Memo

To: SCPD and DDC

From: Disabilities Law Program

Date: 10/13/2023

Re: October 2023 Policy and Law Memo

Please find below, per your request, an analysis of a pertinent proposed regulation identified by councils as being of interest.

I. PROPOSED STATE REGULATIONS

- **PROPOSED DDOE REGULATION AMENDING 14 DE ADMIN. CODE 902 GIFTED AND TALENTED EDUCATION PLAN, 27 DEL. REGISTER OF REGULATIONS 220 (OCTOBER 1, 2023)**

The Delaware Department of Education proposes to amend 14 DE Admin. Code 902 Gifted and Talented Education Plan. There are few primary substantive proposed changes:

1. Throughout the proposed amended regulation, the language has been modified to include charter schools;

2. The amended language makes having a plan for gifted students optional and subject to a school's resources.

   The proposed changes the degree of obligation schools have to create a plan for gifted and talented students (a change from "each school district **shall** have a Plan" to "each school district or charter school **may** have a Plan"). Additionally, throughout the proposed regulation, there is new language that would allow schools to consider their capacity when determining what they offer. The new language includes:

   > "The school districts' or charter schools' capacity to provide the differentiated educational programs or services should also be considered as this varies between school districts and charter schools."

   and

   > "5.0 School District and Charter School Responsibilities
   > 5.1 Each school district or charter school shall provide a Plan that outlines the anticipated services provided based upon each individual district's capacity. This shall include how each district identifies gifted learners and in which defined ability areas.

5.2 Each school district's or charter school's Plan shall be reviewed periodically, but not less than every 5 years, by the Department of Education for compliance with this regulation and equitable practices. Any substantive changes to the Plan shall be provided within 1 year for review for compliance with this regulation."

3. There are minor changes to the language involving charter students. (From schools must "[e]stablish procedures for the identification and placement of a student who was identified as gifted or talented in the school district from which the student transferred" to schools must "[e]stablish procedures for students who transfer into the school district or charter school who have been identified as gifted or talented in their prior school." This minor change suggests that the schools do not need to necessarily identify or place those students, merely to have a plan of what to do when a student previously identified at another school transfers in.

The move from mandatory to permissive language is troubling. Either schools have a requirement to provide differentiated educational programming or not for students identified as gifted and talented. Because the proposed language explicitly says that schools can determine their offerings based on their capacity and resources, this inevitably means that under-resourced schools have the option to forgo additional programming, while better resourced schools may choose to offer additional programming. Further, with a shift in educational research and commentary regarding lack of diversity and perpetuation of existing inequities in gifted and talented programs, the Department of Education should be encouraged to reconsider the goals of a gifted and talented program and how these programs can address equity and opportunity.

Councils should consider supporting the changes to include charter schools in the requirement. However, the rest of the new language waters down any purpose in the regulation and Councils may wish to oppose such programming being optional.

- **PROPOSED DDOE Regulation on 608 Unsafe School Choice Option Policy, 27 Del. Register of Regulations 217 (October 1, 2023)**

The Delaware Department of Education ("DDOE") proposes to amend 14 Del. Admin. C. § 608, which describes the State's unsafe school choice policy. DDOE states that it is proposing to amend this regulation to make corrections to grammar and style to bring it into compliance with the *Delaware Administrative Code Drafting and Style Manual*. However, some of the changes proposed are substantive and could impact all students, including those with disabilities. These proposed substantive changes are described more fully below.

By way of background, the Strengthening and Improvement of Elementary and Secondary Schools Act (hereinafter, the "Act") (most recently known as the Every Student Succeeds Act), Chapter 70 of Title 20 of the United States Code, requires that States establish and implement a statewide policy that allows students attending a persistently dangerous public elementary and secondary school, or students who become victims of a violent criminal offense while in or on the grounds of a public school to attend a safe public school. The Federal statute does not define a "persistently dangerous school" or a "safe school"; definitions are left up to States to

determine. However, the definitions must incorporate objective criteria such as "rates of violent offenses."[1]

Change / non-change to how "unsafe incidents" is defined. The current definition for "unsafe incidents" is found under the definitions section. "Unsafe incidents" means any time the school (1) suspended or expelled a student for a gun free schools violation; (2) suspended or expelled a student for a crime committed on school property which is required to be reported under 14 *Del.C.* § 4112; or (3) reported a crime committee by a non-student on school property which is required to be reported under 14 *Del.C.* § 4112. A "Gun Free Schools Violation" is defined as the "prohibited bringing to school, or possession while in school of a firearm by a student."

