DELAWARE DATA ACCESS REVIEW COMMITTEE

Committee Structure and Business Rules for Reviewing Data Requests

The Delaware Health Data Access Review Committee, DARC will abide by the following committee structure requirements and business rules for reviewing clinical and claims data requests. Requests for information from the Healthcare Claims Database, HCCD is governed by a separate set of regulations until name change is approved by the DHIN Board, (voted approved on 4.29.2024) and Data Access Review Committee is stood up.

Structure and Duties of the Committee

1. The Committee shall have a chairperson and members appointed by the DHIN Board of Directors.
2. The Committee shall be comprised of a minimum of seven (7) to a maximum of eleven (11) voting members and shall be representative of various stakeholder groups who contribute and use clinical and claims data, including, where possible, consumers, employers, health plans, hospitals, physicians, ACO administrators, researchers, and State government.
3. The Committee shall consider any comments received from the DHIN data sender whose data is being considered requested unless the application is one which, pursuant to the enabling legislation or committee rules, does not require committee consideration and response, in which case DHIN will provide the review and response to any such commentary.
4. The Committee shall approve an application by majority vote after finding the following:
    a. The intended use is consistent with the statutory purpose of the clinical and claims data;
    b. Access to the requested data is necessary to achieve the intended goals, including but not limited to the need for identifiable data, if requested;
    c. The request complies with all applicable state and federal laws relating to the privacy and security of PHI;
    d. Where comments were received from data sending entities who's clinical and claims data is being requested, those comments have been satisfactorily addressed, if applicable;
    e. The applicant is qualified to serve as a responsible steward of the requested data.
5. The Committee reserves the right to ask an applicant to acquire Institutional Review Board review, or its equivalent, prior to approving an application.
6. The Committee may ask for any information or assurances from a requesting party that it determines, in its discretion, may be needed in order to evaluate the application.

Committee Member Obligations

1. Committee members shall vote on whether applications for clinical and claims data should be approved. Determinations for providing clinical and claims data to a requesting party will be made based on the majority vote of those Committee members present.

2. All Committee members shall be required, upon their appointment and on an annual basis thereafter, to sign a conflict-of-interest statement on the form approved by the DHIN Board of Directors.
3. All new Committee members will receive an orientation that includes:
    a. Training on the protection of patient privacy and data security, including the federal Health Insurance Portability and Accountability Act; Titles XIX and XXI of the Social Security Act; the Health Information Technology for Economic and Clinical Health (HITECH) Act, and all other applicable state and federal laws relating to the privacy and security of protected health information;
    b. Training on the DHIN conflict of interest statement;
    c. Training on the legal framework and statutory purpose for DHIN and the Regulations governing access to clinical and claims data in DHIN's data repository.
4. Unless the DHIN by-laws say otherwise, each member the Committee continues as such until his or her successor is appointed, unless the committee is sooner terminated, or until his or her earlier death, resignation, or removal. All non-Director members of any committee may be removed by the Board Chair with the consent of a majority of the Board.
5. Unless the DHIN by-laws say otherwise, a Committee member who misses more than 3 consecutive meetings, or more than half of the meetings in any given year, will be subject to removal by the DHIN Board of Directors unless the Board re-instates the Committee member by majority vote.

Role of DHIN Staff

1. In advance of the Committee's review of an application, DHIN staff will perform the following administrative tasks:
    a. Review clinical and claims data access applications to ensure all required sections are complete; the type of data requested is available in the DHINS clinical and claims data repositories and aligns with DHIN's statutory purpose; and the applicant's responses are clear and legible;
    b. Inform the applicant of the date and time of the Committee meeting during which his/her application will be reviewed, and encourage them to attend;
    c. Notify all Reporting Entities or Data Senders whose data is being requested in the application. The notification shall include but need not be limited to a summary of the request; the specific clinical and claims data element(s) being requested; and the name of the requestor;
    d. Consolidate all written comments received from notified Reporting Entities;
    e. Draft an agenda for the Committee meeting, for approval by the Committee chairperson.
2. DHIN staff will serve as the facilitator and secretary for all Committee meetings. Unless specifically appointed as Committee members, DHIN staff will not be considered Committee members and will not vote on applications.
3. Following the Committee's review of an application, DHIN staff will communicate the Committee's decision to the applicant:
    a. If the application is approved, staff will work with the applicant to collect a signed data

use agreement, DUA and analytics service agreement, ASA, outlining fees and other contractual obligations not defined in the DUA, if applicable;

b. If the application is approved with conditions, or requires edits or clarifications, DHIN staff will notify the applicant of the request and/or conditions and ensure these are addressed before moving forward with next steps;
c. If the application is found unsatisfactory by the Committee, DHIN Staff will send a list of major deficiencies identified by Committee members to the applicant. The applicant may make revisions and re-apply at a later date, up to a maximum of 3 total re-submissions

