

Final Report

Joint Legislative Oversight and Sunset Committee Task Force on the Delaware Health Information Network

*Established under the provisions of
Senate Resolution No. 9 of the 150th General Assembly*



*Respectfully submitted to the
Joint Legislative Oversight and Sunset Committee
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Acknowledgements:

The Division of Research staff would like to sincerely thank all of those who were involved in the task force process which made this report possible.

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EXECUTIVE SUMMARY

- 11-member task force held a total of four meetings.
- Meeting discussion included JLOSC Recommendations 2, 4, and 6.
- DHIN provided PowerPoint presentations during meetings 2 and 3.
- Task force reviewed proposed legislative changes, including 7 draft bills.
 - Current items of support include:
 - Use of clinical data for research.
 - Sharing with DHIN important data, such as pharmacy, dental, and post-acute.
 - Gift of Life is excited to work with DHIN and wishes to have secure direct access to support their mission of coordinating organ and tissue donation and transplant efforts for Delaware.
 - DHIN information helped secure a life-saving liver transplant last year.
 - Current concerns received include:
 - Tabatha N. Offutt-Powell, Dr. P.H., M.P.H., DHSS, Division of Public Health.
 - Conflicts between access to HIV results, the current consenting process, and confidentiality.
 - Genetic tests and testing results have higher privacy and confidentiality standards and requirements.
 - Evaluation concerns regarding data requests for HIV and genetic test result data used for research purposes.
 - The requesting institution's Institutional Review Board (IRB) is not the data steward or owner.
 - Mike Records, Department of Corrections
 - The cost and use of data.
 - Interface upgrade costs.
 - Language regarding "summary of each visit" would charge DOC each time they viewed a patient, which would potentially increase their current costs.
 - DOC has policies in place that prohibit the use of offender data in research studies.
 - DHIN recognizes these concerns and agrees that proper measures need to be in place to ensure redisclosure rules are followed so that sensitive data is accessible only by those authorized.
 - The task force agreed that these areas of concern require further discussion prior to statutory changes.

INTRODUCTION

About JLOSC and the Review Process

The Joint Legislative Oversight and Sunset Committee (“JLOSC” or “Committee”) is a bipartisan body comprised of five members of the Senate appointed by the President Pro Tempore and five members of the House of Representatives appointed by the Speaker of the House. JLOSC completes periodic reviews of agencies, commissions, and boards. The review’s purpose is to first determine the public need for the entity and if need exists, to determine whether the entity is effectively performing to meet the need. JLOSC reviews aim to provide strength and support to entities that are providing a State recognized need. JLOSC performs its duties with support provided by the Division of Research’s dedicated and nonpartisan staff in the form of two JLOSC analysts, a legislative attorney, a legislative fellow, and an administrative assistant.

During its 2019 review cycle, JLOSC reviewed the Delaware Health Information Network (“DHIN”). The review process included the completion of a draft report in April of 2019 which included information and performance questionnaire responses received from DHIN. The Committee held a public presentation meeting on April 15, 2019. DHIN presented information about their entity and the Committee received public comment. After the draft report and presentation meeting, the Committee reviewed, considered, and adopted eleven recommendations based on the information received throughout the review process. Four of the eleven recommendations related to proposed statutory changes to DHIN’s governing statute. Three of these four recommendations required additional research and discussion to assist the Committee in making decisions on how to move forward with implementation. Recommendation number six included the bulk of the proposed statutory revisions and an option to create the JLOSC Task Force on DHIN (“task force”) in order to further review them and report back to the JLOSC in January of 2020. This led to the creation, support, and passage of Senate Resolution 9 (“SR 9”).¹ In June of 2019 the JLOSC analysts completed and released the JLOSC Final Report, which is accessible through the Committee’s section of the Delaware General Assembly’s website.

Creating this Task Force

JLOSC sponsored and created this task force through SR 9 for the sole purpose of reviewing and researching proposed statutory changes included in the JLOSC adopted recommendations. The acquisition of two new JLOSC analysts in March of 2019 condensed the 2019 review process. The idea behind this task force was to convene individuals with experience in the field to provide insight and assist in this discussion and review of DHIN’s proposed statutory changes. JLOSC staff co-chaired the task force, performed its administrative duties, and produced the final report.

Structure of Meetings

The task force held a total of four meetings: an organization meeting, two meetings which discussed the recommendations, and a final report meeting.

The public comment period was open until December 4, 2019.

¹ See “SR 9” in Appendix F for the full resolution.

TASK FORCE MEMBERS

- **Holly Vaughn-Wagner, Esq.**, Division of Research Deputy Director and JLOSC legislative attorney, co-chair.
- **Amanda McAtee**, JLOSC analyst, co-chair.
- **Dr. Jan Lee**, Chief Executive Officer of DHIN.
- **Scott Perkins, Esq.**, General Counsel of DHIN.
- **Randy Farmer**, Chief Operating Officer of DHIN.
- **Meredith Stewart Tweedie, Esq.**, designee for the chair of DHIN Board of Directors.
- **Dr. Jonathan Kaufmann**, an individual who represents data senders, such as hospitals or labs, as designated by the DHIN Board of Directors.
- **Tanner Polce**, designee for the Lieutenant Governor.
- **Dr. Kathy Matt**, Dean of the University of Delaware's College of Health Sciences.
- **Elisabeth Scheneman**, designee for the Secretary of the Department of Health and Social Services.
- **Dr. Tabatha Offutt-Powell**, designee for the Director of the Division of Public Health.

TASK FORCE MEETINGS

08/27/2019



Orientation
and
Organization
Meeting

10/08/2019



Recommendation #4
and
Recommendation #6
(first three statutory
update items)

11/20/2019




Recommendation #2
and
Recommendation #6
(four remaining
statutory updates)

12/20/2019



Final report
review



- **First meeting:** Held on August 27, 2019.
 - **Objective:** To review and research recommendations 2, 4, and 6. 
 - **Timeline:** To complete objective within 4 meetings.
-
- **Purpose:** JLOSC selected DHIN for 2019 review. DHIN's review resulted in recommendations that relate to statutory changes to DHIN's governing statute which required additional research and discussion.²
 - **Meeting Documents:** Agendas, minutes, and other meeting documents posted online on the public meeting calendar under the JLOSC and on the General Assembly website.
 - **Roles and Responsibilities of Task Force Members:** To bring expertise and knowledge to the discussion regarding proposed statutory changes within recommendations 2, 4, and 6.
 - **Roles and Responsibilities of Consulting Members:** To work with JLOSC staff in providing resources and expertise in the recommendation topics.
 - **Expected Work Product:** JLOSC staff will prepare a final report of task force findings, due January 2020.
 - **Resources:** JLOSC staff posted, facilitated, and directed meetings. JLOSC analyst Amanda McAtee and legislative attorney Holly Vaughn Wagner served as task force co-chairs.



Quick Reference – Recommendations 2, 4, 6

Recommendation #2 Memorandums of Understanding (“MOUs”) for Health Care Claims Database (“HCCD”): DHIN shall continue to work with the Department of Health and Social Services, Delaware Office of Management and Budget, Division of Public Health, Division of Medicaid and Medical Assistance (“DMMA”), and Delaware Health Care Commission to finalize MOUs permitting those collaborating state agencies to access data in the HCCD. **Option:** DHIN shall explore possible partnerships and develop MOUs with other agencies that will strengthen research and data for the HCCD. For example, DHIN could explore partnership with the Department of Correction (“DOC”) and organ procurement organizations (such as the Gift of Life program) to identify ways in which DHIN data can be used to safely and quickly assist with organ donation suitability determinations.

Note: Recommendation 2 with option was adopted by JLOSC on May 13, 2019.

² Relevant sections of DHIN's governing statute found in Appendix D. A full listing of updated DHIN recommendations used in meeting #1 found in Appendix A.

DHIN Notes on Recommendation #2:

1. A potential partnership with the Gift of Life program would likely be for access to clinical data, not the HCCD. DHIN would need legislation explicitly permitting DHIN to provide data to the Gift of Life program regarding potential donors, which they would then use to supplement their work on suitability for donation. Recommendation number 6 includes an additional suggestion for proposed statutory updates.
2. While the DOC may be able to benefit from the use of claims data, DHIN believes a partnership with DOC with respect to the DOC providing DHIN with clinical data may be helpful to the DOC as well.

Recommendation 4 Annual HCCD Status Report: DHIN shall submit an annual status report, no later than January 1, to the Governor and General Assembly, regarding the HCCD. Reports shall include:

- a. Analysis of strengths and weakness of HCCD.
- b. Current status and future plans of HCCD.
- c. Detailed budget for HCCD operations.
- d. Grant applications and status for HCCD operational funding.
- e. Status of contracts with vendors supporting HCCD operations.
- f. Number of data access requests submitted and granted.

Option 1: The first report shall be submitted no later than January 1, 2020.

Option 2: The annual reports shall be included on the DHIN website.

Note: Recommendation 4 with options 1 and 2 was adopted by JLOSC on May 13, 2019.

Recommendation 6 Statutory Updates to Strengthen HCCD & Ensure DHIN's Continued Success: At DHIN's request, DHIN wishes to work with the Committee's legislative attorney to draft bills that will:

- a. Maximize the number and types of claims that are submitted to the Delaware HCCD.
- b. Permit more detailed reporting of claims related to sensitive diagnoses (by, for example, identifying DHIN as an appropriate holder of data associated with an HIV-related test (16 *Del. C.* § 717) or genetic testing (16 *Del. C.* § 1205)).
- c. Maximize the number and types of entities that submit clinical information to the DHIN.
- d. Permit use of clinical data for public health reporting and research.
- e. Permit the use of de-identified clinical data for appropriate research purposes.
- f. Ensure that pharmacy prescription fill data is provided to the DHIN.
- g. Permit DHIN to provide data to the Gift of Life program on potential donors (this would be needed to establish a partnership between the two entities as referenced in recommendation number 2).

Option 2: Create a small JLOSC task force to discuss the proposed statutory amendments and report back to the JLOSC in January 2020. Task force membership will include DHIN's private counsel, the Committee's legislative attorney, and other members the Committee deems appropriate.

Note: Recommendation 6 with option 2 was adopted by JLOSC on May 13, 2019.



- Second meeting held on October 8, 2019.
 - Brief discussion of recommendation #4 which JLOSC already adopted.
 - DHIN presented a PowerPoint presentation and led discussion on the first three items of recommendation #6.³ The following are the highlights from this discussion.
- DHIN operates as the state-sanctioned provider of health information exchange services.
 - Discussion included information on how to maximize clinical data and data senders.
 - DHIN currently has data from the following:
 - Hospitals - 100%
 - Laboratories - 100%
 - Imaging Centers - ~95%
 - Neighboring State Health Information Exchange (HIE) – 5
 - MD, DC, WV, NJ, and 6 facilities in SEPA
 - Outpatient Practices (CCD) - ~12%
 - Urgent Care/Walk-In Facilities - 30%
 - Post-Acute Facilities (SNFs, home health) - 9%
 - DHIN currently does not have:
 - Pharmacy Data (except in claims)
 - Dental Data
 - Most Outpatient Practices
 - Most urgent care / walk-in Facilities
 - Most post-acute
 - Most telehealth encounters
 - Access to State managed data (social determinants of health)
 - Modify the “Mandatory Reporting Entity” definition to include the Department of Corrections and capture dental insurers.
 - Require pharmacy data to be submitted to DHIN.
 - Connection with pharmacies already exists with the Delaware Division of Professional Regulation for the Delaware Prescription Monitoring Program (PMP) which maintains, and monitors prescription data limited to controlled substances.
 - PMP statute would need an amendment for DHIN to work within their existing set-up.⁴

³ Full PowerPoint presentation is in Appendix B.

⁴ The JLOSC analyst attempted and was unable to obtain comments from the Division of Professional Regulation regarding this proposal.

- Senate Bill 171 is currently in the legislative process and would require urgent care facilities to enroll in DHIN as active users of the Community Health Record, provide primary care physicians with a notification of each visit (notifications could be sent through DHIN), and provide DHIN with a summary of care associated with each patient.
 - The model found in Senate Bill 171 could be applied to skilled nursing and long-term care facilities.
- DHIN proposed modifications to the telemedicine statute to remove the vague language and require telemedicine providers to send care summaries to DHIN.
- Amend the current statute in sections 717 and 1205 to allow DHIN to become the holder of HIV claims information and genetic testing data in accordance with the Health Care Claims Database.
- Meeting discussion included support for valuable data areas such as pharmacy, dental, and post-acute data.
- Concerns discussed involved privacy concerns involving HIV and genetic testing data.



- Third meeting held on November 20, 2019.
 - DHIN presented a PowerPoint presentation and led discussion on the last four items of recommendation #6.⁵ The following are the highlights from this discussion.
 - Incorporated discussion of recommendation #2 into the meeting's discussion as it related to proposed draft bills.
-
- DHIN presented the following draft bills for discussion purposes:
 - Dental Claims Data:
 - Removes the statutory exemption for dental insurers from the Delaware Health Care Claims Database.
 - Dental care is an important indicator of overall health.
 - DOC Participation in DHIN:
 - Adds the DOC as a mandatory reporting entity within the Delaware Health Care Claims Database.
 - Addresses a gap in the coordination of care efforts involving incarcerated individuals.
 - Genetic Testing Data and Claims Information:
 - Adds permissions for DHIN to collect and disclose clinical genetic information and claims associated with genetic testing as permitted by DHIN's enabling statute.
 - HIV Testing Results and Claims Information:
 - Adds permissions for DHIN to hold clinical and claims data associated with HIV testing and to use the data as permitted by DHIN's enabling statute.
 - Long-term Care Facilities:
 - Requires long-term care facilities to enroll in DHIN and provide summaries of care in order to improve the quality and coordination of care within the State of Delaware.
 - PMP Data and DHIN:
 - Adds permissions to share prescription drug dispensing information with DHIN for inclusion in DHIN's clinical data repository so that participating providers and payers participating in the DHIN can access information regarding patients in their care, as permitted by DHIN's enabling statute.
 - Telemedicine and DHIN:
 - Adds requirement for telemedicine practitioners to enroll in DHIN and provide summaries of care to DHIN in order to improve the coordination of care.

