

Memo

To: SCPD, GACEC and DDC

From: Disabilities Law Program

Date: 9/14/2021

Re: September 2021 Policy and Law Memo

Please find below per your request analysis of pertinent regulations from the September Register of Regulations.

DDOE Emergency Order on 105 Residential Child Care Facilities and Day Treatment Programs, 25 Del. Register of Regulations 223 (September 1, 2021)

The Delaware Department of Education (“DDOE”) adopted emergency regulatory amendments to 9 Del. Admin. C. § 105. This section of the code describes the requirements for residential child care facilities and day treatment programs. DDOE is adopting this emergency order pursuant to its authority under 29 Del. C. § 10119, which authorizes it to adopt emergency regulations when an agency determines it is necessary to protect the public health, safety, or welfare from imminent peril. The emergency order adds section 3.7 which prescribes requirements for the mitigation and prevention of COVID-19 in residential child care facilities and day treatment programs.

This Emergency Order was repealed by the Emergency Order adopted and published in the Delaware Register at 25 Del. Register of Regulations 225, discussed directly below.

DDOE Emergency Order on 105 Residential Child Care Facilities and Day Treatment Programs, 25 Del. Register of Regulations 225 (September 1, 2021)

DDOE adopted emergency regulatory amendments to 9 Del. Admin. C. § 105. This section of the code describes the requirements for residential child care facilities and day treatment programs. DDOE is adopting this emergency order pursuant to its authority under 29 Del. C. § 10119, which authorizes it to adopt emergency regulations when an agency determines it is necessary to protect the public health, safety, or welfare from imminent peril. The emergency order adds section 3.7 which prescribes requirements for the mitigation and prevention of COVID-19 in residential child care facilities and day treatment programs.

DDOE is adopting this Emergency Order to establish its tiered strategy to mitigate the spread of the COVID-19 virus. The tiered strategy combines encouraging vaccination with additional steps, including continued mask usage. This approach is based on guidance from the Centers for Disease Control and Prevention (“CDC”).

DDOE adopted this Emergency Order, which repealed and replaced the earlier adopted Emergency Order published in the Delaware Register at 25 Del. Register of Regulations 223, because the earlier language was “inadvertently broad and resulted in requirements that were not intended.”

The adopted Emergency Order requires that all persons or associations conducting child care *recommend* mask use for children aged two (2) through pre-kindergarten and *require* mask use for children in kindergarten through twelfth grade as well as staff, family members, and visitors regardless of vaccination status. These recommendations and requirements extend to transportation provided by the child care facility. There are exceptions to the mask requirement, which include when seated at a table to eat or drink, when sleeping, when engaged in an activity where masking is not feasible (e.g. swimming), when outdoors, when children are not present in the building, or when a person is in a personal space and nobody from that person’s household is present. It further provides that an individual with a medical condition or disability which prevents them from wearing a mask may request a reasonable accommodation from the child care facility.

The Emergency Order is set to expire 120 days after August 16, 2021 with an option to renew the order for a period not to exceed 60 days.

The adopted emergency regulations generally follow CDC’s guidance regarding masking requirements in Early Care Education (“ECE”) programs, which include child care centers and home-based programs. CDC recommends that individuals over the age of two (2) who are not fully vaccinated should wear masks indoors, including children and staff. CDC also recommends that masks be worn outdoors if the individual is not fully vaccinated and it is either in a crowded setting and / or during an activity where there is sustained close contact with others who are not vaccinated, especially in areas of substantial high transmission.¹

However, masking is not the only recommendation made by the CDC for mitigating the spread of COVID-19. Although the adopted emergency order indicates it is for the mitigation and prevention of COVID-19 in residential child care facilities and day treatment programs, it should really be called “Masking Requirements.”