The proposed definition for "unsafe incidents" moved to proposed 14 Del. Admin. C. § 608.3.2. In its proposed new language, DDOE removes (1) above and replaces it with the following two instances: an unsafe incident is one where the school (1) "suspends or expels a student for bringing a firearm to school in violation of 11 Del.C. § 1457A" or (2) "suspends or expels a student for possessing a firearm while in school in violation of 11 Del.C. § 1457A."

Under 11 *Del.C.* § 1457A(b), "[a]ny person who knowingly possesses a firearm while in or on a Safe School Zone shall be guilty of the crime of possession of a firearm in a Safe School Zone." There are exceptions provided for individuals such as police officers, constables, and holders of a valid license to carry a concealed deadly weapon if the firearm is in a vehicle. 11 *Del.C.* § 1457A(c). Both its current language and its proposed language, DDOE has and is likely going to continue bringing ambiguity to this definition of "unsafe incident" because Title 11 only applies to "knowingly possessing a firearm". This could be ameliorated if DDOE instead used language consistent with the definition in Title 11.

Change to how long a school is identified as "persistently dangerous" for failing to meet reporting requirements. Currently, if a school fails to comply with reporting requirements under 14 *Del.C.* § 4112 (reporting crimes to law enforcement), 14 Del. Admin. C. § 601 (reporting crimes to DDOE), and / or fails to provide any expulsion or suspension data required by DDOE, the school is considered "persistently dangerous" for that school year "until such time as it may be determined, in the sole discretion of" DDOE, that the school meets the reporting requirements. 14 Del. Admin. C. § 608.3.3. What this means is that if a school, two years later, complies with the reporting requirements, DDOE could, in its discretion, retroactively remove the school's designation of a "persistently dangerous school" for that particular year. DDOE is proposing to amend this regulation to remove this possibility of retroactive removal of the designation. This change would ensure that parents and students are consistently aware of when schools are designated as "persistently dangerous"; although it is unclear whether DDOE will otherwise identify which schools are so designated because of the number of unsafe incidents or for failing to comply with reporting requirements.

Attendance vs enrollment. Currently, a student who is the victim of a violent felony while in or on the grounds of a school in which he is enrolled is entitled to choice into a "safe school" in the same school district, including a charter school. 14 Del. Admin. C. § 608.5.1. DDOE is proposing to amend this to add the words "and attending". The proposed language would then

[1] https://www2.ed.gov/policy/elsec/guid/unsafeschoolchoice.pdf.

require that the student who is a victim of a violent felony while in or on the grounds of a school, be both enrolled *and attending* the school before he is entitled to choice into a "safe school."

The Act requires that a student be allowed to attend a safe school if he "becomes a victim of a violent criminal offense . . . while in or on the grounds of a public [school] that the student attends[.]" 20 U.S.C. § 7912(a).

This reviewer is unable to locate DDOE's definitions for "attendance" or "enrollment" and how or if they may differ. Regardless, DDOE cannot be more restrictive in its requirements than that of the Act. By requiring *both* enrollment and attendance (if those terms differ), it is adding a more restrictive element to this requirement that is in violation of the Supremacy Clause of the United States Constitution. A State can provide *greater* protections than the federal government, but it cannot provide *less* protections.

Councils may wish to:

1) **recommend that DDOE use language for the definition of an "unsafe incident" to be consistent with the definition in Title 11** – for example, the language could be amended to state "The school suspends or expels a student for knowingly being in possession of a firearm in violation of 11 *Del.C.* § 1457A." Alternatively, the language could merely state, "The school suspends or expels a student for a violation of 11 *Del.C.* § 1457A for possessing a firearm in a Safe School Zone."

2) **provide support for the proposed change to remove the possibility of retroactive removal of a persistently dangerous school designation because change because it will ensure that parents and students are consistently aware of when schools are designated as "persistently dangerous"; however, Councils may wish to recommend that DDOE otherwise identify which schools are so designated because of the number of unsafe incidents or for failing to comply with reporting requirements.**

3) **recommend that DDOE amend the proposed regulation to be consistent with the language in the Act, which uses the term "attend" rather than "enroll". Councils may also wish to ask that DDOE clarify the difference between "attend" and "enroll".**

- **PROPOSED DDOE REGULATION AMENDING 14 DE ADMIN. CODE 1517 PARAEDUCATOR PERMIT, 27 DEL. REGISTER OF REGULATIONS 230 (OCTOBER 1, 2023)**

The Delaware Department of Education proposes to amend 14 DE Admin. Code 1517 Paraeducator Permit. The following amendments have been proposed.