⁵ Full PowerPoint presentation is in Appendix C.

- Mike Records from Department of Corrections (“DOC”) has concerns on the cost and use of data.
 - Concern with interface upgrade costs.
 - Concern with language regarding “summary of each visit” would charge DOC each time they viewed a patient, which would potentially increase their current costs.
 - DOC has policies in place that prohibit the use of offender data in research studies.

- The meeting’s Power Point presentation included a positive discussion regarding the use of clinical data for research and amending DHIN’s statutory enabling legislation to permit:⁶
 - De-identified data sets to be released for research purposes. Only released if the following apply:⁷
 - A Health Insurance Portability and Accountability Act (“HIPAA”) compliant data agreement exists between the researcher and DHIN.
 - The researcher’s agreement compliance is monitored by DHIN as if DHIN were a covered entity under HIPAA.
 - Individually identifiable health information for research only released if patient consent is received in writing compliant with HIPAA requirements.

⁶ This information added after the meeting 4 final report review.

⁷ Note: DHIN will need to modify data use agreements with its data senders.



Date: November 20, 2019

Objective: Approval of the Task Force Report

Vote to Approve Task Force Report:

- 8 Task Force members were physically present to vote.⁸
- After robust discussion, a motion was made to approve the report, contingent on the following:
 - The understanding that additional proofreading and technical or formatting changes would be made prior to submission to JLOSC.
 - The inclusion of information in the meeting 3 summary regarding proposed amendments to DHIN's statutory enabling legislation regarding the use of clinical data for research.
 - Meeting 3 discussion was supportive of the proposal, due to time restraints legislation was not drafted for task force discussion.
 - The inclusion of DHIN's response to concerns regarding genetic testing, HIV data, and DOC:
 - Any data received regarding genetic testing or HIV test results would not be available and accessible in the community health record and that is not the vision or intent with HIV or genetic information.
 - DHIN is seeking approval to have the claims data for HIV and genetics testing in the feeds the payers are required to send, wants the ability to provide aggregated reports that would not identify individuals but would be able to track what happens to people across time and institutions.
 - Currently, this cannot be tracked without the data. If DHIN was the lawful holder of the data, it would permit DHIN to do the analytics in order to provide data and

⁸ One task force member participated in meeting conversation by phone, per FOIA did not count for quorum or meeting votes.

reports that do not identify individuals but provides useful information.

- Data would be subject to redisclosure restrictions.
- DHIN recognizes that necessary precautions would need to be in place and could insert language into the draft bill.
- DHIN is working on data security measures in this area of concern.
- DHIN anticipates additional conversations to take place with DOC, further conversations will be needed before moving forward with legislation involving DOC.
- Due to the points of concern raised by the Division of Public Health, the task force agreed that the discussion areas involving HIV and genetic testing data sets and DOC require further discussion.⁹
- The report was unanimously approved by a vote of 8.

Special Note:

- Because this page is a summary of what occurred at the Task Force's final meeting, it was not considered by the entire Task Force. The JLOSC staff who served as the Task Force co-chairs unilaterally drafted and included this page to serve as a summary of the final meeting.
- Any additional information included in this report after Task Force consideration at its final meeting is indicated by footnote.

⁹ Points of concern are included in the comments received from task force member Tabatha N. Offutt-Powell, Dr. P.H., M.P.H on page 26 of this report.

DRAFT LEGISLATION

SPONSOR:

DELAWARE STATE SENATE

174th GENERAL ASSEMBLY

SENATE BILL NO. ____

AN ACT TO AMEND TITLE 16 OF THE DELAWARE CODE RELATING TO HEALTH AND SAFETY

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF DELAWARE:

Section 1. Amend § 10312, Title 16 of the Delaware Code by making deletions as shown by strike through and insertions as shown by underline as follows:

§ 10312. Definitions.

For purposes of this chapter, unless amended, supplemented, or otherwise modified by regulations adopted under this chapter:

(3) “Health insurer” means as defined in § 4004 of Title 18 and providers of a dental plan or dental plan organization, as defined in § 3802 of Title 18. “Health insurer” does not include providers of casualty insurance, as defined in § 906 of Title 18; or providers of group long-term care insurance or long-term care insurance, as defined in § 7103 of Title 18; ~~or providers of a dental plan or dental plan organization, as defined in § 3802 of Title 18.~~

SYNOPSIS

When the Delaware Health Care Claims Database was created in 2016, providers of dental insurance were exempted from the mandatory reporting requirements. Dental care, however, remains an important indicator of overall health and claims information related to dental care will help the Delaware Health Care Claims Database continue to provide value to the State and researchers to help advance the Triple Aim plus one. This Act removes the exemption for dental insurers from the statute.

Author:

SPONSOR:

DELAWARE STATE SENATE

174th GENERAL ASSEMBLY

SENATE BILL NO. ____

AN ACT TO AMEND TITLE 16 OF THE DELAWARE CODE RELATING TO THE DEPARTMENT OF CORRECTION'S PARTICIPATION IN THE DELAWARE HEALTH INFORMATION NETWORK

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF DELAWARE:

Section 1. Amend § 10312, Title 16 of the Delaware Code by making deletions as shown by strike through and insertions as shown by underline as follows:

§ 10312. Definitions.

For purposes of this chapter, unless amended, supplemented, or otherwise modified by regulations adopted under this chapter:

(4) "Mandatory reporting entity" means all of the following entities, to the extent permitted under federal law:

f. The Department of Correction, or any third-party entity contracted to provide health care services to individuals within the custody or care of the Department of Correction.

Section 2. Amend Chapter 89, Title 29 of the Delaware Code by making deletions as shown by strike through and insertions as shown by underline as follows:

§ 8916. Participation in the Delaware Health Information Network.

The Department of Correction, or any third-party providing medical care to individuals within its custody or care, must enroll in the Delaware Health Information Network as active users of the Community Health Record and enter into an agreement with DHIN to provide DHIN with a summary of each visit or episode of care in an electronic format established by DHIN.

SYNOPSIS

This Act aims to address a gap in care coordination efforts for individuals within the custody of the Department of Correction, by ensuring that appropriate health data regarding the care provided to those individuals and the cost of such care is provided to the Delaware Health Information Network for inclusion in that entity's clinical health data repository and the Delaware Health Care Claims Database, respectively. Such data will only be able to be accessed or used consistent with the DHIN's enabling legislation, Chapter 103 of Title 16.

Author:

SPONSOR:

DELAWARE STATE SENATE

174th GENERAL ASSEMBLY

SENATE BILL NO. ____

AN ACT TO AMEND TITLE 16 OF THE DELAWARE CODE RELATING TO HEALTH AND SAFETY
BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF DELAWARE:

Section 1. Amend § 1205, Title 16 of the Delaware Code by making deletions as shown by strike through and insertions as shown by underline as follows:

§ 1205. Conditions for disclosure to others of genetic information.

(a) Regardless of the manner of receipt or the source of genetic information, including information received from an individual, a person shall not disclose or be compelled, by subpoena or other means, to disclose the identity of an individual upon whom a genetic test has been performed or to disclose genetic information about the individual in a manner that permits identification of the individual, unless:

(11) Disclosure is authorized in accordance with § 1201(4)c. of this title; ~~or~~

(12) ~~Disclosure is otherwise permitted by law.~~ Disclosure is made by the Delaware Health Information Network, as permitted by Chapter 103 of this Title;

(13) Disclosure does not contain the results of any genetic test and is made by persons sending claims information to the Delaware Health Information Network pursuant to subchapter 2 of Chapter 103 of this Title; or

(14) Disclosure is otherwise permitted by law.

SYNOPSIS

This Act makes one clarification and one change. With respect to the former, the Act confirms that clinical genetic information that is provided to the Delaware Health Information Network as currently permitted by this section may be further disclosed by the DHIN as permitted by its enabling legislation. The Act also permits persons providing claims information to the Delaware Health Care Claims Database to provide claims associated with genetic testing to the DHIN, so long as those claims do not contain the results of the genetic tests at issue.

Author:

SPONSOR:

DELAWARE STATE SENATE

174th GENERAL ASSEMBLY

SENATE BILL NO. ____

AN ACT TO AMEND TITLE 16 OF THE DELAWARE CODE RELATING TO HEALTH AND SAFETY

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF DELAWARE:

Section 1. Amend § 717, Title 16 of the Delaware Code by making deletions as shown by strike through and insertions as shown by underline as follows:

§ 717. Confidentiality.

- (a) No person may disclose or be compelled to disclose the identity of any person upon whom an HIV-related test is performed, or the results of such test in a manner which permits identification of the subject of the test, except to the following person:

(12) The Delaware Health Information Network, for inclusion in the clinical data repositories of that organization.

- (b) No person to whom the results of an HIV-related test have been disclosed pursuant to subsection (a) of this section shall disclose the test results to another person except as authorized by subsection (a) of this section or, in the case of the Delaware Health Information Network, for uses permitted by Chapter 103 of this Title.
- (c) The provisions in this section shall not interfere with the transmission of information as may be necessary to obtain third-party payment for medical care related to HIV infection or with the documentation of cause of death on death certificates. Nor shall the provisions in this section interfere with the transmission of information to the Delaware Health Information Network from persons sending claims information to the Delaware Health Care Claims Database as set forth in subchapter 2 of Chapter 103 of this Title.

SYNOPSIS

This Act adds the Delaware Health Information Network, the state-created instrumentality tasked with serving as the state's sanctioned provider of health information exchange services, as an entity that is permitted to hold clinical and claims data related to HIV testing. The Act requires the DHIN to use that data only as permitted by its enabling legislation.

Author:

SPONSOR:

DELAWARE STATE SENATE

174th GENERAL ASSEMBLY

SENATE BILL NO. ____

AN ACT TO AMEND TITLE 16 OF THE DELAWARE CODE RELATING TO LONG TERM CARE FACILITIES AND THE DELAWARE HEALTH INFORMATION NETWORK

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF DELAWARE:

Section 1. Amend Chapter 11, Title 24 of the Delaware Code by making deletions as shown by strike through and insertions as shown by underline as follows:

§ 1119D. Coordination of Care.

(a) On or before January 1, 2021, each long term care facility must enroll in the DHIN as an active user of the Community Health Record.

(b) On or before January 1, 2021, each long term care facility that utilizes an electronic health record or electronic medical record must enter into an agreement with DHIN to provide DHIN with a summary of each episode of care in an electronic format established by DHIN.

SYNOPSIS

In an attempt to improve quality and coordination of care across the State, this Act requires long term care facilities to enroll in the Delaware Health Information Network and provide summaries of care to the DHIN.

Author:

SPONSOR:

DELAWARE STATE SENATE

174th GENERAL ASSEMBLY

SENATE BILL NO. ____

AN ACT TO AMEND TITLE 16 OF THE DELAWARE CODE RELATING TO HEALTH AND SAFETY

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF DELAWARE:

Section 1. Amend § 4798, Title 16 of the Delaware Code by making deletions as shown by strike through and insertions as shown by underline as follows:

§ 4798. The Delaware Prescription Monitoring Program.

(c) The Office of Controlled Substances shall establish and maintain a PMP program to monitor the prescribing and dispensing of all Schedule II, III, IV and V controlled substances by prescribers in this State, and to research the prescribing and dispensing of drugs of concern. The PMP must not interfere with the legal use of a controlled substance or drug of concern. The PMP may be used for the following purposes:

(5) Provide prescription drug data to the Delaware Health Information Network for inclusion in that entity's clinical data repositories and for uses permitted by Chapter 103 of this Title.

(l) The Office of Controlled Substances shall maintain procedures to ensure that the privacy and confidentiality of patients and patient information collected, recorded, transmitted, and maintained is not disclosed, except as provided for in this section.

(3) The Office of Controlled Substances may provide data in the prescription monitoring program to the DHIN as permitted by this Section.

SYNOPSIS

This Act permits the Office of Controlled Substances to provide data in the prescription drug monitoring program to the Delaware Health Information Network for inclusion in the DHIN's clinical data repository. The inclusion of that data within DHIN will provide medical providers and payers participating in DHIN with the ability to access prescription drug dispensing information regarding patients in their organization. Such data can only be accessed or used consistent with the DHIN's enabling legislation, Chapter 103 of Title 16.

Author:

SPONSOR:

DELAWARE STATE SENATE

174th GENERAL ASSEMBLY

SENATE BILL NO. ____

AN ACT TO AMEND TITLE 24 OF THE DELAWARE CODE RELATING TO TELEMEDICINE AND THE DELAWARE HEALTH INFORMATION NETWORK

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF DELAWARE:

Section 1. Amend § 1769D, Title 24 of the Delaware Code by making deletions as shown by strike through and insertions as shown by underline as follows:

§ 1769D. Telemedicine and telehealth.

(e) Telemedicine shall include, at such time as feasible and when appropriate, utilizing the Delaware Health Information Network (DHIN) in connection with the practice. In order to ensure compliance with this provision and to ensure the appropriate coordination of care:

(1) On or before January 1, 2021, any physician treating a patient through telemedicine must enroll in the DHIN as an active user of the Community Health Record.