Instead of only incorporating masking requirements in this Emergency Order, Councils may wish to recommend that DDOE also include some of the other applicable CDC recommendations for mitigating and preventing the spread of COVID-19 in ECE facilities. Those other recommendations include but are not limited to (1) physical distancing and cohorting; (2) improving ventilation; (3) cleaning and disinfecting; (4) limiting nonessential visitors, volunteers, and activities involving external groups or organizations with people who are not fully vaccinated; (5) conducting workplace hazard assessments²; and (6) developing emergency operations plans.³

¹ <https://www.cdc.gov/coronavirus/2019-ncov/community/schools-childcare/child-care-guidance.html>.

² <https://www.osha.gov/safety-management/hazard-identification>

³ <https://www.cdc.gov/coronavirus/2019-ncov/community/schools-childcare/child-care-guidance.html>

Lastly, CDC also indicates that where ECE facilities decide to lax or remove their layered prevention strategies, each strategy should be removed one at a time and monitored for any resulting outbreaks or increases in COVID-19 cases. It recommends that ECE facilities work closely with local public health officials for this as well as other monitoring. Councils may wish to request that DDOE amend its Emergency Order to include a requirement that the entities covered under these regulations work closely with the Division of Public Health (“DPH”) and DDOE on monitoring and implementation of these tiered strategies.

Councils may wish to support this Emergency Order with the above-mentioned recommendations.

DDOE Emergency Order on 815 Health Examinations and Screening, 25 Del. Register of Regulations 227 (September 1, 2021)

DDOE adopted emergency regulatory amendments to 14 Del. Admin. C. § 815. This section of the code describes the requirements surrounding health examinations and screenings for public school students. DDOE is adopting this emergency order pursuant to its authority under 29 Del. C. § 10119, which authorizes it to adopt emergency regulations when an agency determines it is necessary to protect the public health, safety, or welfare from imminent peril. The emergency order adds section 6.0 which prescribes masking requirements for the mitigation and prevention of COVID-19 in schools and child care facilities.

This Emergency Order was repealed by the Emergency Order adopted and published in the Delaware Register at 25 Del. Register of Regulations 229, discussed directly below.

DDOE Emergency Order on 815 Health Examinations and Screening, 25 Del. Register of Regulations 229 (September 1, 2021)

DDOE adopted emergency regulatory amendments to 14 Del. Admin. C. § 815. This section of the code describes the requirements surrounding health examinations and screenings for public school students. DDOE is adopting this emergency order pursuant to its authority under 29 Del. C. § 10119, which authorizes it to adopt emergency regulations when an agency determines it is necessary to protect the public health, safety, or welfare from imminent peril. The emergency order adds section 6.0 which prescribes masking requirements for the mitigation and prevention of COVID-19 in schools and child care facilities.

DDOE is adopting this Emergency Order to establish its tiered strategy to mitigate the spread of the COVID-19 virus. The tiered strategy combines encouraging vaccination with additional steps, including continued mask usage. This approach is based on guidance from the CDC.

DDOE adopted this Emergency Order, which repealed and replaced the earlier adopted Emergency Order published in the Delaware Register at 25 Del. Register of Regulations 227, because the earlier language was “inadvertently broad and resulted in requirements that were not intended.”

The adopted Emergency Order requires that all schools serving students kindergarten through twelfth grade *require* mask use by all students, faculty, staff, and visitors while inside school buildings regardless of vaccination status. Further, it requires that all persons or associations conducting child care *recommend* mask use for children aged two (2) through pre-kindergarten and *require* mask use for children in kindergarten through twelfth grade as well as staff, family members, and visitors regardless of vaccination status. These recommendations and requirements extend to transportation provided by the school or child care facility. There are exceptions to the mask requirement, which include when seated at a table to eat or drink, when sleeping, when engaged in an activity where masking is not feasible (e.g. swimming), when outdoors, when children are not present in the building, or when a person is in a personal space and nobody from that person's household is present. It further provides that an individual with a medical condition or disability which prevents them from wearing a mask may request a reasonable accommodation from the school or child care facility.

The Emergency Order is set to expire 120 days after August 16, 2021 with an option to renew the order for a period not to exceed 60 days.

The adopted emergency regulations generally follow CDC's guidance regarding masking requirements in schools and child care facilities.