2.0 Definitions : Multiple definitions have been added or removed.

3.0 Issuance of a Paraeducator Permit

Substantial changes have been made to this section. All language regarding a Title I Paraeducator requirements and application requirements and procedures have been removed. Instead, new language has been included to state that the requirements for an Instructional Paraeducator and a Service Paraeducator can be found in other sections of the regulation. Additionally, language is added stating that:

> The Department shall not act on an application for a Paraeducator Permit if the applicant is under official investigation by any national, state, or local authority with the power to issue educator licenses or certifications. The Department shall not act where the allegations include but are not limited to conduct such as Immorality, misconduct in office, incompetence, willful neglect of duty, disloyalty, or falsification of credentials until the applicant provides evidence of the investigation's resolution.

4.0 Requirements for an Instructional Paraeducator Permit

There are substantial amendments to this section.

Language barring an applicant from licensure if they have engaged in misconduct is removed because it appears above in a revised section 3.0 that applies to all paraprofessionals.

Critically, the proposed language now offers new pathways for applicants to become licensed as a paraprofessional. The proposed amendment adds additional options for meeting licensure requirements. These two additional opportunities to meet licensing requirements include holding a Registered Behavior Technician (RBT) certificate issued by the Behavior Analyst Certification Board or holding an Applied Behavior Analysis Technician (ABAT) certificate issued by the Qualified Applied Behavior Analysis Credentialing Board.

The proposed language also changes the language of the requirement needed if an applicant is claiming eligible for licensure through education. The language has been changed from requiring that an applicant has at least two years of instruction at a:

> regionally accredited institution of higher education or an institution of higher education that is accredited by an accrediting agency that the Secretary, in his or her discretion, deems to be equivalent to a regional accrediting agency

to at least two years of instruction at a:

> postsecondary institution that is accredited by an accrediting body recognized by the United States Secretary of Education as a reliable authority concerning the quality of education or training offered by the postsecondary institutions or programs the accrediting body accredits.

This description of the necessary education is repeated in subsequent references in this section.

5.0 Requirements for a Service Paraeducator Permit

Language barring an applicant from licensure if they have engaged in misconduct is removed because it appears above in a revised section 3.0 that applies to all paraprofessionals.

Language about requirements for new licensure for applicants who previously held a Delaware Service Paraeducator Permit has been removed.

Language about application requirements and procedures have been removed.

Sections 6.0 Validity and 7.0 Renewal have been removed.

They have been replaced with three new sections:

6.0 Requirements for Reissuance of an Expired Delaware Paraeducator Permit

7.0 Application Requirements for Issuance of a Paraeducator Permit

8.0 Renewal of the Paraeducator Permit

These sections explain in detail the processes of reissuance, application, and renewal of a paraeducator permit. The language removed in previous sections about process have largely been added here, with much more detail provided.

9.0 Professional Development Activities for Renewal of a Paraeducator Permit

The changes here primarily relate to how a permit holder can document education and the exact requirements of each form of professional development.

There are two new opportunities added for ways a permit holder can receive professional development credit: Mentoring or Coaching through a Comprehensive Education Induction Program, a Microcredential, Professional Learning Community, or a Paraprofessional of the Year or other district, state, or national recognition award or program activities.

9.0 Criminal Conviction History section requirement for an applicant to disclose criminal history is removed, but this requirement is still included in the new section 7.0, which goes into greater detail about how requirements in general must be provided with the application.

10.0 Validity of a Paraeducator Permit

Requirements of validity of permit changed from:

> Unless stated otherwise herein, a Title I, Instructional, or Service Paraeducator Permit shall be valid for five (5) years from the Date of Issuance unless revoked.

To:

> 10.1 For an applicant who applied for and met the requirements of the Paraeducator Permit under subsections 3.1.1 or 3.1.2, the Paraeducator Permit is issued for a period of 5 years.
>
> 10.2 For an applicant who applied for and met the requirements for renewal of the applicant's Paraeducator Permit under Section 8.0, the Paraeducator Permit may be renewed for a 5-year period.

A new section **11.0 Requirements Related to Retention of the Paraeducator Permit** was added requirements that a paraeducator qualified through ABAT or RBT certification, they must hold and maintain that respective credential, and if they fail to do so, they must notify the District in writing.

A new section **12.0 Disciplinary Action** was added, stating that permits "may be revoked, suspended, or limited for cause as provided in 14 DE Admin. Code 1514." Description of notice for fair hearing is included.

A new section **13.0 Contact Information and Change of Name or Address** is added, requiring applicants and paraeducator permit holders to keep their contact information current.