(2) On or before January 1, 2021, any provider at which physicians treat patients through telemedicine must enter into an agreement with DHIN to provide DHIN with a summary of each telemedicine visit or episode of care in an electronic format established by DHIN.

SYNOPSIS

In an attempt to improve coordination of care and ensure compliance with existing statutory language, this Act requires physicians and practices providing telemedicine services to enroll in the Delaware Health Information Network and provide summaries of care to the DHIN.

Author:

COMMENTS RECEIVED

Comments received from:
Tabatha N. Offutt-Powell, Dr. P.H., M.P.H.
State Epidemiologist and Section Chief
Epidemiology, Health Data, and Informatics
Delaware Department of Health and Social Services
Division of Public Health

HIV-test results

The main concern is **access to** HIV results because a consenting process still exists for HIV testing and the test and associated results are held to stricter privacy rules than other test results. A secondary concern is **using HIV test result data for research purposes** and the process in place to evaluate data requests/research projects not relying solely on the requesting institution's IRB since the requesting IRB isn't the data steward or data owner.

1. If clients are still required to consent to HIV testing (no such consent process exists for other testing such as metabolic panel, cell count, liver enzymes, etc.), then the expectation is that there is a higher level of privacy for HIV results vs other test results.
2. The HIPAA Minimum necessary rule should be followed. People with access to DHIN do not necessarily have a need or right to have access to HIV results. Many EMR's have an additional safeguards for HIV results compared to other results. Also, many processes force the patient to call for results and do not allow a passive resulting process via phone or mail as counseling may be needed regardless of result. <https://www.hhs.gov/hipaa/for-professionals/faq/207/how-are-covered-entities-to-determine-what-is-minimum-necessary/index.html>
 - Because there are other non-healthcare providers or healthcare providers who access the DHIN who do not have a need to know the HIV results, given the consenting process associated with HIV testing, availability of the HIV results in the Community Health Record would violate HIPAA minimum necessary rule and the statute.
3. (Inadvertent or not) Redisclosure of the HIV tests results from the non-ordering provider to the patient and potential redisclosure of an HIV test result of a minor 12 years and older to a parent or guardian is a concern.
4. There are instances in which informed consent was not obtained (Title 16 Chap 7 §715(d)(1), (4), and (5)) in which redisclosure could be a concern or in cases where a court order was in place and an alias was used.

5. Because of the emotional nature of learning the test results, Title 16 Chap 7 §715(f) states that “at the time of learning the test result, the subject of the test or the subject’s legal guardian shall be provided with counseling or coping with the emotional consequences of learning the result, for understanding the interpretation of the test result, for understanding the measures for preventing infection to others, to urge the voluntary notification of sexual and needle sharing partners or the risk of infection and the availability of any appropriate healthcare services including mental healthcare and social and supportive services.”

- Thus, access to and knowledge of these results requires a greater level of care and privacy than other results as described in the statute.

6. Title 16 Chap 7 §717 Confidentiality

- (a) states that no person may disclose or be compelled to disclose the identity of any person upon an **HIV related test (referring not only to the result but to the fact that a test was actually performed) or the results of such test in a manner which permits identification** of the subject of the test. The exception that I want to bring attention to is under (3). The concern that is being raised is twofold (1) the healthcare facility or healthcare provider is authorized to obtain the results (2) more importantly “the agent has a medical need to know such information to provide healthcare to the patient.” Again, not every healthcare provider or person who has access to the DHIN’s clinical database/community health record has a need to know this information; furthermore, not everyone is a healthcare provider who has access to the DHIN’s clinical database/community health record.
- (b) no person whom the results of an HIV-related test have been disclosed pursuant to subsection (a) shall disclose the test results to another person except as authorized.
 - Again, concerns regarding the risk associated with having the HIV test and testing results in DHIN given the confidentiality and consents that exist for HIV testing and the appropriate legal handling of the HIV test results.

Summary: As such, HIV results need to be treated differently - if patients no longer need a separate consent process for HIV testing and confidentiality of HIV testing and test results is changed, then there may be implications that HIV testing and test results are considered of equal privacy and confidentiality as for other results.

Genetic test and test results

The main concern is **access to** genetic tests and test results, which require a consenting process that differs from other medical testing and as such held to a higher privacy and confidentiality standard and requirements. A secondary concern is **using genetic test result data for research purposes** and the process in place to evaluate data requests/research projects not relying solely on the requesting institution's IRB since the requesting IRB isn't the data steward or data owner.

1. If clients are required to consent to genetic testing, the expectation is that there is a higher level of privacy for genetic testing and genetic test results compare with other medical testing; therefore, these test results should be held to a higher privacy standard than other information contained within medical records and claims databases. Title 16 Chap 12 §1202. How will informed consent be managed for all genetic tests that are conducted and information restricted by the patient?
2. Title 16 Chap 12 §1205: Conditions for disclosure to others of genetic information.
 - a. States "regardless of the manner of receipt or the source of genetic information including information received from an individual, a person shall not disclose or be compelled to disclose the identity of an individual upon whom a **genetic test has been performed** (so just having the test result listed in the HCCD – would be concern even without the test result) or to **disclose genetic information about the individual in a manner that permits identification of the individual.**
 - The exception that is concern is the one that states (5) disclosure is authorized by obtaining informed consent of the tested individual describing the information to be disclosed and to whom
 - How will this be addressed if results are available in the DHIN for any genetic test result?
 - Having genetic tests even without the test result would not be allowed in the Healthcare Claims Database under this exception because there is no way for the payers to be able to know informed consent details for each test since claims are related to billing and informed consent details aren't captured in billing systems.

Summary: (1) Based on the existing law, genetic tests performed, or test results cannot be stored in the HCCD given the requirements for informed consent for disclosure of this information (see below). (2) There is a requirement for informed consent to disclose genetic test results through DHIN that is not necessarily captured for every genetic test performed. Newborn screening is an exception already listed in the statute.

Research use of HIV and genetic data

****Data received from DPH and stored in the Community Health Record or HCCD****

1. DPH is considered the stewards of these data.
2. Any DPH data cannot be used for marketing purposes.
3. Use of protected health information described under Title 16 §1211, legitimate public health purpose applies to identifiable AND **nonidentifiable** health information.
4. These data, if being requested in aggregate/summary, limited, or protected forms, must be reviewed by the DPH Privacy Board
5. The data request must be reviewed by the DHSS Human Subjects Review Board if any research is being conducted regardless of whether there is another IRB review on record.
6. Are subject to the HIPAA and other related privacy and confidentiality state laws.

Comments received from: Christopher Graham, Gift of Life

From: Christopher Graham
To: "Scott Perkins"
Cc: McAtee, Amanda A (LegHall); Shannon Kaminski; Jacqueline Giuffrida; Stephen
Subject: Tornone RE: Gift of Life access to DHIN
Date: Monday, November 18, 2019 6:06:07 PM

Hi Scott,

Very happy to receive your update this morning! Thank you for your continued work on our behalf. Please let me know if I can be of any assistance to you moving forward.

Amanda,

I'm sure that Scott has shared our story. We are excited and hopeful that we can secure direct access to DHIN, so that we may better support our mission of coordinating Delaware's organ & tissue donations and transplants. When a patient is transferred to Christiana from one of Delaware's smaller hospitals, for instance, comprehensive medical records rarely come with them. DHIN has the potential to be a powerful tool to provide the most accurate information to our transplant surgeons. Working through physicians at Christiana last year, DHIN information literally was the difference between a case being canceled and a patient receiving a life-saving liver transplant!

I look forward to working with you in any way you may need.

Sincerely,
Christopher J. Graham

One organ and tissue donor can save or improve the lives of more than 75 other people. Learn more about how Mary's son Eric saved Arlinda's life at www.donors1.org/hero

From: Scott Perkins
Sent: Monday, November 18, 2019 9:06 AM
To: Christopher Graham
Cc: McAtee, Amanda A (LegHall)
Subject: Gift of Life access to DHIN

Chris,

I'm writing to give you a "heads up" and provide an introduction. I have copied Amanda McAtee, who works for the Delaware General Assembly. DHIN is currently involved in a legislative process to update and modernize our statute, and one of the things that we raised was our desire to provide Gift of Life clinical staff with access to the Community Health Record in situations where that would be helpful to you to identify suitability for organ and tissue donation.

This Wednesday, November 20, DHIN will be proposing to a task force that it recommend changing DHIN's statute to allow that access to go forward. Amanda asked me to provide an introduction so that she could answer any questions you may have. I also am available to discuss.

Thanks,
Scott

Scott W. Perkins
General Counsel
DELAWARE HEALTH INFORMATION NETWORK

APPENDIX A UPDATED DHIN RECOMMENDATIONS

Delaware Health Information Network: Recommendations

<u>Recommendation</u>	<u>Status</u>
<p style="text-align: center;">Recommendation 1: Continue or Terminate</p> <p>Under §10213(a), Title 29, the Committee must determine whether there is a genuine public need for an agency under review. To meet this requirement, the Committee may select one of the following options.</p> <p><u>Option 1:</u> DHIN shall continue, subject to any further recommendations that JLOSC adopts.</p> <p style="text-align: center;">- OR -</p> <p><u>Option 2:</u> DHIN is terminated and the Committee will sponsor legislation to implement this recommendation.</p>	<p>5/13: First consideration of this recommendation 5/13: JLOSC adopted recommendation 1 with option 1.</p> <p>No updates required from DHIN for this recommendation.</p>
<u>Recommendation</u>	<u>Status</u>
<p style="text-align: center;">Recommendation 2: MOUs for HCCD</p> <p>DHIN shall continue to work with the Department of Health and Social Services, Delaware Office of Management and Budget, Division of Public Health, Division of Medicaid and Medical Assistance (DMMA), and Delaware Health Care Commission to finalize MOUs permitting those collaborating state agencies to access data in the HCCD.</p> <p><u>Option:</u> DHIN shall explore possible partnerships and develop MOUs with other agencies that will strengthen research and data for the HCCD. For example, DHIN could explore partnership with the Department of Correction (DOC) and organ procurement organizations (such as the Gift of Life program) to identify ways in which DHIN data can be used to safely and quickly assist with organ donation suitability determinations.</p>	<p>5/13: First consideration of this recommendation 5/13: JLOSC adopted recommendation 2 with option. 10/31: October update from DHIN is due. 12/30: December update from DHIN is due.</p> <p>DHIN Notes:</p> <ol style="list-style-type: none"> 1. A potential partnership with the Gift of Life program would likely be for access to clinical data, not the HCCD. DHIN would need legislation explicitly permitting DHIN to provide data to the Gift of Life program regarding potential donors, which they would then use to supplement their work on suitability for donation. Recommendation number 6 includes an additional suggestion for proposed statutory updates. 2. While the DOC may be able to benefit from the use of claims data, DHIN believes a partnership with DOC with respect to the DOC providing DHIN with clinical data may be helpful to the DOC as well.

Delaware Health Information Network: Recommendations

<u>Recommendation</u>	<u>Status</u>
<p>Recommendation 3: Continued Federal Funding Initiatives DHIN shall continue their work with DMMA to leverage their previously-appropriated state funding for the HCCD by seeking a federal match through the Implementation Advance Planning Document (IAPD) process.</p> <p><u>Option:</u> Should the IAPD process be unsuccessful for any reason, DHIN shall work with JLOSC to ensure that the \$2 million already appropriated funds remain available to DHIN for its work setting up and maintaining the HCCD.</p>	<p>5/13: First consideration of this recommendation 5/13: JLOSC adopted recommendation 3 with option. 10/31: October update from DHIN is due. 12/30: December update from DHIN is due.</p>
<u>Recommendation</u>	<u>Status</u>
<p>Recommendation 4: Annual HCCD Status Report DHIN shall submit an annual status report, no later than January 1, to the Governor and General Assembly, regarding the HCCD. Reports shall include:</p> <ul style="list-style-type: none"> a. Analysis of strengths and weakness of HCCD. b. Current status and future plans of HCCD. c. Detailed Budget for HCCD operations. d. Grant applications and status for HCCD operational funding. e. Status of contracts with vendors supporting HCCD operations. f. Number of data access requests submitted and granted. <p><u>Option 1:</u> The first report shall be submitted no later than January 1, 2020. <u>Option 2:</u> The annual reports shall be included on the DHIN website.</p>	<p>5/13: First consideration of this recommendation 5/13: JLOSC adopted recommendation 4 with options 1 and 2. 10/31: October update from DHIN is due. 12/30: December update from DHIN is due.</p>
<u>Recommendation</u>	<u>Status</u>
<p>Recommendation 5: Statutory Update & Technical Corrections JLOSC will sponsor a bill to make technical corrections to DHIN's entire governing statute, Chapter 103, Title 16.*</p>	<p>5/13: First consideration of this recommendation 5/13: JLOSC adopted recommendation 5.</p> <p>No updates required from DHIN for this recommendation.</p>

* The Committee's legislative attorney will draft any legislation resulting from approved recommendations, unless otherwise noted.
Updated July 2019

