) following the online publication of a data release application to enhance the transparency and public trust of the database's use of individual health data that it collects. Information on applications submitted and the Committee's final decision (approved, denied, or revisions requested) [should] be publicly posted	In the interest of public transparency, DHIN will post public notice of: • Allowable uses of Claims Data by Collaborating State Agencies as defined in interagency agreements. Section 3.3.4 will have the following sentence added: <u>The allowable uses of Claims Data by Collaborating State Agencies will be posted on DHIN's web site for public transparency.</u> • The nature of applications for access to Claims Data and the decision of the Committee – see line 25 above. • A yearly summary of disclosures of Claims Data. The following language is added: <u>3.6 DHIN will post an annual summary of disclosures on its website.</u>	United, HM DHA

	Rule Section	Feedback Received	Response	Submitted by:
			The Committee will not include a period of public comment prior to its deliberations.	
30		Section 5.2.1 Description of Data Use Agreement should stipulate compliance with HIPAA.	No change; the current language references DHIN's existing confidentiality and security protocols and all applicable state and federal laws, which include HIPAA and HITECH protections.	HM
31		New Sections in Description of Data Use Agreement: 5.2.5 Confirmation of compliance with all statutory and regulatory requirements; 5.2.6 Such other terms as required by DHIN for the purpose of assuring DHIN's objectives and standards.	Paragraph 5.2.5 will be added as recommended. Paragraph 5.2.6 will not be added. The current language allows for DHIN to add requirements to the Data Use Agreement.	HM
32	6. Public reports	Define "aggregation;" it should not allow sensitive information (including pricing methodologies) to be inferred and therefore disclosed from the summary data.	Section 6.2.3 will be added as follows: 6.2.3 Follow guidance found in Statement 6 of the Department of Justice and Federal Trade Commission Enforcement Policy regarding the exchange of price and cost information.	DHA, HM
33		Add a definition of "re-disclosure requirements" noted in 6.1. and 3.3.4.2	Change accepted. Retitle Section 6: ~~Public Reports and~~ Re-disclosure Requirements Add a definition of "re-disclosure" to the Definitions: **"Re-disclosure"** means the publication, distribution or other dissemination of Claims Data released to an Approved User using any medium and in any format,	HM

	Rule Section	Feedback Received	Response	Submitted by:
			context or structure.	
34	7.Fees	In section §7.2 the DHIN should exempt DSAMH, DDDS, and DSAAPD from paying fees.	No change. The designated Collaborating State Agencies are exempted by statute from a requirement to pay fees for access to HCCD Claims Data. Section 7.3 allows for reduction or waiving of fees "including but not limited to" certain organizations. This allows the DHIN to consider reducing or waiving fees to state agencies in addition to those named in section 7.2.	SCPD and GACEC
35		In section §7.1 add language "and such other costs or fees as DHIN determines necessary."	Change accepted	HM
36	8.0 Penalties	Remedies for violating Data Use Agreement terms and conditions are too narrow.	Change accepted. The following paragraphs will be added: 8.1.3. Notify the requester's licensing body, if any, and if none, its accreditation body 8.2 If the violation pertains to access or misuse of the data, the DHIN shall report the violation to the office of the Attorney General, pursuant to 16 Del.C. §10307(c).	SCPD,GACEC, HM
37	General	The statute requires DHIN to consult with the Health Care Commission on data release regulations and the "appropriate form and content of an application to receive claims data."	• The draft regulation was submitted to the members of the Health Care Commission at its meeting on Dec 7, 2018. • The Executive Director of the Health Care Commission is currently a member of the DHIN Board of Directors, and was included in the working group of the DHIN board that drafted the language of this regulation and the sub-regulatory documents, "Data Access Application" and "HCCD Data Use Agreement." • The log of public comments and proposed responses	OSEC

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			was provided to members of the Health Care Commission on Feb 1, 2018. • The Data Access Application and Data Use Agreement are sub-regulatory documents, and DHIN will continue to collaborate with the Health Care Commission on the form and content of these documents.	