A new section **14.0 Past Title 1 Paraeducator Permit** recognized was added, stating that:

> The Department shall recognize a Title I Paraeducator Permit that was issued by the Department prior to the effective date of his regulation. An individual holding such a Title I Paraeducator Permit shall be considered permitted to work as an Instructional Paraeducator.

Councils should consider offering support of the proposed changes that offer additional alternatives for paraeducator licensure and continued education to help address the shortage of necessary paraprofessionals in schools.[2] Individuals with ABAT or RBT certificates have been provided with relevant training that is more substantial than other existing alternatives to paraprofessional licensure (for example, individuals with these certificates have more specific training, observation, and hands on experience with students than applicants who qualify for paraprofessional licensure with a high school diploma and a passing score on the ParaPro assessment, an existing avenue to licensure). The alternatives remove some obstacles to entry to paraprofessional licensure classrooms while maintaining standards of training and preparation, which in turn could contribute to getting staff in classrooms. Similarly, expanding the opportunities for continuing education lowers the burden of recertification, allowing experienced paraprofessionals to use hours spent in professional learning communities and mentoring roles or in developing curriculum and materials toward recertification continuing education credit. These changes reward experienced and skilled paraprofessionals and contribute toward learning and innovation in the field.

- **PROPOSED DEPARTMENT OF HEALTH AND SOCIAL SERVICES DIVISION OF MEDICAID AND MEDICAL ASSISTANCE PUBLIC NOTICE REGARDING**

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[2] See: Heather L. Schwartz, Melissa Kay Diliberti, *Flux in the Educator Labor Market: Acute Staff Shortages and Projected Superintendent Departures, Selected Findings from the Fourth American School District Panel Survey*, RAND (2022).
https://www.rand.org/pubs/research_reports/RRA956-9.html; Mark Lieberman, *Staff Shortages in School are Here to Stay. Here's Why,* EDWEEK, https://www.edweek.org/leadership/staff-shortages-in-schools-are-here-to-stay-heres-why/2023/08

STATE PLAN AMENDMENT ADDING DOULA SERVICES, 27 DEL. REGISTER OF REGULATIONS 235 (OCTOBER 1, 2023).

DMMA proposes to amend the Medicaid State Plan to include the provision of doula services. This change is being made in accordance with HB 80 which DLP evaluated for councils in March[3], and which was signed and passed into law this past summer. HB 80 follows the enactment of HB 343 in 2022, which required DMMA to perform a study, which was shared with the legislature, and which prompted this proposed amendment. This initiative has gotten a fair amount of press.[4]

The State Plan amendment, in a very bare bones way, attempts <u>and fails</u> to mirror the language in HB 80. The proposed language can be interpreted to only require 90-minute sessions for postpartum visits, and not prenatal ones, while the statute very clearly indicates that both can be up to 90 minutes. The proposed amendment 3.1-A Page 3 reads as follows:

> *Delaware Medicaid doula benefit is coverage for doula support in the perinatal period, including prenatal support, labor and delivery support, and postpartum support. The*

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[3] ***House Bill No. 80 – Proposed Amendment to Title 31 of the Delaware Code Relating to the Coverage of Doulas***

The proposed amendment to Title 31 is supported by many data points: the amendment notes that while Black women made up 28% of Delaware live births in 2019, they represent 78% of pregnancy-related fatalities over the 2017-2021 period, aligning with the national trend; Black women are three times more likely to experience pregnancy-related mortality than white women in the United States. The data additionally notes that the Maternal Mortality Review found that the most common accompanying issues to infant death were those related to the provision of support in making medical decisions, the ability to access care, and effective communication with healthcare professionals. The Bill further notes that doulas provide positive and nurturing environments throughout the pregnancy and birthing process and provide care "that is more informed of their patient's experiences, values, or identities[.]"

Using this data, the amendment adds that beginning on January 1, 2024, all entities that provide health insurance under § 505(3) of Title 31 must provide coverage of doula services that include (1) three prenatal visits of up to 90 minutes; (2) three postpartum visits of up to 90 minutes; (3) attendance through labor and birth. Moreover, the amendment adds that the Division of Medicaid and Medical Assistance (DMMA) "shall establish, in collaboration with stakeholders, a process for doulas to be certified and to enroll as participating providers, as well as a reimbursement rate for doula services that supports a livable annual income for full-time practicing doulas."

Pertinently, doula care has been found to more positively affect women who are socially disadvantaged, low income, unmarried, giving birth for the first time, are without a companion, or who experience language or cultural barriers.[3] Finally, doula-assisted mothers were "four times less likely to have a low birth weight [] baby [and] two times less likely to experience a birth complication involving themselves or their baby." Given the state-wide and national statistics regarding pregnancy-related fatalities, the inclusion of doulas in insurance-coverage is a life-saving effort which will also prevent disability. As such, councils should consider endorsement.