Delaware Health Information Network: Recommendations

<u>Recommendation</u>	<u>Status</u>
<p style="text-align: center;">Recommendation 6: Statutory Updates to Strengthen HCCD & Ensure DHIN's Continued Success</p> <p>At DHIN's request, DHIN wishes to work with the Committee's legislative attorney to draft bills that will:</p> <ul style="list-style-type: none"> a. Maximize the number and types of claims that are submitted to the Delaware HCCD. b. Permit more detailed reporting of claims related to sensitive diagnoses (by, for example, identifying DHIN as an appropriate holder of data associated with an HIV-related test (16 <i>Del. C.</i> § 717) or genetic testing (16 <i>Del. C.</i> § 1205)). c. Maximize the number and types of entities that submit clinical information to the DHIN. d. Permit use of clinical data for public health reporting and research. e. Permit the use of de-identified clinical data for appropriate research purposes. f. Ensure that pharmacy prescription fill data is provided to the DHIN. g. Permit DHIN to provide data to the Gift of Life program on potential donors (this would be needed to establish a partnership between the two entities as referenced in recommendation number 2). <p><u>Option 1:</u> Create a small JLOSC subcommittee to will discuss the proposed statutory amendments and report back to the JLOSC in January 2020. Subcommittee membership will include DHIN's private counsel, the Committee's legislative attorney, and other members the Committee deems appropriate.</p> <p><u>Option 2:</u> Same as Option 1, but create a task force instead of a JLOSC subcommittee.</p> <p style="text-align: center;">- OR -</p> <p><u>Option 3:</u> The Committee's legislative attorney will work with DHIN's private counsel to draft proposed bills and report back to the JLOSC in January 2020.</p>	<p>5/13: First consideration of this recommendation</p> <p>5/13: JLOSC adopted recommendation 6 with option 2.</p> <p>8/27: First task force meeting scheduled.</p>

Delaware Health Information Network: Recommendations

<u>Recommendation</u>	<u>Status</u>
<p>Recommendation 7: Reduce Overlap and Duplicated Efforts</p> <p>At DHIN’s request, DHIN shall identify areas of overlap between its capabilities and those separately contracted for or provided by State agencies, and work with those agencies to eliminate overlap or redundancies. As a part of these efforts, DHIN shall explore whether it can reasonably be the “single point of contact” for delivery of health data on Delaware residents to assist state and federal public health efforts. By statute, DHIN is the “State’s sanctioned provider of health information exchange (HIE) services” (16 <i>Del. C.</i> § 10301).</p> <p><u>Option:</u> DHIN will report back to the JLOSC on progress of this research in January 2020.</p>	<p>5/13: First consideration of this recommendation</p> <p>5/13: JLOSC adopted recommendation 7 with option.</p> <p>10/31: October update from DHIN is due.</p> <p>12/30: December update from DHIN is due.</p>
<u>Recommendation</u>	<u>Status</u>
<p>Recommendation 8: Update Current Regulations</p> <p>DHIN shall update its regulations to reflect current operational procedures.</p> <p><u>Option:</u> DHIN will report back to the JLOSC on progress of these efforts in January 2020.</p>	<p>5/13: First consideration of this recommendation</p> <p>5/13: JLOSC adopted recommendation 8 with option.</p> <p>10/31: October update from DHIN is due.</p> <p>12/30: December update from DHIN is due.</p>
<u>Recommendation</u>	<u>Status</u>
<p>Recommendation 9: Update Current HCCD Internal Procedures</p> <p>DHIN shall review and apply updates as needed to internal procedures involving HCCD operations. Areas of focus must include:</p> <ul style="list-style-type: none"> a. Data staging, storage, and management. b. Reviewing and granting data access applications. c. Reviewing data access pricing. d. Reviewing and implementing marketing strategies and goals. <p><u>Option:</u> DHIN will report back to the JLOSC on progress of these efforts in January 2020.</p>	<p>5/13: First consideration of this recommendation</p> <p>5/13: JLOSC adopted recommendation 9 with option.</p> <p>10/31: October update from DHIN is due.</p> <p>12/30: December update from DHIN is due.</p>

Delaware Health Information Network: Recommendations

<u>Recommendation</u>	<u>Status</u>
<p style="text-align: center;">Recommendation 10: Website Updates</p> <p>DHIN shall make the following updates to their website to advertise and promote the use of the HCCD to increase private funding opportunities associated with granting data access applications:</p> <ol style="list-style-type: none"> Create a banner for the HCCD on the DHIN homepage. Include an icon on the DHIN homepage for the HCCD (current icons only include Patients, Healthcare Providers, and Data Senders). Add a specific webpage menu for the HCCD that would be included at the top of all DHIN webpages. Update the “in the news” section of the DHIN website and include recent news regarding the HCCD. The most recent news item was from August 2018. Create and include a HCCD brochure for the website. Redesign the HCCD webpage in order to adequately market the HCCD and attract data access applications. Make the HCCD data access application a fillable PDF document or fillable web form for easier submissions. Include a prominent link to the HCCD Committee’s information including meeting agendas and minutes. 	<p>5/13: First consideration of this recommendation 5/13: JLOSC adopted recommendation 10. 10/31: October update from DHIN is due. 12/30: December update from DHIN is due.</p> <p>As of 5/13/19 - DHIN’s webpage menu included:</p> <ul style="list-style-type: none"> • Home • Patients • Healthcare Providers • Data Senders • About DHIN • Contact Us • Search Icon
<u>Recommendation</u>	<u>Status</u>
<p style="text-align: center;">Recommendation 11: Release from Review or Hold Over</p> <p><u>Option 1:</u> DHIN is released from review upon enactment of recommended legislation and any required reporting.</p> <p style="text-align: center;">- OR -</p> <p><u>Option 2:</u> DHIN is held over and shall report to the Committee in January 2020.</p>	<p>5/13: First consideration of this recommendation 5/13: JLOSC adopted recommendation 11 with option 2.</p> <p>No updates required from DHIN for this recommendation.</p>

APPENDIX B
DHIN PRESENTATION
MEETING 2
OCTOBER 8, 2019

Senate Resolution 9 Task Force Meeting #2

JLOSC Recommendations 6(a)-6(c)



Dr. Jan Lee
Chief Executive Officer
Delaware Health Information Network
October 8, 2019

JLOSC Recommendation #6

DHIN instructed to work with the committee and report back with proposed legislation that will:

- A. Maximize the number and types of claims that are submitted to the Delaware Health Care Claims Database.*
- B. Permit more detailed reporting of claims related to sensitive diagnoses.*
- C. Maximize the number and types of entities that submit clinical information to the DHIN.*

How can we maximize data provided to HCCD?

Current scope (from 16 *Del. C. § 10312(4)*):

(4) “Mandatory reporting entity” means all of the following entities, to the extent permitted under federal law:

- a) The State Employee Benefits Committee and the Office of Management and Budget, under each entity’s respective statutory authority to administer the State Group Health Insurance Program in Chapter 96 of Title 29, and any health insurer, third-party administrator, or other entity that receives or collects charges, contributions, or premiums for, or adjusts or settles health claims for, any State employee, or their spouses or dependents, participating in the State Group Health Insurance Program, except for any carrier, as defined in § 5290 of Title 29, selected by the State Group Health Insurance Plan to offer supplemental insurance program coverage under Chapter 52C of Title 29.
- b) The Division of Medicaid and Medical Assistance, with respect to services provided under programs administered under Titles XIX and XXI of the Social Security Act [42 U.S.C. §§ 1396 et seq. and 1397aa et seq.].
- c) Any health insurer or other entity that is certified as a qualified health plan on the Delaware Health Insurance Marketplace for plan year 2017 or any subsequent plan year, except for any health insurer or other entity that is not otherwise required to provide claims data as a condition of certification as a qualified health plan on the Delaware Health Insurance Marketplace for plan year 2017 or any subsequent plan year.
- d) Any federal health insurance plan providing health-care services to a resident of this State, including Medicare and the Federal Employees Health Benefits Plan.
- e) Any health insurer providing health-care coverage to a resident of this State.

How can we maximize data provided to HCCD?

Practical effect: What does HCCD not contain?

- Veterans Affairs, Indian Health Service, TriCare, Department of Correction
- Workers Compensation
- Federal Employees Health Benefit Plan
- Uninsured or Private Pay
- Small Private Insurers*
- Self-funded plans that are not publicly-funded (e.g. ERISA plans)
- Dental claims

* DE Regulations require participation of health plans with 1,000 DE covered lives or more

How can we maximize data provided to HCCD?

Proposed areas of improvement:

- Modify definition of “Mandatory Reporting Entity” to include the Department of Correction (or any contracted private party providing health care to individuals within the care of DOC).
- Modify definition of “Mandatory Reporting Entity” to capture dental insurers.
- Group discussion: Are there ways that the State could encourage ERISA plans to provide data to the HCCD voluntarily? How about VA, DoD, federal employees, and Bureau of Indian Affairs plans?
 - Ex: Maryland – requires *providers of care* (at least hospitals) to submit claims data, rather than just the payers.

How can we permit more detailed reporting of claims?

- DHIN is currently operating as the state-sanctioned provider of health information exchange services.
- In that role, DHIN holds, maintains, and provides appropriate access to a myriad of protected health information, consistent with state and federal laws and regulations.
- The more complete the information provided to DHIN, the better that DHIN will be able to ensure that the HCCD is as successful as intended by the General Assembly.
 - In particular, lack of identifiable HIV data is a problem – limits ability to track an individual across time and determine costs and quality of care as they potentially move between payers and providers.

How can we permit more detailed reporting of claims?

Reduce Delaware-specific limitations

- Title 16, Section 717: Confidentiality of HIV-related tests
 - Limits the potential recipients of information regarding the identity of any person upon whom an HIV-related test has been performed, and the results of any such test.
 - The legislation contains a number of exceptions, including for health-care providers “providing medical care to the subject of the test, when knowledge of the test results is necessary to provide appropriate emergency care or treatment” and the transmission of information necessary to obtain third-party payment for medical care (i.e., a claim).
 - The legislation does not permit identifiable data related to that claim to be provided to DHIN, nor does it permit DHIN to make the clinical results of such a test available to health care providers who have a need to access the information for the purposes of the patient’s emergency or treatment.

How can we permit more detailed reporting of claims?

Reduce Delaware-specific limitations

- Title 16, Section 1205: Disclosure of Genetic Information
 - Limits the ability of any individual who has access to the information from disclosing “the identity of an individual upon whom a genetic test has been performed or to disclose genetic information about the individual in a manner that permits identification of the individual.”
 - Contains a number of exceptions, including for disclosures that are “otherwise permitted by law” and for situations where a notice explicitly indicates that the information will be available to individuals who will have access to DHIN.
 - With an appropriate notice to patients and authorization, this means that providers can provide clinical information to the DHIN that will be available to other care providers in DHIN’s community health record. There is no similar exemption for claims data associated with genetic testing.

How can we permit more detailed reporting of claims?

Proposed Areas of Improvement:

- Amend Section 717
 - Permit DHIN to be a steward of HIV-related claims information (which will not include the results of tests) for purposes consistent with the HCCD legislation
 - Permit DHIN to be a steward of HIV-related clinical information
- Amend Section 1205
 - Explicitly include DHIN as an entity to whom claims data associated with genetic testing can be provided, to be used in accordance with the HCCD legislation and associated regulations.
- Issue for discussion: should there be a statutory requirement that anyone who wants to access *identifiable* claims data with respect to HIV or genetic information obtain actual patient consent?

How do we maximize clinical data and data senders?

What We Have

Hospitals – 100%

Laboratories – ~100%

Imaging Centers -- ~ 95%

Neighboring State HIE – 5
(MD, DC, WV, NJ, and 6 facilities in SEPA)

Outpatient Practices (CCD) -~12%

Urgent Care/Walk-In Facilities – 30%

Post-Acute Facilities (SNFs, home health)– 9%

What We Don't Have

Pharmacy Data (except in claims)

Dental Data

Most Outpatient Practices

Most urgent care / walk-in Facilities

Most post-acute

Most telehealth encounters

Access to State-managed data (social determinants of health)

How to maximize clinical data and data senders?

Proposed Areas for Improvement:

- Require pharmacy data to be submitted to DHIN.
 - Discussion: limit to prescription drug monitoring program data, or should DHIN receive all pharmaceutical fill information? If the former, just amend PDMP statute; if the latter, likely need to amend Title 24 to require connection and provision of information to DHIN as a part of licensure, or could require pharmacies to submit all fill information to PDMP, and allow DHIN to pull that data into its own network to aggregate with clinical data.
- Increase number of specialty and urgent care practices required to coordinate care with primary care doctors.
 - Make participating in DHIN a way in which the specialty or urgent care practice can comply with its care coordination efforts.
 - Example: SB 171 (currently pending), requires urgent care facilities (as a care coordination effort) to (i) enroll in the DHIN as active users of the Community Health Record; (ii) provide DHIN with summaries of care associated with each of their patients; and (iii) provide primary care physicians with notifications of each visit – which notifications can be made through DHIN.
 - Apply SB 171 model to Skilled Nursing and Long Term Care facilities.

How to maximize clinical data and data senders?

Proposed Areas for Improvement:

- Require DOC (or its third party contractor) to access and provide care summaries to DHIN's clinical record database.
 - Requires an amendment to DOC enabling legislation.
- Amend telemedicine statute
 - Currently requires telemedicine practitioners, “at such time as feasible and when appropriate” to utilize DHIN.
 - Take out the vagueness – require telemedicine providers to send care summaries to DHIN, which will add value to care coordination efforts.

How to maximize clinical data and data senders?