Meetings of the Committee

1. The meetings of the Committee shall be held at the principal office of the DHIN or virtually via video-conference web-based services as and if permitted by State of Delaware Open Meeting rules (e.g. Zoom, Google Meet, Microsoft Teams, etc.) or at any place within the State of Delaware that the Committee may from time to time designate.
2. Regular meetings of the Committee shall be scheduled monthly or whenever called by the Chairperson.
3. The Committee shall conduct its business through in-person meetings, or meetings may be convened by video-conference or other alternative means, as may be required under special circumstances as determined by the Chairperson, and as is consistent with Delaware's Freedom of Information Act.
4. Unless otherwise provided in the DHIN by-laws the Committee shall be authorized to conduct its business by a majority of a quorum. A quorum will be determined in accordance with the DHIN By-Laws. Once a quorum is present to organize the meeting, the meeting shall continue in effect notwithstanding the subsequent withdrawal of any of those present unless the status of a quorum is questioned by a Committee member.
5. The Chairperson shall preside at all meetings. If the Chairperson is unable to attend a meeting, the Chairperson may designate another Committee member to lead the meeting.
6. The DHIN staff shall attend each meeting to present applications and record decisions.
7. The order of business at all meetings of the Committee shall be proposed by DHIN staff and approved by the Chairperson, in the form of a meeting agenda.
8. The applicant is strongly encouraged, but not required, to attend the Committee meeting during which his/her application is being reviewed:
    a. The applicant may attend the meeting in-person or via phone;
    b. The applicant's role is to respond to clarifying questions from Committee members rather than to present the application to the Board.

Committee Voting Procedure

1. The Committee will follow the procedures below when voting on an application:
    a. The Committee Chairperson will facilitate the voting process by requesting a motion to vote and a second to motion.

b. Committee members will each vote on one of the following decisions:
    i. Approve application;
    ii. Approve application if certain conditions are met to address minor deficiencies;
    iii. Deny applications due to major deficiencies.
c. Each Committee member's vote will be recorded individually;
d. The Chairperson will document the majority decision in writing;
e. In the event of a split vote, the Chairperson will review each opinion and make a final decision.

2. The Committee will follow the procedures below regarding conflicts of interest:
    a. Conflicts of interest are defined according to the DHIN conflict of interest rule;
    b. Each Committee member is responsible for self-identifying a conflict of interest.
    c. When a Committee member identifies a conflict of interest, the Committee member shall:
        i. Notify the Chairperson of the conflict as soon as possible, and at the latest at the start of the meeting during which the application will be reviewed.
        ii. Recuse him or herself from the application discussion, if the member feels his or her participation in the discussion will influence the voting process.

<u>Committee Review of the clinical and claims DATA ACCESS Applications</u>

3. The role of the Committee is to review applications for clinical and claims data by assessing the following:
    a. Whether the intended use is consistent with the statutory purpose of clinical and claims;
    b. Whether access to the requested data is necessary to achieve the intended goals, including but not limited to the need for identifiable data, if requested;
    c. Whether access to the requested data may provide an unfair competitive advantage to the requestor;
    d. Whether any comments were received from Reporting Entities or Data Senders whose claims or clinical data is being requested, if applicable;
    e. Whether the request complies with all applicable state and federal laws relating to the privacy and security of PHI;
    f. Whether the applicant's proposed reports, analysis and subsequent data use and distribution conform to Antitrust Laws regarding the exchange of price and cost information and DHINs enabling legislation;
    g. Whether the applicant is qualified to serve as a responsible steward of the requested data.
    h. If the application includes request to publish, all publications, (e.g. print, electronic, lecture, slides, etc.) must conform as follows:
        i. Adhere to federal Centers for Medicare & Medicaid Services ("CMS") cell size suppression requirements for CMS research identifiable files;
        ii. Exclude any Reporting Entity-specific Pricing Information that includes post-adjudicated claims data; and

iii. To the extent applicable, 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.

4. The Committee may request additional documentation, including third party security documents Institutional Review Board review, or Principal Investigator credentials, from the applicant at any time during the review.