However, as mentioned above, there are many strategies recommended by the CDC for the prevention and mitigation of the COVID-19 virus. In addition to those mentioned above, the CDC recommends that schools implement screening testing, which can be used to identify infected people, including those with or without symptoms, who may be contagious, so steps can be taken to prevent an outbreak or further transmission.⁴ Specifically for schools, screening testing can be used to promptly identify, isolate, and quarantine those who may have been exposed as well as identify clusters to reduce the risk to in-person education.⁵ To be effective, the CDC recommends that screening testing be conducted at least once a week and can be completed in batches or pooled testing of cohorts.⁶

The CDC, in Appendix 2, provides resources to help support school screening testing programs, including the CDC ELC Cooperative Agreement Reopening Schools Award, which provides \$10 billion to support COVID-19 screening testing in schools for safe, in-person learning. Schools, districts, and the DDOE should also consider using the monies it received under the American Rescue Plan and the Elementary and Secondary School Emergency Relief Fund to help establish and implement a screening testing program.⁷

As this Emergency Order is identical to the Emergency Order amending 9 Del. Admin. C. § 105, Councils may wish to support this emergency regulation with the recommendations mentioned in the earlier analysis as well as the addition of implementation of a screening testing protocol.

⁴ <https://www.cdc.gov/coronavirus/2019-ncov/community/schools-childcare/k-12-guidance.html>

⁵ <https://www.cdc.gov/coronavirus/2019-ncov/community/schools-childcare/k-12-guidance.html>

⁶ <https://www.cdc.gov/coronavirus/2019-ncov/community/schools-childcare/k-12-guidance.html>

⁷ <https://www.cdc.gov/coronavirus/2019-ncov/community/schools-childcare/k-12-guidance.html#aped2>

DDOE Emergency Order on 933 DELACARE: Regulations for Early Care and Education and School-Age Centers, 25 Del. Register of Regulations 233 (September 1, 2021)

DDOE adopted emergency regulatory amendments to 14 Del. Admin. C. § 933. This section of the code describes the minimum standards that all licensed early care and education and school-age centers are required to follow. DDOE is adopting this emergency order pursuant to its authority under 29 Del. C. § 10119, which authorizes it to adopt emergency regulations when an agency determines it is necessary to protect the public health, safety, or welfare from imminent peril. The emergency order adds section 5.3 which prescribes masking requirements for the mitigation and prevention of COVID-19 in covered licensed facilities. It is added to the section regarding the Office of Child Care Licensing’s (“OCCL”) authority to inspect the licensee.

This Emergency Order was repealed by the Emergency Order adopted and published in the Delaware Register at 25 Del. Register of Regulations 235, discussed directly below.

DDOE Emergency Order on 933 DELACARE: Regulations for Early Care and Education and School-Age Centers, 25 Del. Register of Regulations 235 (September 1, 2021)

DDOE adopted emergency regulatory amendments to 14 Del. Admin. C. § 933. This section of the code describes the minimum standards that all licensed early care and education and school-age centers are required to follow. DDOE is adopting this emergency order pursuant to its authority under 29 Del. C. § 10119, which authorizes it to adopt emergency regulations when an agency determines it is necessary to protect the public health, safety, or welfare from imminent peril. The emergency order adds section 5.3 which prescribes masking requirements for the mitigation and prevention of COVID-19 in covered licensed facilities. It is added to the section regarding OCCL’s authority to inspect the licensee.

DDOE is adopting this Emergency Order to establish its tiered strategy to mitigate the spread of the COVID-19 virus. The tiered strategy combines encouraging vaccination with additional steps, including continued mask usage. This approach is based on guidance from the CDC.

DDOE adopted this Emergency Order, which repealed and replaced the earlier adopted Emergency Order published in the Delaware Register at 25 Del. Register of Regulations 233, because the earlier language was “inadvertently broad and resulted in requirements that were not intended.”