Proposed Areas for Improvement:

- Support DHSS grant-funding initiative for primary care connectivity
 - DHIN fees to access the CHR are very low -- \$400 per year (if practice is not a data sender) or \$200 per year (for practices that are also sending DHIN data).
 - DHIN leveraged grant funding to establish connections with 9 major EMRs used in Delaware. By utilizing that funding, DHIN is able to allow practices to provide information to DHIN *without an integration fee*. For entities that are not using one of those 9 EMRs, DHIN may charge an integration fee commensurate with its costs. EMRs, on the other hand, typically charge fees to practices to connect to DHIN.
- Discussion: How best to authorize stage agencies holding data pertaining to social determinants of health to work with DHIN and allow providers using DHIN's services to access that data.
 - E.g., My Healthy Community tool created by DHSS (<https://myhealthycommunity.dhss.delaware.gov/>)

Thank you



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APPENDIX C
DHIN PRESENTATION
MEETING 3
NOVEMBER 20, 2019

Senate Resolution 9 Task Force Meeting #3

JLOSC Recommendations 6(d)-6(g)



Dr. Jan Lee
Chief Executive Officer
Delaware Health Information Network
November 20, 2019

JLOSC Recommendations 6(d)-(g)

DHIN instructed to work with the committee and report back with proposed legislation that will:

- D. Permit use of clinical data for public health reporting and research.*
- E. Permit the use of de-identified clinical data for appropriate research purposes.*
- F. Ensure that pharmacy prescription fill data is provided to the DHIN.*
- G. Permit DHIN to provide data to the Gift of Life program on potential donors.*

How can DHIN permit use of clinical data for research?

DHIN's ability to use clinical data in its possession is governed by at least three sources:

- HIPAA and associated regulations.
 - Identifiable data may be released without patient consent for purposes of “treatment, payment and operations.”
 - Permits use of patient data for research in identified circumstances.
- DHIN's enabling legislation (16 *Del. C.* §10307(a)).
 - “The DHIN shall by rule or regulation ensure that patient specific health information be disclosed only in accordance with the patient's consent or best interest to those having a need to know.”
- Data Use Agreements with data senders.
 - Earlier agreements are more restrictive than those executed in recent years

How can DHIN permit use of clinical data for research?

Practical effect: What is happening now?

- Limited instances of clinical data used for research:
 - De-identified data is used to identify practices with a concentration of possible clinical trial candidates; the practice recruits patients
 - De-identified data may be used for research *if* permitted by the data sender.
 - Agreements with outpatient data providers and one hospital explicitly permit the research use case
 - Agreements with other hospitals and most labs allow use of their data for Treatment, Payment, Operations, as required by law or regulation, and by patient consent or patient request.
 - Agreement with Quest restricts permitted data uses to treatment, and explicitly disallows use of even de-identified data for secondary purposes
 - Currently working on project with the CDC to supplement HCCD data it has been permitted to obtain with matching clinical data – requires amended agreements with three hospitals and two reference laboratories.

How can DHIN permit use of clinical data for research?

Proposed areas of improvement:

- Amend DHIN's enabling legislation to explicitly permit:
 - Release of de-identified data sets for research purposes
 - Release of limited data sets for research purposes ONLY IF:
 - DHIN enters into a HIPAA-compliant data use agreement with a researcher; and
 - DHIN monitors the researchers compliance with the agreement as if DHIN were a covered entity under HIPAA.
 - Release of individually identifiable health information for research ONLY IF the patient consents, in a writing compliant with HIPAA
- NOTE: DHIN will still have to seek amendments to its data use agreements with data senders.

How can DHIN obtain prescription fill data?

- Discussed generally at task force meeting #2.
- Currently have a proposal to transfer data from the Prescription Drug Monitoring Program to DHIN.
- *Discussion question:* Should pharmacies be required to provide *all* fill data to PDMP, rather than just controlled substances and drugs of interest?

How can DHIN provide Gift of Life with access to appropriate clinical data?

Gift of Life Donor Program

- Hospitals are currently required to provide Gift of Life with appropriate clinical information when organ or tissue donation becomes a possibility.
- Portions of the Delaware code explicitly require hospitals to notify and provide this information.
- Gift of Life has contacted DHIN.
 - In certain circumstances, DHIN has information that would be helpful to Gift of Life in determining whether certain organs or tissues are suitable for donation.

How can DHIN provide Gift of Life with access to appropriate clinical data?

Proposed area of improvement:

- Require DHIN to provide Gift of Life clinicians with access to the Community Health Record.
- Access would be limited to the same circumstances that trigger a hospital's duty to provide information to Gift of Life.
- Access would be audited and reviewed pursuant to existing DHIN policies and procedures.

Thank you



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APPENDIX D

RELEVANT DHIN

STATUTES

TITLE 16

Health and Safety

Regulatory Provisions Concerning Public Health

CHAPTER 7. Sexually Transmitted Diseases

Subchapter II. HIV Testing and Counseling

§ 714 Definitions.

For purposes of this subchapter the following definitions shall apply:

- (1) “AIDS” shall mean Acquired Immunodeficiency Syndrome, a stage of HIV illness.
- (2) “Approved laboratory” shall mean a laboratory approved by the Department for the purpose of performing standard tests for HIV as recognized as such by the Department.
- (3) “Clinical setting” shall mean prenatal clinics, hospital emergency departments, urgent care clinics, inpatient services, substance abuse treatment clinics, public health clinics, nursing homes, community clinics, correctional health-care facilities, blood banks, blood centers, sperm banks, primary care settings, and other public or private settings as defined by the Division.
- (4) “Health-care provider” shall mean any nurse, physician, dentist or other dental worker, optometrist, podiatrist, chiropractor, laboratory or blood bank technologist or technician, phlebotomist, dialysis personnel, emergency health-care provider (including any paramedic, emergency medical technician, law-enforcement personnel or firefighter), others whose activities involve contact with patients, their blood or corpses, and other public or private providers as defined by the Division.
- (5) “Health facility” shall mean a hospital, nursing home, clinic, blood bank, blood center, sperm bank, laboratory, or other health-care institution.
- (6) “HIV” shall mean the Human Immunodeficiency Virus, a virus that can be transmitted sexually and that is identified as the causative agent of AIDS.
- (7) “HIV-related tests” shall mean HIV tests, CD4 cell count tests, viral load tests, or any other tests related to HIV.
- (8) “HIV test” shall mean a test to detect HIV infection.

- (9) “Informed consent” means consent of the subject of the test or subject’s legal guardian to the performance of HIV testing by a health-care provider who has informed the subject or the subject’s legal guardian both verbally and in writing, to an extent reasonably comprehensive to general lay understanding, of the nature of the proposed testing and of the risks and alternatives to testing which a reasonable person would consider material to the decision whether or not to undergo testing.
- (10) “Invasive medical procedure” shall mean any procedure involving surgical entry into tissues, cavities, or organs.
- (11) “Legal guardian” shall mean a person appointed by a court to assume legal authority for another who has been found incompetent or, in the case of a minor, a person who has legal custody of the minor.
- (12) “Manner known to transmit HIV” shall mean parenteral exposure to blood or blood products including but not limited to injection through the skin, sexual exposure, or exposure as otherwise determined by the Division.
- (13) “Nonclinical setting” shall mean community-based organizations (CBO), outreach and education settings, mobile vans, and other settings as defined by the Division.
- (14) “Person” shall mean any natural person, partnership, association, joint venture, trust, public, or private corporation, or health facility.
- (15) “Prevention counseling” shall mean an interactive process of assessing risk, recognizing specific behaviors that increase the risk for acquiring or transmitting HIV, and developing a plan to take specific steps to reduce risks.
- (16) “Release of test results” shall mean a written authorization for disclosure of test results, which is signed, dated and specifies to whom disclosure is authorized and the time period during which the release is to be effective.
- (17) “Routine/opt-out testing” shall mean that the general consent for medical care shall encompass testing for HIV and that testing may be performed as a part of routine care unless it is declined and that declination is noted in the medical record. A separate consent for HIV testing is not required.
- (18) “Test counseling” shall include information that includes an explanation of the testing process/procedure, the meaning of possible test results, and provision of resources for additional information about relevant infections. The information may be provided orally or in writing and the subject of the counseling given the opportunity to ask questions.

66 Del. Laws, c. 336, § 1; 71 Del. Laws, c. 458, § 1; 78 Del. Laws, c. 277, § 2.;

§ 715 Consent for HIV testing.

(a) A health-care provider or other person who performs HIV testing services in a clinical setting may provide routine/opt-out testing provided that the following occurs:

- (1) The subject is informed, orally or in writing, that routine/opt-out HIV testing is

encompassed by the general consent for medical services.

(2) The subject is given the opportunity to refuse consent to HIV testing at each instance of testing. Documentation of such refusal shall be noted in the subject's medical record.

(3) The subject is provided HIV test counseling, orally or in writing, at the first instance of testing and by request thereafter.

(b) The health-care provider or other person who performs HIV testing services in a nonclinical setting must obtain written documentation of informed consent at each instance of HIV screening.

(1) Informed consent to an HIV test in a nonclinical setting shall consist of a voluntary agreement executed by the subject of the test or the subject's legal guardian.

(2) At each instance of testing, the subject of the test must be offered HIV test counseling and prevention counseling prior to consent for HIV testing.

(c) Notwithstanding any other provision of law, a minor 12 years of age or older may consent or refuse consent to be a subject of HIV-related testing and to counseling relevant to the test. The consent or refusal of the minor shall be valid and binding as if the minor had achieved majority, and shall not be voidable, nor subject to later disaffirmance, because of minority.

(d) Notwithstanding subsection (a) of this section the provisions of subsections (b) and (c) of this section do not apply when:

(1) Knowledge of such test results is necessary for medical diagnostic purposes to provide appropriate emergency care or treatment and the subject of the test is unable to grant or withhold consent.

(2) The testing is done for the purposes of research; provided that the test is performed in a manner by which the identity of the test subject is not known and may not be retrieved by the researcher.

(3) A health-care provider or health-care facility procures, processes, distributes or uses:

a. Blood;

b. A human body part donated for a purpose specified under the Uniform Anatomical Gift Act (Chapter 27 of this title); or

c. Semen provided prior to July 11, 1988, for the purpose of artificial insemination, and such test is necessary to assure the medical acceptability of such gift or semen for the purposes intended.

(4) The health of a health-care worker has been threatened during the course of a health-care worker's duties, as a result of exposure to blood or body fluids of the patient in a manner known to transmit HIV.

(5) It is necessary to control the transmission of HIV infection as may be allowed pursuant to this chapter as it relates to sexually transmitted diseases, or § 6523(b) of Title 11 as it relates to the Department of Correction.

(6) Testing is ordered by a court of competent jurisdiction within the confines of civil or criminal litigation where the results of an HIV-related test of a party, or a person in the custody or under the legal control of another party, is relevant to the ultimate issue of culpability and/or liability. Said order must be issued in compliance with the following provisions:

- a. No court of this State shall issue such order unless the court finds that there is a compelling need for such test results, which cannot be accommodated by other means. In assessing compelling need, the court shall weigh the need for testing and disclosure of the test results against the privacy interest of the test subject and the public interest, which may be disserved, by disclosure which deters future testing or which may lead to discrimination.
- b. Pleadings pertaining to ordering of an HIV-related test shall substitute a pseudonym for the true name of the subject of the test. The true name shall be communicated confidentially, in documents not filed with the court.
- c. Before granting any such order, the court shall provide the subject of the test with notice and a reasonable opportunity to participate in the proceedings if the individual is not already a party.
- d. Court proceedings as to disclosure of test results so ordered shall be conducted in camera unless the subject of the test agrees to a hearing in open court or unless the court determines that a public hearing is necessary to the public interest and the proper administration of justice.

(e) Any person on whom an HIV-related test was performed without first having obtained informed consent pursuant to paragraphs (d)(1), (4) and (5) of this section shall be given notice promptly, personally and confidentially that a test sample was taken and the results of such test may be obtained upon request.

(f) At the time of learning the test result, the subject of the test or the subject's legal guardian shall be provided with counseling for coping with the emotional consequences of learning the result, for understanding the interpretation of the test result, for understanding measures for preventing infection to others, to urge the voluntary notification of sexual and needle-sharing partners of the risk of infection and the availability of any appropriate health-care services, including mental health-care and appropriate social and supportive services.

66 Del. Laws, c. 336, § 1; 70 Del. Laws, c. 186, § 1; 77 Del. Laws, c. 109, § 1; 78 Del. Laws, c. 277, § 2.;

§ 716 HIV testing of pregnant women.

(a) A perinatal care provider may provide routine/opt-out testing pursuant to § 715(a) of this title.

(1) In addition to the provisions of this subsection, a licensed health-care provider who renders the primary prenatal care for a pregnant woman must offer HIV testing upon intake to perinatal services, during the third trimester, and at intake into labor and delivery if the result of previous test are not available or documented in the patient's chart.

(2) In addition to the provisions this subsection, a licensed health-care provider who renders the primary prenatal care for a pregnant woman must also counsel a pregnant woman that is found to be HIV-infected, orally or in writing, about the dangers to her fetus and about the treatment options for maintaining her health and reducing chances of transmission of HIV to her fetus.

(b) A pregnant woman shall have the right to refuse consent to testing HIV infection at any instance of testing and to refuse any recommended treatment. Documentation of such refusal shall be maintained in the patient's medical record. All other provisions of this subchapter shall apply to such counseling, testing, and disclosure, which take place pursuant to this section.

70 Del. Laws, c. 520, § 1; 70 Del. Laws, c. 186, § 1; 71 Del. Laws, c. 458, § 1; 75 Del. Laws, c. 434, § 1; 77 Del. Laws, c. 109, § 2; 78 Del. Laws, c. 277, § 2.;

§ 717 Confidentiality.

(a) No person may disclose or be compelled to disclose the identity of any person upon whom an HIV-related test is performed, or the results of such test in a manner which permits identification of the subject of the test, except to the following person:

(1) The subject of the test or the subject's legal guardian.

(2) Any person who secures a legally effective release of test results executed by the subject of the test or the subject's legal guardian.