[4] https://www.delawarepublic.org/science-health-tech/2023-08-11/delawareans-gain-more-access-to-doulas-as-state-works-to-increase-positive-birth-outcomes; https://www.delawarepublic.org/show/the-green/2023-02-24/why-black-maternal-mortality-is-rising-and-what-delaware-is-doing-to-combat-it;

scope of the Medicaid doula benefit is to provide doula support to Medicaid members that include:

• Maximum of three (3) prenatal visits

• Maximum of three (3) postpartum visits • 90 minutes per visit

• Labor/birth attendance

Moreover, the reimbursement mechanism described lacks clarity. The language indicates that services are to be billed in 15 minute increments, and then imposes a billing limit of "four units" per visit.

Each perinatal service visit may be billed for and reimbursed separately. All visits are reimbursed in fifteen (15) minute increments. Each visit has a maximum unit capacity of four (4) units.

DLP has no expertise regarding Medicaid rate setting and no idea what unit capacity is, but if the "four units" are the 15 minute increments, then this is imposing a limit of 60 minutes that is eligible for reimbursement per visit, when the statutory language clearly indicates that recipients are eligible for up to 90 minutes per visit.

DLP did not have an opportunity to review the DMMA study that formed the basis of HB 80. However, there is a great deal of literature available[5] regarding best practices for developing a doula program, especially in the Medicaid context. Based on some of the experiences in other states, two areas in particular that require expertise and planning are reimbursement rates[6] and developing doula service infrastructure, particularly around training and licensure. There are a number of somewhat thorny regulatory issues, including access to acute care hospitals and birthing centers.

Councils may wish to recommend that the language be revised to clarify that:

1) **The benefit includes three visits of up to 90 minutes for both prenatal and postpartum visits (a change in punctuation or formatting might do the trick); and**
2) **That doula sessions can be billed in 15 minute increments up to the 90 minute limit for each visit. These modifications are necessary in order for the state amendment to be consistent with the parameters set by the legislature.**

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[5] https://healthlaw.org/resource/current-state-of-doula-medicaid-implementation-efforts-in-november-2022/; https://www.marchofdimes.org/sites/default/files/2023-04/Doulas-and-birth-outcomes-position-statement-final-January-30.pdf; https://www.aspe.hhs.gov/sites/default/files/documents/dfcd768f1caf6fabf3d281f762e8d068/ASPE-Doula-Issue-Brief-12-13-22.pdf;

[6] https://healthconnectone.org/publication/doula-medicaid-storybook/

Additionally, while the State Plan is not the place to completely flesh out the development of the program, councils may wish to inquire regarding next steps in planning and implementation, so that this important service gets the attention, expertise and funding it deserves in order to be a success.

- **PROPOSED DEPARTMENT OF HEALTH AND SOCIAL SERVICES DIVISION OF MEDICAID AND MEDICAL ASSISTANCE PUBLIC NOTICE REGARDING STATE PLAN AMENDMENT CONCERNING PHARMACY VALUE BASED PURCHASING, 27 DEL. REGISTER OF REGULATIONS 237 (OCTOBER 1, 2023).**

With this notice, the Delaware Department of Health and Social Services (DHSS), Division of Medicaid and Medical Assistance (DMMA), is proposing amendments to Title XIX Medicaid State Plan in order to participate in the Pharmacy Value Based Purchasing (VPB) Program. Written comments, suggestions, compilations, testimony, briefs, or other materials are due by the close of business on October 31, 2023. The proposed amendments would be effective October 1, 2023.

By way of background, in 1990 the Medicaid Drug Rebate Program (MDRP) was created by the Omnibus Budget Reconciliation Act of 1990.[7] To participate in the program, a drug manufacturer that wants its drug covered by Medicaid must enter into a rebate program with the Secretary of Health and Human Services providing that it will rebate a portion of the Medicaid payment for the drug to the states, which will then share the rebates with the federal government.

The Value Based Purchasing (VBP) Program was established under the Affordable Care Act (ACA).[8] The VBP program is also known as the Value Based Purchasing Arrangement (VBA). Under the Medicaid regulations,

> "*Value-based purchasing (VBP) arrangement* means an arrangement or agreement intended to align pricing and/or payments to an observed or expected therapeutic or clinical value in a select population and includes, but is not limited to:
> (1) Evidence-based measures, which substantially link the cost of a covered outpatient drug to existing evidence of effectiveness and potential value for specific uses of that product; and/or
> (2) Outcomes-based measures, which substantially link payment for the covered outpatient drug to that of the drug's actual performance in patient or a population, or a reduction in other medical expenses." 42 *C.F.R.* § 447.502.