The adopted Emergency Order requires that all persons or associations conducting child care *recommend* mask use for children aged two (2) through pre-kindergarten and *require* mask use for children in kindergarten through twelfth grade as well as staff, family members, and visitors regardless of vaccination status. These recommendations and requirements extend to transportation provided by the child care facility. There are exceptions to the mask requirement, which include when seated at a table to eat or drink, when sleeping, when engaged in an activity where masking is not feasible (e.g. swimming), when outdoors, when children are not present in the building, or when a person is in a personal space and nobody from that person’s household is present. It further provides that an individual with a medical condition or disability which

prevents them from wearing a mask may request a reasonable accommodation from the child care facility.

The Emergency Order is set to expire 120 days after August 16, 2021 with an option to renew the order for a period not to exceed 60 days.

The adopted emergency regulations generally follow CDC's guidance regarding masking requirements in schools and child care facilities.

This reviewer is unclear why DDOE decided to include this Emergency Order under OCCL's authority to inspect. Although not *necessary*, Councils may wish to recommend that DDOE move this Emergency Order to under the PART IV PHYSICAL ENVIRONMENT AND SAFETY section as it would make more sense if placed there.

As this Emergency Order is identical to the Emergency Order amending 9 Del. Admin. C. § 105, Councils may wish to support this emergency regulation with the recommendations mentioned in the earlier analysis as well as the recommendation on the location of the Emergency Order.

DDOE Emergency Order on 934 Regulations for Family and Large Family Child Care Homes, 25 Del. Register of Regulations 237 (September 1, 2021)

DDOE adopted emergency regulatory amendments to 14 Del. Admin. C. § 934. This section of the code describes the minimum standards that all licensed family and large family child care homes are required to follow. DDOE is adopting this emergency order pursuant to its authority under 29 Del. C. § 10119, which authorizes it to adopt emergency regulations when an agency determines it is necessary to protect the public health, safety, or welfare from imminent peril. The emergency order adds section 5.3 which prescribes masking requirements for the mitigation and prevention of COVID-19 in covered licensed facilities. It is added to the section regarding OCCL's authority to inspect the licensee.

This Emergency Order was repealed by the Emergency Order adopted and published in the Delaware Register at 25 Del. Register of Regulations 239, discussed directly below.

DDOE Emergency Order on 934 Regulations for Family and Large Family Child Care Homes, 25 Del. Register of Regulations 239 (September 1, 2021)

DDOE adopted emergency regulatory amendments to 14 Del. Admin. C. § 934. This section of the code describes the minimum standards that all licensed family and large family child care homes are required to follow. DDOE is adopting this emergency order pursuant to its authority under 29 Del. C. § 10119, which authorizes it to adopt emergency regulations when an agency determines it is necessary to protect the public health, safety, or welfare from imminent peril. The emergency order adds section 5.3 which prescribes masking requirements for the mitigation and prevention of COVID-19 in covered licensed facilities. It is added to the section regarding OCCL's authority to inspect the licensee.

DDOE is adopting this Emergency Order to establish its tiered strategy to mitigate the spread of the COVID-19 virus. The tiered strategy combines encouraging vaccination with additional steps, including continued mask usage. This approach is based on guidance from the CDC.

DDOE adopted this Emergency Order, which repealed and replaced the earlier adopted Emergency Order published in the Delaware Register at 25 Del. Register of Regulations 237, because the earlier language was “inadvertently broad and resulted in requirements that were not intended.”

The adopted Emergency Order requires that all persons or associations conducting child care *recommend* mask use for children aged two (2) through pre-kindergarten and *require* mask use for children in kindergarten through twelfth grade as well as staff, family members, and visitors regardless of vaccination status. These recommendations and requirements extend to transportation provided by the child care facility. There are exceptions to the mask requirement, which include when seated at a table to eat or drink, when sleeping, when engaged in an activity where masking is not feasible (e.g. swimming), when outdoors, when children are not present in the building, or when a person is in a personal space and nobody from that person’s household is present. It further provides that an individual with a medical condition or disability which prevents them from wearing a mask may request a reasonable accommodation from the child care facility.