(3) An authorized agent or employee of a health facility or health-care provider if the health facility or health-care provider itself is authorized to obtain the test results, the agent or employee provides patient care or handles or processes specimens of body fluids or tissues, and the agent or employee has a medical need to know such information to provide health-care to the patient.

(4) Health-care providers providing medical care to the subject of the test, when knowledge of the test results is necessary to provide appropriate emergency care or treatment.

(5) When part of an official report to the Division as may be required by law or regulation.

(6) A health facility or health-care provider which procures, processes, distributes or uses:

a. Blood;

b. A human body part from a deceased person donated for a purpose specified under

the Uniform Anatomical Gift Act [Chapter 27 of this title]; or

c. Semen provided prior to July 11, 1988, for the purpose of artificial insemination.

(7) Health facility staff committees or accreditation or oversight review organizations which are conducting program monitoring, program evaluation or service reviews, including the Child Death Review Commission conducting reviews pursuant to Title 31.

(8) Pursuant to Chapter 9 of this title as it relates to investigation of child abuse.

(9) Pursuant to subchapter I of this chapter as it relates to sexually transmitted diseases and their control.

(10) A person allowed access to said record by a court order which is issued in compliance with § 715(d)(6) of this title. Upon the issuance of an order to disclose test results, the court shall impose appropriate safeguards against unauthorized disclosure, which shall specify the persons who may have access to the information, the purposes for which the information shall be used and appropriate prohibitions on future disclosures.

(11) Pursuant to Chapter 12A of this title as it relates to notification of emergency medical care providers.

(b) No person to whom the results of an HIV-related test have been disclosed pursuant to subsection (a) of this section shall disclose the test results to another person except as authorized by subsection (a) of this section.

(c) The provisions in this section shall not interfere with the transmission of information as may be necessary to obtain third-party payment for medical care related to HIV infection or with the documentation of cause of death on death certificates.

66 Del. Laws, c. 336, § 1; 68 Del. Laws, c. 415, § 2; 70 Del. Laws, c. 186, § 1; 75 Del. Laws, c. 361, § 3; 78 Del. Laws, c. 277, § 2; 80 Del. Laws, c. 187, § 3.;

§ 718 Enforcement of subchapter.

(a) Any person aggrieved by a violation of this subchapter shall have a right of action in the Superior Court and may recover for each violation:

(1) Against any person who negligently violates a provision of this subchapter, damages of \$1,000 or actual damages, whichever is greater.

(2) Against any person who intentionally or recklessly violates a provision of this subchapter, damages of \$5,000 or actual damages, whichever is greater.

(3) Reasonable attorneys' fees.

(4) Such other relief, including an injunction, as a court may deem appropriate.

(b) Any action under this subchapter is barred unless the action is commenced within 3 years after the cause of action accrues. A cause of action will accrue when the injured party becomes aware of an unauthorized disclosure pursuant to § 717 of this title, or that an HIV-related test has been conducted without informed consent pursuant to § 715 of this title.

(c) The Attorney General may maintain a civil action to enforce this subchapter in which a

Court may order any relief authorized by subsection (a) of this section.

(d) Nothing in this subchapter shall be construed to impose civil liability or criminal sanction for disclosure of an HIV-related test result in accordance with any reporting requirement by the Division.

66 Del. Laws, c. 336, § 1; 70 Del. Laws, c. 520, § 1; 71 Del. Laws, c. 458, § 1; 78 Del. Laws, c. 277, § 2.;

TITLE 16

Health and Safety

Regulatory Provisions Concerning Public Health

CHAPTER 12. Informed Consent and Confidentiality

Subchapter I. Genetic Information

§ 1201 Definitions.

As used in this subchapter:

(1) “Genetic characteristic” means any inherited gene or chromosome, or alternation thereof, that is scientifically or medically believed to predispose an individual to a disease, disorder or syndrome, or to be associated with a statistically significant increased risk of development of a disease, disorder or syndrome.

This includes, but is not limited to, information regarding carrier status, information regarding an increased likelihood of future disease or increased sensitivity to any substance, information derived from laboratory tests that identify mutations in specific genes or chromosomes, requests for genetic services or counseling, tests of gene products and direct analysis of genes or chromosomes.

(2) “Genetic information” means information about inherited genes or chromosomes, and of alterations thereof, whether obtained from an individual or family member, that is scientifically or medically believed to predispose an individual to disease, disorder or syndrome or believed to be associated with a statistically significant increased risk of development of a disease, disorder or syndrome.

(3) “Genetic test” means a test for determining the presence or absence of an inherited genetic characteristic in an individual, including tests of nucleic acids such as DNA, RNA, and mitochondrial DNA, chromosomes or proteins in order to identify a predisposing genetic characteristic associated with disease, disorder or syndrome.

(4) “Informed consent”

a. For the purpose of obtaining genetic information, means the signing of a consent form which includes a description of the genetic test or tests to be performed, its purpose or purposes, potential uses, and limitations and the meaning of its results, and that the individual will receive the results unless the individual directs otherwise;

- b. For the purpose of retaining genetic information, means the signing of a consent form which includes a description of the genetic information to be retained, its potential uses and limitations;
- c. For the purpose of disclosing genetic information, means the signing of a consent form which includes a description of the genetic information to be disclosed and to whom or a notice that the information will be available to individuals who have access to Electronic Medical Records (EMR) or to the Delaware Health Information Network (DHIN).
- d. For the purpose of obtaining insurance, there may be a single signing which shall allow the obtaining, retaining and disclosure of genetic information, which, in addition to the requirements of paragraphs (4)a. and b. of this section, shall:
 - 1. Be written in plain language;
 - 2. Be dated;
 - 3. Name or identify by generic reference the persons authorized to disclose information about the individual;
 - 4. Specify the nature of the information authorized to be disclosed;
 - 5. Name or identify by generic reference the person to whom the individual is authorizing information to be disclosed, or subsequently redisclosed;
 - 6. Describe the purpose for which the information is collected;
 - 7. Specify the length of time such authorization shall remain valid; and,
 - 8. Be signed by:
 - A. The individual;
 - B. Such other person authorized to consent for such individual, if such individual lacks the capacity to consent; or;
 - C. The claimant for the proceeds of an insurance policy.

71 Del. Laws, c. 458, § 2; 78 Del. Laws, c. 277, § 3; 80 Del. Laws, c. 126, § 1.;

§ 1202 Informed consent required to obtain genetic information.

- (a) No person shall obtain genetic information about an individual without first obtaining informed consent from the individual.
- (b) The requirements of this section shall not apply to genetic information obtained:
 - (1) By a state, county, municipal or federal law-enforcement agency for the purposes of establishing the identity of a person in the course of a criminal investigation or prosecution;
 - (2) To determine paternity;
 - (3) Pursuant to the DNA analysis and data bank requirements of § 4713 of Title 29;

- (4) To determine the identity of deceased individuals;
- (5) For anonymous research where the identity of the subject will not be released;
- (6) Pursuant to newborn screening requirements established by state or federal law; or
- (7) As authorized by federal law for the identification of persons.

71 Del. Laws, c. 458, § 2; 78 Del. Laws, c. 277, § 3.;

§ 1203 Authorization to retain genetic information and samples from which genetic information is derived.

(a) No person shall retain an individual's genetic information without first obtaining informed consent from the individual unless:

- (1) Retention is necessary for the purposes of a criminal or death investigation or a criminal or juvenile proceeding;
- (2) Retention is necessary to determine paternity;
- (3) Retention is authorized by order of a court of competent jurisdiction;
- (4) Retention is made pursuant to the DNA analysis and data bank requirements of § 4713 of Title 29;
- (5) Retention of information is for anonymous research where the identity of the subject will not be released; or
- (6) Retention is pursuant to newborn screening requirements established by state or federal law.

(b) The sample of an individual from which genetic information has been obtained shall be destroyed promptly unless:

- (1) Retention is necessary for the purposes of a criminal or death investigation or a criminal or juvenile proceeding;
- (2) Retention is authorized by order of a court of competent jurisdiction; or
- (3) Retention is authorized by the individual; or
- (4) Retention is for anonymous research where the identity of the subject will not be released.

71 Del. Laws, c. 458, § 2; 78 Del. Laws, c. 277, § 3; 80 Del. Laws, c. 96, § 2.;

§ 1204 Genetic information access by the subject.

An individual promptly upon request, may inspect, request correction of and obtain genetic information from the records of that individual.

71 Del. Laws, c. 458, § 2; 78 Del. Laws, c. 277, § 3.;

§ 1205 Conditions for disclosure to others of genetic information.

(a) Regardless of the manner of receipt or the source of genetic information, including information received from an individual, a person shall not disclose or be compelled, by subpoena or any other means, to disclose the identity of an individual upon whom a genetic test has been performed or to disclose genetic information about the individual in a manner that permits identification of the individual, unless:

- (1) Disclosure is necessary for the purposes of a criminal or death investigation or a criminal or juvenile proceeding or to protect the interests of an issuer in the detection or prevention of fraud, material misrepresentation or material nondisclosure;
- (2) Disclosure is necessary to determine paternity;
- (3) Disclosure is authorized by order of a court of competent jurisdiction;
- (4) Disclosure is made pursuant to the DNA analysis and data bank requirements of § 4713 of Title 29;
- (5) Disclosure is authorized by obtaining informed consent of the tested individual describing the information to be disclosed and to whom;
- (6) Disclosure is for the purpose of furnishing genetic information relating to a decedent for medical diagnosis of blood relatives of the decedent;
- (7) Disclosure is for the purpose of identifying bodies;
- (8) Disclosure is pursuant to newborn screening requirements established by state or federal law;
- (9) Disclosure is authorized by federal law for the identification of persons; or
- (10) Disclosure is by an insurer to an insurance regulatory authority;
- (11) Disclosure is authorized in accordance with § 1201(4)c. of this title; or
- (12) Disclosure is otherwise permitted by law.

(b) This section shall apply to any subsequent disclosure by any person after another person has disclosed genetic information or the identity of an individual upon whom a genetic test has been performed.

71 Del. Laws, c. 458, § 2; 78 Del. Laws, c. 277, § 3; 80 Del. Laws, c. 126, § 1.;

§ 1206 Subchapter applicability.

This subchapter applies only to genetic information or samples that can be identified as belonging to an individual or family. This subchapter does not apply to any law, contract or other arrangement that determines a person's rights to compensation relating to substances or information derived from a sample of an individual from which genetic information has been obtained.

71 Del. Laws, c. 458, § 2; 78 Del. Laws, c. 277, § 3.;

§ 1207 Parental rights.

This subchapter does not alter any right of parents or guardians to order medical and/or

genetic tests of their children.

71 Del. Laws, c. 458, § 2; 78 Del. Laws, c. 277, § 3.;

§ 1208 Violations, penalties for unlawful disclosure of genetic information, jurisdiction.

(a) Any person who wilfully retains an individual's genetic information or retains an individual's sample in violation of this subchapter shall be punished by a fine of not less than \$1,000 nor more than \$10,000.

(b) Any person who wilfully obtains or discloses genetic information in violation of this subchapter shall be punished by a fine not less than \$5,000 nor more than \$50,000.

(c) Any person who wilfully discloses an individual's genetic information in violation of this subchapter, shall be liable to the individual for all actual damages, including damages for economic, bodily or emotional harm which is proximately caused by the disclosure.

(d) The Superior Court shall have jurisdiction over all violations of this subchapter.

71 Del. Laws, c. 458, § 2; 78 Del. Laws, c. 277, § 3.;

TITLE 16

Health and Safety

Delaware Health Information Network

CHAPTER 103. Delaware Health Information Network

Subchapter II. The Delaware Health Care Claims Database

§ 10311 The Delaware Health Care Claims Database — Findings; purpose; creation.

(a) The General Assembly finds that:

(1) The establishment of effective health-care data analysis and reporting initiatives is essential to achieving the “Triple Aim” of the State’s ongoing health-care innovation efforts: improved health, health-care quality and experience, and affordability for all Delawareans.

(2) The ongoing work of the Delaware Center for Health Innovation to transform the State’s health-care system from a fee-for-service system to a value-based system that rewards health-care providers for quality and efficiency of care is a worthy effort, and, to that end, the General Assembly supports the establishment of a health-care claims database that would assist in the State’s efforts to achieve the Triple Aim.

(3) Claims data is an important component of population health research and analysis, and that appropriate access to claims data can facilitate the development of value-based health-care purchasing and the study of the prevalence of illness or injury across the broader population of Delaware and in particular communities or neighborhoods.

(4) Providers and other health-care entities accepting financial risk for managing the health-care needs of a population, including the State as a self-insured employer, should have access to claims data as necessary to effectively manage that risk.

(b) The purpose of this subchapter is to create a centralized health-care claims database to enable the State to more effectively understand utilization across the continuum of health care in Delaware and achieve the Triple Aim.

(c) The DHIN, assisted by the Department of Health and Social Services and the Delaware Health Care Commission as necessary, shall administer a centralized health-care claims database, known as the “Delaware Health Care Claims Database.”

(d) The Delaware Health Care Claims Database is created within the DHIN to facilitate data-driven, evidence-based improvements in access, quality, and cost of health care and to promote and improve the public health through increased transparency of accurate health-care claims data and information. The DHIN shall collect and maintain claims data under this subchapter.

80 Del. Laws, c. 329, § 5.;

§ 10312 Definitions.