In March 2022, the Centers for Medicare and Medicaid Services (CMS) issued guidance regarding how drug manufacturers are to report best prices[9] for drugs to the MDRP under VBP

[7] OBRA-90; Pub. L. 101-508, 104 Stat. 1388.
[8] Patient Protection and Affordable Care Act, 124 Stat. 119.
[9] Under the Medicaid statute, best price is "the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or government entity within

arrangements.[10] VPB arrangements are a payment model under which a state may be able to obtain rebates or price concessions based on the clinical outcome of a drug in Medicaid beneficiaries.

At the present time, the State does not have a State Plan Amendment (SPA) that permits participation in the VBP program. The proposed amendments would allow the State to participate in the VPB program. Specifically, the proposed amendments state: "The State may enter into value-based contracts with manufacturers on a voluntary basis." (§12.a). The proposed amendments are subject to approval by the CMS. **As costs for prescription drugs is always a concern, allowing the State to participate in a program that could reduce the costs for drugs for Medicaid beneficiaries is prudent and worthwhile. Councils may wish to support the proposed amendments.**

II. Final State Regulations

FINAL DEPARTMENT OF HEALTH AND SOCIAL SERVICES DIVISION OF MEDICAID AND MEDICAL ASSISTANCE PUBLIC NOTICE REGARDING the 2023 QUALITY STRATEGY, 27 DEL. REGISTER OF REGULATIONS 250 (OCTOBER 1, 2023).

In the June 2023 *Delaware Register of Regulations,* the Delaware Department of Health and Social Services (DHSS), Division of Medicaid and Medical Assistance (DMMA), proposed amendments to the Diamond State Health Plan Medicaid Managed Care Strategy, regarding Quality Strategy for 2023. Written comments, suggestions, compilations, testimony, briefs, or other materials were due by the close of business on July 3, 2023.

This reviewer analyzed the regulations and made specific recommendations that Councils should consider making to DHSS/DMMA about the 2023 Quality Strategy. Along with the Delaware Association for Home & Community Care (DAHCC), Councils made suggestions and comments regarding the 2023 Quality Strategy. This reviewer was asked to review the response of DHSS/DMMA to the comments and review the final regulation.

The following are the comments DHSS/DMMA received and their responses:

"Comment: DMMA should more aggressively address areas with an insufficient provider network and require the managed care organizations (MCOs) to provide the required services.

the United States." There are some exclusions, including the Department of Veteran Affairs, the Department of Defense, the Public Health Service, and the Indian Health Service. 42 *U.S.C.* § 1396r-8 (c)(1)(C).

[10] Medicaid Drug Rebate Program Notice For Participating Drug Manufacturers Release No. 116, medicaid.gov/prescription drugs/downloads/mfr-rel-116.pdf.

Agency Response: Per page 15 of the Quality Strategy document, DMMA requires that each MCO develop a Provider Network Development and Management Plan that outlines the MCO's process to develop, maintain, and monitor an adequate provider network that is supported by written agreements and is sufficient to provide access to all services under its contract. As displayed on page 27 of the document, DMMA has adopted an Early Alert System that includes review of monthly and quarterly Quality Care Management and Monitoring Report data and geo-spatial analysis. DMMA also reviews Consumer Assessment of Healthcare Providers and Systems (CAHPS®) and National Core Indicators Aging and Disabilities (NCI-AD) surveys to assess the member experience of care which includes provider access and availability to required services. DMMA is also preparing for compliance with CMS proposed rules for increased access in Medicaid managed care programs.

Comment: DMMA should use both prongs of the Balanced Quality Model and require any MCO that is not in compliance to submit a Corrective Action Plan (CAP) to address the deficiencies.

Agency response: We appreciate the support for our commitment in the Quality Strategy to use both prongs of the Balanced Quality Model. Any MCO that is not in compliance with federal regulation, contractual requirements, or the Quality Strategy expectations will be subject to the need for corrective actions and may be required to submit a CAP.

Comment: Individualized plans should be promoted for all consumer groups.

Agency response: DMMA agrees that the MCOs should develop individualized care plans as needed for all consumer groups. As noted in the tables of Goals and Performance Measures (pages 33-41) of the Quality Strategy document, the MCOs are required to develop an individualized plan of care for waiver populations. Compliance with this expectation is assessed by external quality review as well as ongoing monitoring and oversight by DMMA.