The Emergency Order is set to expire 120 days after August 16, 2021 with an option to renew the order for a period not to exceed 60 days.

The adopted emergency regulations generally follow CDC’s guidance regarding masking requirements in child care facilities.

This reviewer is unclear why DDOE decided to include this Emergency Order under OCCL’s authority to inspect. Although not *necessary*, Councils may wish to recommend that DDOE move this Emergency Order to under the PART IV ADDITIONAL PROVISIONS FOR FAMILY CHILD CARE HOMES section as it would make more sense if placed there.

As this Emergency Order is identical to the Emergency Order amending 9 Del. Admin. C. § 105, Councils may wish to support this emergency regulation with the recommendations mentioned in the earlier analysis as well as the recommendation on the location of the Emergency Order.

DDOE Emergency Order on 938 Regulations for Youth Camps, 25 Del. Register of Regulations 242 (September 1, 2021)

DDOE adopted emergency regulatory amendments to 14 Del. Admin. C. § 938. This section of the code describes the minimum standards that all licensed youth camps are required to follow. This section was recently added to the Delaware Code on July 1, 2021.⁸ DDOE is adopting this emergency order pursuant to its authority under 29 Del. C. § 10119, which authorizes it to adopt emergency regulations when an agency determines it is necessary to protect the public health, safety, or welfare from imminent peril. The emergency order adds section 5.3 which prescribes

⁸ <https://regulations.delaware.gov/register/august2021/final/25%20DE%20Reg%20172%2008-01-21.htm>

masking requirements for the mitigation and prevention of COVID-19 in covered licensed facilities. It is added to the section regarding OCCL's authority to inspect the licensee.

This Emergency Order was repealed by the Emergency Order adopted and published in the Delaware Register at 25 Del. Register of Regulations 244, discussed directly below.

DDOE Emergency Order on 938 Regulations for Youth Camps, 25 Del. Register of Regulations 244 (September 1, 2021)

DDOE adopted emergency regulatory amendments to 14 Del. Admin. C. § 938. This section of the code describes the minimum standards that all licensed youth camps are required to follow. This section was recently added to the Delaware Code on July 1, 2021.⁹ DDOE is adopting this emergency order pursuant to its authority under 29 Del. C. § 10119, which authorizes it to adopt emergency regulations when an agency determines it is necessary to protect the public health, safety, or welfare from imminent peril. The emergency order adds section 5.3 which prescribes masking requirements for the mitigation and prevention of COVID-19 in covered licensed facilities. It is added to the section regarding OCCL's authority to inspect the licensee.

DDOE is adopting this Emergency Order to establish its tiered strategy to mitigate the spread of the COVID-19 virus. The tiered strategy combines encouraging vaccination with additional steps, including continued mask usage. This approach is based on guidance from the CDC.

DDOE adopted this Emergency Order, which repealed and replaced the earlier adopted Emergency Order published in the Delaware Register at 25 Del. Register of Regulations 242, because the earlier language was "inadvertently broad and resulted in requirements that were not intended."

The adopted Emergency Order requires that all persons or associations conducting child care *recommend* mask use for children aged two (2) through pre-kindergarten and *require* mask use for children in kindergarten through twelfth grade as well as staff, family members, and visitors regardless of vaccination status. These recommendations and requirements extend to transportation provided by the child care facility. There are exceptions to the mask requirement, which include when seated at a table to eat or drink, when sleeping, when engaged in an activity where masking is not feasible (e.g. swimming), when outdoors, when children are not present in the building, or when a person is in a personal space and nobody from that person's household is present. It further provides that an individual with a medical condition or disability which prevents them from wearing a mask may request a reasonable accommodation from the child care facility.

The Emergency Order is set to expire 120 days after August 16, 2021 with an option to renew the order for a period not to exceed 60 days.

The adopted emergency regulations generally follow CDC's guidance regarding masking requirements in child care facilities.