For purposes of this chapter, unless amended, supplemented, or otherwise modified by regulations adopted under this chapter:

- (1) “Claims data” includes required claims data and any additional health-care claims information that a voluntary reporting entity elects, through entry into an appropriate data submission and use agreement under this subchapter, to submit to the Delaware Health Care Claims Database.
- (2) “Health-care services” means as defined in § 6403 of Title 18.
- (3) “Health insurer” means as defined in § 4004 of Title 18. “Health insurer” does not include providers of casualty insurance, as defined in § 906 of Title 18; providers of group long-term care insurance or long-term care insurance, as defined in § 7103 of Title 18; or providers of a dental plan or dental plan organization, as defined in § 3802 of Title 18.
- (4) “Mandatory reporting entity” means all of the following entities, to the extent permitted under federal law:
 - a. The State Employee Benefits Committee and the Office of Management and Budget, under each entity’s respective statutory authority to administer the State Group Health Insurance Program in Chapter 96 of Title 29, and any health insurer, third-party administrator, or other entity that receives or collects charges, contributions, or premiums for, or adjusts or settles health claims for, any State employee, or their spouses or dependents, participating in the State Group Health Insurance Program, except for any carrier, as defined in § 5290 of Title 29, selected by the State Group Health Insurance Plan to offer supplemental insurance program coverage under Chapter 52C of Title 29.
 - b. The Division of Medicaid and Medical Assistance, with respect to services provided under programs administered under Titles XIX and XXI of the Social Security Act [42 U.S.C. §§ 1396 et seq. and 1397aa et seq.].
 - c. Any health insurer or other entity that is certified as a qualified health plan on the Delaware Health Insurance Marketplace for plan year 2017 or any subsequent plan year, except for any health insurer or other entity that is not otherwise required to provide claims data as a condition of certification as a qualified health plan on the Delaware Health Insurance Marketplace for plan year 2017 or any subsequent plan year.

d. Any federal health insurance plan providing health-care services to a resident of this State, including Medicare and the Federal Employees Health Benefits Plan.

e. Any health insurer providing health-care coverage to a resident of this State.

(5) “Pricing information” includes the preadjudicated price charged by a provider or facility to a reporting entity for health-care services, the amount paid by a patient or insured party, including copays and deductibles, and the postadjudicated price paid by a reporting entity to a provider for health-care services.

(6) “Provider” means a hospital or any health-care practitioner licensed, certified, or authorized under state law to provide health-care services and includes hospitals and health-care practitioners participating in group arrangements, including accountable care organizations, in which the hospital or health-care practitioners agree to assume responsibility for the quality and cost of health care for a designed group of beneficiaries.

(7) “Reporting date” means a calendar deadline, to be scheduled on a regularly recurring basis, by which required claims data must be submitted by a mandatory reporting entity to the Delaware Health Care Claims Database.

(8) “Required claims data” includes the basic claims information that a mandatory reporting entity is required to submit to the Delaware Health Care Claims Database by the reporting date, including all of the following:

a. Basic demographic information, including the patient’s gender, age, and geographic area of residency.

b. Basic information relating to an individual episode of care, including the date and time of the patient’s admission and discharge; the identity of the health-care services provider; and the location and type of facility, such as a hospital, office, or clinic, where the service was provided.

c. Information describing the nature of health-care services provided to the patient in connection with the encounter, visit, or service, including diagnosis codes.

d. Health insurance product type, such as HMO or PPO.

e. Pricing information.

(9) “Third-party administrator” means as defined in § 102 of Title 18.

(10) “Voluntary reporting entity” includes, except as prohibited under applicable federal law, any of the following entities, unless such entity is a mandatory reporting entity:

a. Any health insurer.

b. Any third-party administrator.

c. Any entity, which is not a health insurer or third-party administrator, when such entity receives or collects charges, contributions, or premiums for, or adjusts or settles health-care claims for, residents of this State.

§ 10313 Submission of required claims data by mandatory reporting entities; submission of claims data by voluntary reporting entities.

(a) Requirements for submission of required claims data by a mandatory reporting entity.

(1) A mandatory reporting entity shall submit required claims data to the Delaware Health Care Claims Database by the reporting date.

(2) The DHIN, subject to the provisions of this subchapter and regulations promulgated under this subchapter, shall collect the required claims data from mandatory reporting entities by the reporting date.

(3) The DHIN shall, under § 10306 of this title, promulgate a template form for a data submission and use agreement for the submission of required claims data by a mandatory reporting entity.

(4) The DHIN and each mandatory reporting entity shall execute a mutually acceptable data submission and use agreement. Such agreement shall include procedures for submission, collection, aggregation, and distribution of claims data and shall provide for, at a minimum, all of the following:

a. The protection of patient privacy and data security under provisions of this chapter and state and federal privacy laws, including the federal Health Insurance Portability and Accountability Act [P.L. 104-191]; Titles XIX and XXI of the Social Security Act [42 U.S.C. §§ 1396 et seq. and 1397aa et seq.]; and the Health Information Technology for Economic and Clinical Health (HITECH) Act [42 U.S.C. §§ 300jj et seq. and 17901 et seq.], and all other applicable state and federal laws relating to the privacy and security of protected health information.

b. The identification of any claims data, in addition to required claims data, that the mandatory reporting entity elects to submit to the Delaware Health Care Claims Database.

c. A detailed summary of how claims data submitted by the mandatory reporting entity may be used for geographic, demographic, economic, and peer group comparisons.

d. A representation and warranty that the DHIN shall, abide to the fullest extent possible, by nationally recognized data collection standards and methods, including the standards promulgated by the APCD Council or successor organization, to establish and maintain the database in a cost-effective manner and to facilitate uniformity among various health-care claims databases of other states and specification of data fields to be included in the submitted claims, consistent with such national standards, allowing for exemptions when submitting entities do not collect the specified data or pay on a per-claim basis.

(5) *Exclusions from required claims data reporting requirement.* — The required claims data reporting requirements under this subchapter, and any rules and regulations promulgated under this chapter, do not apply to required claims data created for any

employee welfare benefit plan or other employee health plan that is regulated by the Employee Retirement Income Security Act of 1974 (ERISA), 88 Stat. 829, as amended, 29 U.S.C. § 1001 et seq., unless otherwise permitted by federal law or regulation.

(b) *Submission of claims data by a voluntary reporting entity.* — (1) The DHIN shall collect claims data from voluntary reporting entities under the terms and conditions of the applicable data submission and use agreement.

(2) The DHIN may promulgate regulations to clarify the types of claims data that may be submitted by a voluntary reporting entity.

(3) The DHIN and any voluntary reporting entity that elects to submit claims data to the Delaware Health Care Claims Database shall execute a mutually acceptable data submission and use agreement. The DHIN shall publish a template form data submission and use agreement that includes the required data submission and use agreement provisions under paragraph (a)(4) of this section.

(c) Unless modified or supplemented by regulations promulgated under this chapter, in instances where more than 1 entity is involved in the administration of a policy, a health insurer shall be responsible for submitting the claims data on policies that it has written, and the third-party administrator shall be responsible for submitting claims data on self-insured plans that it administers.

80 Del. Laws, c. 329, § 5.;

§ 10314 External and public reporting of claims data.

(a) The DHIN shall provide Delaware health-care payers, providers, and purchasers with access to the Delaware Health Care Claims Database for the purpose of facilitating the design and evaluation of alternative delivery and payment models, including population health research and provider risk-sharing arrangements.

(1) Claims data provided to the Delaware Health Care Claims Database shall only be provided to a requesting party when a majority of the DHIN Board of Directors, or of a subcommittee established under the DHIN's bylaws for purposes of administering the Health Care Claims Database, determines that the claims data should be provided to the requesting party to facilitate the purposes of this subchapter or to the Delaware Health Care Commission.

a. The determination under this paragraph (a)(1) shall be reduced to writing and provided to the requesting party.

b. The determination under this paragraph (a)(1) shall be final and not subject to appeal, and there is no private right of action to a requesting party against the DHIN or any other party to enforce the requirements of this section.

(2) The DHIN shall, in consultation with the Delaware Health Care Commission, promulgate rules and regulations regarding the appropriate form and content of an application to receive claims data, providing examples of requests for claims data that will generally be deemed consistent with the purposes of this subchapter.

(b) Claims data provided to a requesting party under this section shall be provided under the DHIN's existing confidentiality and data security protocols and in compliance with all applicable state and federal laws relating to the privacy and security of protected health information, including compliance, to the fullest extent practicable consistent with the purposes under this subchapter, 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. Individually identifiable patient health information shall be maintained by providers and purchasers in accordance with all applicable state and federal laws relating to the confidentiality and security of protected health information and any additional privacy and security requirements set forth in regulations promulgated under this chapter.

(c) The Office of Management and Budget, State Employee Benefits Committee, Division of Public Health, State Council for Persons with Disabilities, and Division of Medicaid and Medical Assistance shall have access to all claims data reported by the Delaware Health Care Claims Database under this subchapter at no cost for the purposes of public health improvement research and activities. These entities are authorized to enter into appropriate agreements with the DHIN to allow the Delaware Health Care Claims Database to perform data warehousing and analytics functions that have been performed pursuant to the existing statutory authority of the Office of Management and Budget, the State Employee Benefits Committee, State Council for Persons with Disabilities, or the Department of Health and Social Services.

(d) The DHIN may promulgate regulations to make available to the public certain nonindividually identifiable data extracts and analyses, as the DHIN determines is consistent with, and necessary to, achieve the goals and policies of this subchapter. Prior to the release of such data extracts and analyses, the same processes identified in subsection (e) of this section shall be completed.

(e) The DHIN shall promulgate regulations to notify a mandatory reporting entity or voluntary reporting entity when claims data submitted by the mandatory reporting entity or voluntary reporting entity may be released for a purpose permitted under this subchapter and provide the mandatory reporting entity or voluntary reporting entity with an opportunity to comment on the data release request prior to its release. Any comments received from a mandatory reporting entity or voluntary reporting entity during the comment period shall be reviewed, considered, and responded to by DHIN prior to the data release. If a party requesting the release of data is identified by a mandatory reporting entity or voluntary reporting entity as a potential competitor of the reporting entity, the DHIN shall limit disclosure of any pricing information that includes postadjudicated claims data, to the fullest extent practicable and consistent with the purposes of this subchapter, to a summary format that allows for analysis without revealing contracted pricing information.

(f) The DHIN shall promulgate regulations to ensure confidentiality, privacy, and security protections of health-care data and all other information collected, stored, or released by DHIN, subject to all applicable state and federal health-care privacy, confidentiality, and data security laws.

80 Del. Laws, c. 329, § 5; 81 Del. Laws, c. 392, § 4; 82 Del. Laws, c. 156, § 1.;

§ 10315 Funding of Delaware Health Care Claims Database.

(a) The DHIN may not require any mandatory reporting entity, voluntary reporting entity, or provider to pay any cost or fee to submit or verify the accuracy of claims data or otherwise to enable the operation of the Delaware Health Care Claims Database with respect to required claims data submissions.

(b) The DHIN may enter contracts under § 10303(a)(11) of this title with individuals and entities who voluntarily subscribe to access the database.

(c) The DHIN, with the assistance of the Department of Health and Social Services, shall develop short-term and long-term funding strategies for the creation and operation of the Delaware Health Care Claims Database that may include public and private grant funding, subscriptions for access to data reports, access fees, and revenue for specific data projects, subject to the limitations of this section.

80 Del. Laws, c. 329, § 5.;

APPENDIX E

SENATE BILL 171



SPONSOR: Sen. Poore & Rep. Griffith
Sens. Hansen, Lockman; Reps. Briggs King, Jaques,
Michael Smith

DELAWARE STATE SENATE
150th GENERAL ASSEMBLY

SENATE BILL NO. 171

AN ACT TO AMEND TITLE 16 OF THE DELAWARE CODE RELATING TO URGENT CARE FACILITIES.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF DELAWARE (Three-fifths of all members elected to each house thereof concurring therein):

Section 1. Amend Title 16, of the Delaware Code by making deletions as shown by strike through and insertions as shown by underline as follows and adding a new Subchapter 10B as follows:

§ 1001B Purpose.

To establish standards with respect to safety and sanitary conditions of urgent care facilities as defined in § 1002B of this subchapter and to investigate and inspect any such urgent care facility for unsafe or unsanitary conditions upon receipt of a complaint by a patient or current urgent care facility employee in accordance with this subchapter or upon the occurrence of any adverse event in connection with any such facility.

§ 1002B Definitions.

As used in this Chapter, the following terms mean:

(1) "Adverse event" means:

a. The death or serious injury of any patient at an urgent care facility;

b. A reasonable determination by the Department that death or serious injury may result from any unsafe or unsanitary condition at an urgent care facility; or

c. The initiation of any criminal investigation arising out of, or relating to, any diagnosis, treatment or other medical care at an urgent care facility.

(2) "Approved Accrediting Body" means those accrediting organizations approved by the Department pursuant to criteria that may be further outlined by regulation.

(3) "Complaint" means a complaint filed by a patient or current facility employee in writing, in such format as the Department shall require.

(4) "Patient" means a person who has received diagnosis, treatment, or other medical care at an urgent care facility or such person's spouse, as well as any parent, legal guardian, or legal custodian of such person who is under 18 years of age or any legal guardian or legal custodian of such person who is an adult.

(5) “Urgent Care Facility” means a facility that provides urgent care services, such as, without limitation, facilities known as “walk-in” clinics or centers or “urgent care centers.”

(6) “Urgent Care Services” means a model of episodic care for the diagnosis, treatment, management, or monitoring of acute and chronic disease or injury that is: (i) for the treatment of illness or injury that is immediate in nature but does not require emergency services and (ii) otherwise holds itself out to the public as a facility that provides immediate medical care for non-emergency conditions outside of the customary primary care office setting.

§ 1003B Regulations.