Comment: To ensure that individuals with disabilities are receiving the services they should, it is recommended that DMMA require the MCOs to provide claims denial data to DMMA, and that they track the claims denials to determine whether the MCOs are providing the required services.

Agency response: Per page 8 of the Quality Strategy document, the External Quality Review Organization (EQRO) assesses compliance with federal regulation, contractual requirements, and the Quality Strategy expectations for appropriate application of clinical practice guidelines, management of prior authorization requests, denials and appeals to ensure members receive medically necessary services and appropriate supports. Additionally, claims management (including claim denials) is assessed during an Information Systems Capabilities Assessment.

Comment: DMMA should formulate a questionnaire that the MCO's should be required to use to gauge satisfaction with the services and quality of care.

Agency response: Per page 31 of the Quality Strategy document, DMMA requires the MCOs to annually conduct the CAHPS survey to assess member experience of care. The CAHPS survey asks members (or in some cases their families) about their experiences with, and ratings of, their health care providers and plans, including hospitals, home health care agencies, doctors, and health and drug plans, among others. The CAHPS survey focuses on matters that members themselves say are important to them and for which members are the best and/or only source of information. Additionally, DMMA conducts the NCI-AD survey which utilizes core indicators that are standard measures used across states to assess the outcomes of services provided to members and families.

These core indicators address key areas of concern including service planning, rights, community inclusion, choice, health and care coordination, safety, and relationships. DMMA is also preparing for compliance with the proposed CMS rules for access in Medicaid managed care. CMS proposed additional survey requirements, including state-administered surveys and "secret shopper" surveys.

Comment: To improve transparency, it is recommended that DMMA should, at the very least, put on its website the results of the EQRO's assessments and findings for each MCO, as well as post any CAPs on its website for each MCO.

Agency response: The External Quality Review Technical report is posted annually to the following website: https://www.dhss.delaware.gov/dhss/dmma/info_stats.html. This report includes items evaluated, findings from the review, and recommendations for improvement. As a part of ongoing oversight and monitoring for improvement, each MCO is required to submit a CAP to DMMA for each EQR finding and recommendation. At this time, DMMA does not intend to post CAPs on DMMA's website.

Comment: There was a comment asking if there's anything they should be aware of in relation to this proposed change in strategy or that they can help with.

Agency response: Thank you for reviewing the Diamond State Health Plan Draft Quality Strategy. DMMA appreciates your willingness to support DMMA's ongoing quality improvement initiatives and will request assistance as issues arise."[11]

Although DHSS/DMMA acknowledged the input and comments received from DAHCC and Councils (SCPD), unfortunately, **they did not adopt any of the recommendations.** Councils can take some solace from the fact they made pertinent comments that DHSS/DMMA had to consider and address. The proposed regulations as set forth in the June 2023 *Register of Regulations* were adopted and will be effective October 11, 2023.

III. Federal Regulations

- **PROPOSED CMS REGULATION REGARDING MINIMUM NURSING HOME STAFFING, available at** https://www.federalregister.gov/documents/2023/09/06/2023-18781/medicare-and-medicaid-programs-minimum-staffing-standards-for-long-term-care-facilities-and-medicaid. **PRELIMINARY ANALYSIS AND SUMMARY.**

On September 1, CMS, after several years of discussion, issued proposed regulations related to staffing at nursing homes. The comment period for these regulations remains open until November 6. Comments can be submitted here: https://www.regulations.gov/commenton/CMS-2023-0144-0001;

[11] Summary of Comments Received with Agency Response and Explanation of Changes. https://regulations.delaware.gov/documents/October2023c.pdf

Over twenty-years ago an in-depth, evidenced-based CMS study[12] found that each nursing home resident required at least 4.1 hours of direct care each day to avoid compromised care that placed residents at risk of harm. The proposed standards do not come close to that. In summary:

- Nursing homes would be required to provide only 3 hours of direct care per resident per day. This requirement would include only .55 hours of Registered Nurse (RN) care and 2.45 hours of certified nurse aide (CNA) care. The regulation does not propose a minimum for licensed practical nurses (LPNs) who play a critical role in nursing home care.
- Facilities would be eligible for waivers from complying with this minimum if they met certain criteria.
- Implementation of the requirement would be phased in over a 3-year period.
- Facilities would be required to have an RN on staff 24 hours a day, 7 days a week. This requirement would be an increase from the current requirement of eight hours per day.