⁹ <https://regulations.delaware.gov/register/august2021/final/25%20DE%20Reg%20172%2008-01-21.htm>

This reviewer is unclear why DDOE decided to include this Emergency Order under OCCL's authority to inspect. Although not *necessary*, Councils may wish to recommend that DDOE move this Emergency Order to under the PART IV PHYSICAL ENVIRONMENT AND SAFETY section as it would make more sense if placed there.

As this Emergency Order is identical to the Emergency Order amending 9 Del. Admin. C. § 105, Councils may wish to support this emergency regulation with the recommendations mentioned in the earlier analysis as well as the recommendation on the location of the Emergency Order.

Proposed DHSS Regulations on 4202 Control of Communicable and Other Disease Conditions, 25 Del. Register of Regulations 262 (September 1, 2021)

The Department of Health and Social Services ("DHSS") proposes to amend 16 Del. Admin. C. § 4202 which includes the regulations governing control of communicable and other disease conditions. The proposed amendments include requirements for mask use among all students, faculty, staff, and visitors inside K-12 school buildings, regardless of vaccination status, as well as a severability clause. Specifically, it adds sections 7.7 and 12.0, which add COVID-19 mitigation and prevention procedures and severability, respectively.

The proposed § 7.7 requires that all schools *require* mask use for children in kindergarten through twelfth grade as well as staff, faculty, and visitors regardless of vaccination status. The proposed amendment also requires that "Authorities of the State...require masks in congregate settings." There are exceptions to the mask requirement, which include when seated at a table to eat or drink, when sleeping, when engaged in an activity where masking is not feasible (e.g. swimming), when outdoors, when children are not present in the building, or when a person is in a personal space and nobody from that person's household is present. Proposed § 7.7.1.4 provides that for schools with student housing, masks are not required inside an individual student's residence hall room. It further provides that an individual with a medical condition or disability which prevents them from wearing a mask may request a reasonable accommodation from the school.

The adopted emergency regulations generally follow CDC's guidance regarding masking requirements in schools.

Councils, however, may wish to request that DHSS clarify proposed § 7.7.1.4 regarding the exception for student residence hall rooms. It is unclear whether this exception applies only to the student whose room it is or if the exception would apply to all students and visitors who enter that room. If it is the latter interpretation, it would be at odds with proposed § 7.7.1.3.3, which provides an exception to the mask requirement when in a personal space and others outside of the person's household are not present.

Proposed § 12.0 includes a severability clause providing that if any particular clause or section of these regulations should be declared invalid or unconstitutional by any court of competent jurisdiction, the remaining portions shall remain in full force and effect. This reviewer believes this is included as a response to the litigation around the country concerning school mask

mandates and school mask mandate bans.¹⁰ The addition of this section does not impact the substantive portions of the proposed amendments or the existing regulation. It seems to be a prophylactic in the event the school masking requirements are challenged in Delaware courts.

As the language included in this proposed regulation is nearly identical to the Emergency Order amending 9 Del. Admin. C. § 105, Councils may wish to support this proposed amendment with the recommendations mentioned in the earlier analyses as well as requesting clarification on proposed § 7.7.1.4. Lastly, because this is a proposed amendment to an existing regulation, there is no date at which it will expire. Councils may wish to inquire about whether an expiration date should be included or whether it should include guidance on when and how schools can and should explore relaxing their masking requirements.

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

The Delaware Health Information Network (DHIN) has proposed updates to its existing regulations, which can be found at 1 Del. Admin. Code 100, et seq. The DHIN is a statewide health information exchange first launched in 2007 and widely used by medical providers throughout the state. In addition to other clinical data, the DHIN also maintains the Health Care Claims Database.

The DHIN is proposing these amendments in part to implement the changes to the DHIN's enabling statute by SB 88, which was passed by the General Assembly in June 2021, and is awaiting signature by the Governor. Numerous bills have been introduced since the Joint Legislative Oversight and Sunset Committee (JLOSC) issued recommendations based on its review of the DHIN, which concluded in 2020, seeking to implement those recommendations. SB 88 specifically updated provisions in the DHIN's enabling statute to more clearly allow for the sharing of certain clinical data "for appropriate analytic and public health purposes," according to the Synopsis of the bill as introduced. The proposed amendments are discussed in further detail below by section.