(1) The Department shall promulgate regulations in accordance with the Administrative Procedures Act, 29 Del. C. § 10101, et seq., to further outline the parameters of its inspection and enforcement authority and to further establish the operational protocols contemplated in paragraphs (a) through (h) of this Section, consistent with the limitations as set forth in this subchapter. Specifically, at a minimum, the Department shall develop, establish, and enforce regulations:

a. Governing the operation of urgent care facilities to protect and promote the public health and welfare;

b. Setting forth criteria the Department will utilize in assessing whether a facility may be offering urgent care services without a license to operate as an urgent care facility, including whether the facility holds itself out to the public as a provider of immediate medical care for non-emergent conditions that provides care outside of the customary primary care office setting or relationship on a walk-in basis and outside of routine primary care business hours;

c. Governing the criteria for which organizations shall be designated as an approved accrediting body;

d. Governing when reports, documentation, and proof required by this subchapter shall be provided to the Department;

e. Setting forth criteria under which the Department shall investigate and inspect any urgent care facility upon receipt of a complaint by a patient or current facility employee or upon occurrence of any adverse event in connection with any such urgent care facility;

f. Governing whether and under what circumstances and conditions a facility fee may be charged or added to the costs of services provided to a patient by an urgent care facility;

g. Governing patient care coordination, including working with the Delaware Health Information Network (“DHIN”) and other necessary stakeholders, to establish procedures for appropriate notifications to primary care providers of urgent care utilization by the primary care provider’s assigned or attributed patients; and

h. Revoking any existing Department regulations or sub-regulatory guidance or documents that conflict with the requirements of this subchapter, including the requirements set forth in 16 Del. Reg. § 4404 that prohibit

or otherwise restrict the use of the name or title “urgent care” by any facility that is not licensed by the Department as a free standing emergency center.

§ 1004B Licensing By Accreditation Requirement.

(1) To provide urgent care services and operate in this State, an urgent care facility must obtain a license, whether provisional or regular, from the Department.

(2) The Department shall issue a provisional license, which shall be valid for no more than 9 months from the date issued, to any existing or new urgent care facility when such facility provides the Department with the following:

a. An application made on a form prepared by or approved by the Department and published by regulation; and

b. Proof satisfactory to the Department that the existing or new urgent care facility is seeking accreditation from an approved accrediting body.

Provided both subsections (a) and (b) of this subsection (2) are satisfied, the Department shall issue a provisional license to such facility within 10 business days of the urgent care facility submitting its application. A provisional license may only be renewed one time.

(3) The Department shall issue a regular license, which shall be valid for no more than twenty-four months from the date issued, to any existing urgent care facility or any urgent care facility holding a provisional license when such facility provides the Department with the following:

a. An application made on a form prepared by or approved by the Department and published by regulation; and

b. Proof satisfactory to the Department that the existing urgent care facility or urgent care facility holding a provisional license has been accredited by an approved accrediting body.

Provided both subsections (a) and (b) of this subsection (2) are satisfied, the Department shall issue a regular license to such facility within 10 business days of the urgent care facility submitting its application.

(4) All urgent care facilities must submit proof of accreditation to the Department at regular intervals as the Department may proscribe. After each survey of any facility hereunder by an approved accrediting body, the facility must submit the approved accrediting body’s survey report to the Department within 30 days.

(5) If the facility fails to maintain current accreditation or if the accreditation is revoked or is otherwise no longer valid, the license of that urgent care facility shall immediately cease to operate. The Department shall also revoke the license granted to the urgent care facility

(6) An approved accrediting body shall report to the Department, at a minimum, all of the following regarding urgent care facilities the organization has accredited under this subchapter:

a. Findings of surveys; and

b. Findings of complaint and incident investigations;

Each approved accrediting body shall makes these reports to the Department at regular intervals as the Department may proscribe. Documents provided under this section are not public records under the Freedom of Information Act, Chapter 100 of Title 29.

(7) If an urgent care facility holds a current certification for participation in either Medicare or Medicaid through an affiliated hospital, such certification shall be deemed to be the equivalent of being accredited by an approved accrediting body provided the urgent care facility provides proof satisfactory to the Department that the urgent care facility holds, through an affiliated hospital, a current certification for participation in either Medicare or Medicaid. Such proof shall be provided to the Department at regular intervals as the Department may proscribe.

(8) The Department shall charge a fee of up to two thousand dollars (\$2,000) per facility that shall accompany the application for licensure of an urgent care facility. The fee shall be used to offset the costs of administering the licensing requirements set forth in this subchapter.

§ 1005B Other Department Authority.

(a) The Department can make and enforce such orders as it deems necessary to protect the health and safety of the public hereunder. Without limitation of the foregoing, if the Department determines during the course of any investigation or inspection that any facility hereunder poses a substantial risk to the health or safety of any person, the Department may order that such facility be closed until such time as it no longer poses a substantial risk.

(b) The Department shall share information regarding facilities with the Department of State, Division of Professional Regulation.

§ 1006B Coordination of Care.

(a) No later than January 1, 2020, each urgent care facility must enroll in the DHIN as active users of the Community Health Record and enter into an agreement with DHIN to provide DHIN with a summary of each visit or episode of care in an electronic format established by DHIN.

(b) If the patient has a primary care provider, the urgent care facility must notify the patient's primary care provider of the urgent care visit. Such notifications may be made through DHIN's Electronic Notification Service.

§ 1007B Enforcement.

111 (1) Any person constructing, managing, or operating any urgent care facility without complying with the
112 procedures set forth in this Chapter shall be fined by the Department no more than \$5,000 for the first offense and no more
113 than \$10,000 for each subsequent offense. Each day of a continuing violation shall be considered a separate offense.

114 Section 2. This Act shall become effective at the earlier of 180 days following enactment or 90 days after final
115 regulations specified under Section § 1003B are published in accordance with the Administrative Procedures Act.

SYNOPSIS

This Act establishes a new subchapter of Title 16 regulating urgent care facilities. It requires such facilities, existing and new, to obtain a license from DHSS, which requires the urgent care facility to either be accredited by an approved accrediting body or be seeking such accreditation. If the urgent care facility is seeking accreditation, it can operate on a provisional license for nine months. If accreditation is not obtained, the urgent care facility can apply once for a renewal of a provisional license. Operating without a license or accreditation will subject urgent care facilities to fines. The Act grants DHSS the power to promulgate various regulations to enforce the Act. DHSS can also make and enforce orders to protect the public health and share information with the Division of Professional Regulation. The Act requires each urgent care facility in the State to enroll in the Delaware Health Information Network ("DHIN") and to notify a patient's primary care provider through DHIN to facilitate the coordination of care.

Author: Senator Poore

APPENDIX F

SENATE RESOLUTION 9



SPONSOR: Sen. Lockman
Sens. Delcollo, Hansen, Lopez, Walsh

DELAWARE STATE SENATE
150th GENERAL ASSEMBLY

SENATE RESOLUTION NO. 9

ESTABLISHING A TASK FORCE TO RESEARCH, DISCUSS, AND MAKE FINDINGS AND
RECOMMENDATIONS REGARDING THE JOINT LEGISLATIVE OVERSIGHT AND SUNSET COMMITTEE'S
REVIEW OF THE DELAWARE HEALTH INFORMATION NETWORK.

1 WHEREAS, the Joint Legislative Oversight and Sunset Committee ("JLOSC") reviewed the Delaware Health
2 Information Network ("DHIN") in 2019; and

3 WHEREAS, DHIN's review resulted in 4 recommendations that relate to statutory changes to DHIN's governing
4 statute, Chapter 103 of Title 16 being presented for JLOSC's consideration; and

5 WHEREAS, 3 of the 4 recommendations require additional research and discussion among interested agencies and
6 citizens to assist JLOSC in making decisions whether to adopt the recommendations; and

7 WHEREAS, JLOSC expressed its desire to create a task force, comprised of JLOSC staff, relevant agencies, and
8 members of the public, to address the implementation of the 3 recommendations and report back to JLOSC in January
9 2020.

10 NOW, THEREFORE:

11 BE IT RESOLVED by the Senate of the 150th General Assembly of the State of Delaware that the Joint
12 Legislative Oversight and Sunset Committee Task Force on the Delaware Health Information Network ("Task Force") is
13 established.

14 BE IT FURTHER RESOLVED that the Task Force research, discuss, and make findings regarding
15 Recommendations 2, 4, and 6 of the JLOSC's 2019 review of DHIN, and report its findings and recommendations to the
16 JLOSC. The Task Force may find that the JLOSC should consider additional recommendations that the Task Force
17 identifies.

18 BE IT FURTHER RESOLVED that the Task Force is composed of 11 members. A member who serves by virtue
19 of position may appoint a designee to serve in that member's stead and at that member's pleasure. Membership is
20 comprised as follows:

21 (1) One JLOSC Analyst.

22 (2) One JLOSC Legislative Attorney.

23 (3) The Chief Executive Officer of DHIN.

(4) General Counsel of DHIN.

(5) Chief Operating Officer of DHIN.

(6) The Chair of the DHIN Board of Directors.

(7) An individual who represents data senders, such as hospitals or labs, as designated by the DHIN Board of Directors.

(8) The Lieutenant Governor, or the Lieutenant Governor may appoint a designee from the Behavioral Health Consortium.

(9) The Dean of the University of Delaware's College of Health Sciences.

(10) The Secretary of the Department of Health and Social Services.

(11) The Director of the Division of Public Health.

BE IT FURTHER RESOLVED that at least 5 individuals serve as consultants to the Task Force. A consultant who serves by virtue of position may appoint a designee to serve in that consultant's stead and at that consultant's pleasure. A consultant does not vote or have any duties or powers reserved for a Task Force member. Consultants are comprised as follows:

(1) One analyst from the Controller General's Office.

(2) The Chief Information Officer of the Department of Technology and Information.

(3) The Chief Executive Officer of the Gift of Life Program.

(4) The Bureau Chief of the Bureau of Correctional Healthcare Services.

(5) An individual who specializes in pharmacy data, selected by the Task Force members.

(6) Any other organization or individual that the Task Force may determine helpful in meeting its duties.

BE IT FURTHER RESOLVED that a member or consultant may appoint a designee. A member or consultant who appoints a designee must provide the designation in writing to the chair. A designee has the same duties and rights as the member or consultant the designee represents.

BE IT FURTHER RESOLVED that the JLOSC Analyst and JLOSC Legislative Attorney serve as co-chairs of the Task Force.

BE IT FURTHER RESOLVED that the co-chairs of the Task Force are responsible for guiding the administration of the Task Force by doing, at a minimum, all of the following:

(1) Notifying all Task Force members of their selection to serve on the Task Force and all consultants of their selection to serve as consultants.

(2) Setting a date, time, and place for the initial organizational meeting.

(3) Supervising the preparation and distribution of meeting notices, agendas, minutes, correspondence, and reports of the Task Force.

(4) Sending, after the first meeting of the Task Force, a list of the members of the Task Force and the person who appointed them to the Joint Legislative Oversight and Sunset Committee and the Director of the Division of Research of Legislative Council.

(5) Providing meeting notices, agendas, and minutes to the Director of the Division of Research of Legislative Council.

(6) Ensuring that the final report of the Task Force is submitted to the Joint Legislative Oversight and Sunset Committee with a copy to DHIN, the Director and the Librarian of the Division of Research of Legislative Council, and the Delaware Public Archives.

BE IT FURTHER RESOLVED that the Task Force must hold its first meeting no later than August 31, 2019.

BE IT FURTHER RESOLVED that a quorum of the Task Force is a majority of its members. A vacant position is not counted for quorum purposes.

BE IT FURTHER RESOLVED that:

(1) Official action by the Task Force, including making findings and recommendations, requires the approval of a majority of the members of the Task Force.

(2) The Task Force may adopt rules necessary for its operation. If the Task Force does not adopt rules or if the adopted rules do not govern a given situation, *Mason's Manual of Legislative Procedure* controls.

BE IT FURTHER RESOLVED that the Division of Research is responsible for providing reasonable and necessary support staff, materials, and meeting locations for the Task Force.

BE IT FURTHER RESOLVED that the co-chairs must compile a report containing a summary of the Task Force's work regarding the matters assigned to it in lines 14 through 17 of this Resolution, including any findings and recommendations adopted by the Task Force, and submit the report to the JLOSC and the Director and the Librarian of the Division of Research of Legislative Council no later than January 10, 2020.

BE IT FURTHER RESOLVED that this Resolution expires on the date the Task Force submits its findings and recommendations

SYNOPSIS

The Joint Legislative Oversight and Sunset Committee ("JLOSC") reviewed the Delaware Health Information Network ("DHIN") in 2019. As a result of that review, 4 recommendations relating to statutory changes to DHIN's governing statute were presented for JLOSC's consideration. JLOSC determined that a task force should be created to research, discuss, and report back to JLOSC its findings on the implementation of 3 of the 4 recommendations. JLOSC decided to form the task force through a simple resolution.

This Resolution establishes the Joint Legislative Oversight and Sunset Committee Task Force on the Delaware Health Information Network ("DHIN"). In addition to the 11 members of the Task Force, several consultants are also named, to share their expertise with the Task Force. The Task Force must hold its first meeting by August 31, 2019, and submit a final report of its findings and recommendations to JLOSC by January 10, 2020.

The Task force will not approve the implementation of a recommendation or authorize or require a change in any statute, policy, or practice. The Task Force is designed, authorized, and limited to do only the following:

- Research the background of and relevant information relating to JLOSC's Recommendations 2, 4, and 6.
- Discuss the merits and concerns of each recommendation.
- Report back to JLOSC on what the Task Force found in its research and discussions.

Consultants are specified to ensure their participation in the Task Force, while the number of members is kept limited in the interest of meeting quorum and scheduling requirements more easily.

Author: Senator Lockman