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

The proposed amendments to this section of the regulations strike all of the existing text, which pertains to the governance and administration of the DHIN. The new proposed regulations relate to participation in the DHIN and permitted uses of data, which are governed by section 102 of the existing regulations.

The proposed regulations would require that "Data Sending Organizations" comply with all submission standards established by the DHIN, and that establish that such standards would be published on the DHIN's website. The proposed regulations also state that data that would be subject to legal disclosure restrictions beyond what is dictated by the Health Insurance Portability and Accountability Act ("HIPAA") should not be sent to the DHIN until an appropriate data use agreement is in place. The proposed regulations also make clear that Data

¹⁰ <https://www.forbes.com/sites/alisondurkee/2021/09/08/here-are-the-states-where-school-mask-mandate-bans-have-been-struck-down-in-court-at-least-for-now/?sh=3472d1e1384b>

Sending Organizations must authorize certain specific uses for the data shared with DHIN so that DHIN can satisfy its other obligations and requirements, including but not limited to “public health activities and reporting” and “research or analytic purposes” (see proposed regulations at 3.2). The DHIN may also use data for other purposes “if permitted by the Board and its agreements with relevant Data Sending Organizations” and “if such uses are permitted by the Act and relevant law” (see proposed regulations at 3.3).

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

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

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

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

The stricken provisions from the existing Section 101, which primarily covered the operations of the DHIN Board, do not appear to be replaced in another subsection. The enabling statute contains some language regarding composition of the Board but does not go into as much

detail regarding the Board's operations and committees, though presumably the Board's by-laws would contain some more specific requirements.

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

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

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

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

Requests for access to available clinical data would need to be submitted to the Committee in a written application form to be developed by the Committee. Information to be provided in the application would include the intended use of the data, justification of the request, and an explanation of the “security and privacy measures” to be taken by the applicant to protect the data if disclosed by the DHIN. The DHIN must notify a Data Sending Organization “when an application is received for a limited data set or identified data containing Available Clinical Data that was submitted to DHIN by that Data Sending Organization,” and provide ten days for the Data Sending Organization to provide written comments relating to the request.

The Committee shall consider each application and related comments from Data Sending Organizations as applicable and must approve each application by a majority vote. According to the proposed regulations the Committee has the discretion to request additional information from the applicant as needed to inform its decision. The Committee may also ask for an applicant “to

acquire Institutional Review Board review” (see proposed regulations at 4.5). Information regarding applications received by the DHIN for access to clinical data as well as the Committee’s decision on the application would be published on the DHIN website. According to the regulations, decisions by the Committee would not be appealable. Additionally, the DHIN may not disclose identified clinical data without written consent from the individual patient, and all re-disclosure of data must be approved by the Committee.

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

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

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

One notable difference between these proposed regulations and the existing regulations regarding the disclosure of data from the Health Care Claims Database at Section 104 is that under Section 104, more allowances are made for Collaborating State Agencies to use and re-disclose data contained in the Health Care Claims database, and the regulations are clear that data will be provided to Collaborating State Agencies at no cost. These provisions were not included in the proposed regulations for disclosure of other clinical data under Section 102. That could be due to the broader nature of clinical data potentially available, but that difference is not explained in the summary included with the proposed regulations.

104 Delaware Health Care Claims Database Data Access Regulation

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

that would be considered by the Committee in making a decision about approving disclosure of data and may still ask for Institutional Review Board review (see proposed regulations at subsection 4.7).

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

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

As they would promote the use of data for public health research/analysis, which would likely be a net positive for people with disabilities, and it makes sense for there to be a clear process, councils may wish to endorse these changes. DLP does not have a great basis for comparison in terms of how reasonable / user-friendly these policies are, but didn’t see any major red flags. SPCD might have some other thoughts based on more direct interaction with the DHIN and data from the DHIN/Health Care Claims Database.