In contrast, Delaware law (16 Del Code Section 1162(a)) requires that: " Every residential health facility must at all times provide a staffing level adequate to meet the care needs of each resident, including those residents who have special needs due to dementia or a medical condition, illness or injury." In addition, the Delaware law imposes a direct care staffing requirement, found in 16 Del. Code Section 1162(e) (Eagles Law"), which is *no less than* 3.67 hours of direct care per day. Delaware code also sets staffing ratios; however these ratios were suspended by DHSS during the pandemic, with the suspension extended at the request of DHSS in budget language in the last legislative session. Section 1168 allows limited time waivers of 1162(e) staffing requirements. Delaware code also requires a "full time" director of nursing.

Delaware's minimum required direct care hours are actually slightly higher than the proposed CMS rule, and below the minimum that experts say is necessary to provide adequate, safe care.

Very briefly, advocates for the most part, while believing that federal mandatory staffing minimums are necessary, are deeply dissatisfied with the very low bar that CMS has set, the too generous and vague waiver standards, and the lengthy implementation period. [13] Ironically, the nursing home industry doesn't like them either. What seems to be lost on CMS and also the nursing home industry is that insufficient staffing leads to burn out, which leads to people quitting, which leads to worse staffing problems. And at the end of the day, short staffing leads to poor resident care and bad outcomes.

There are some new reporting requirements related to how much facilities compensate their workers- namely what percentage of Medicaid dollars are spent on direct care, which are viewed

[12] https://theconsumervoice.org/uploads/files/issues/CMS-Staffing-Study-Phase-II.pdf;

[13] https://kffhealthnews.org/news/article/cms-study-nursing-home-staffing-levels; https://ldi.upenn.edu/our-work/research-updates/pa-set-new-standards-on-nursing-home-staffing-are-they-sufficient/; https://theconsumervoice.org/news/detail/latest/cms-must-make-staffing-rule-stronger;

positively, as is the requirement that there be a nurse on staff 24 hours a day, though there is a concern that facilities will let go of LPNs rather than hire more RNs.

Councils should consider whether to file comments regarding the regulation, as well as actively inquire of DHCQ what the compliance level for direct care currently is for Delaware facilities. Councils may also wish to inquire of DHSS why they suspended staff ratios and how they are monitoring the $5 million additional that the legislature gave the nursing home industry to address staffing this year.

- **PROPOSED HHS REGULATION REGARDING SECTION 504, available at** https://www.federalregister.gov/documents/2023/09/14/2023-19149/discrimination-on-the-basis-of-disability-in-health-and-human-service-programs-or-activities **PRELIMINARY SUMMARY.**

On September 14, the U.S. Department of Health and Human Services "HHS", issued proposed regulations related to implementation of Section 504 of the Rehabilitation Act. The comment period for these regulations remains open until November 13. Comments can be submitted here: https://www.regulations.gov/commenton/HHS-OCR-2023-0013-0001;

HHS explains in its summary that the proposed regulations are to update and amend regulations prohibiting of discrimination on the basis of disability. The proposed rule would add new provisions that clarify existing requirements under section 504 prohibiting recipients of financial assistance from discriminating on the basis of disability. The proposed rule includes some new focus areas, including:

- new regulations on child welfare services, to expand on and clarify the obligation to provide nondiscriminatory child welfare services.[14]

[14] **§84.60 Children, parents, caregivers, foster parents, and prospective parents in the child welfare system.**
(a) Discriminatory actions prohibited.
(1) No qualified individual with a disability shall, on the basis of disability, be excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination under any child welfare program or activity that receives Federal financial assistance.
(2) Under the prohibition set forth in the previous subsection, discrimination includes: (i) Decisions based on speculation, stereotypes, or generalizations that a parent, caregiver, foster parent, or prospective parent, because of a disability, cannot safely care for a child; and (ii) Decisions based on speculation, stereotypes, or generalizations about a child with a disability.
(b) Additional prohibitions. The prohibitions in paragraph (a) of this section apply to actions by a recipient of Federal financial assistance made directly or through contracts, agreements, or other arrangements, including any action to:
(1) Deny a qualified parent with a disability custody or control of, or visitation to, a child;
(2) Deny a qualified parent with a disability an opportunity to participate in or benefit from reunification services is equal to that afforded to persons without disabilities;
(3) Terminate the parental rights or legal guardianship of a qualified individual with a disability; or (4) Deny a qualified caregiver, foster parent, companion, or prospective parent with a disability the opportunity to participate in or benefit from child welfare programs and activities. (c) Parenting evaluation procedures. A recipient to which this subpart applies shall establish procedures for referring individuals who, because of disability, need or are believed to need adapted services or reasonable modifications, and shall ensure that tests, assessments, and other evaluation materials, are tailored to assess specific areas of disability-related needs, and not merely those which are designed to provide a single general intelligence quotient.

- new requirements prohibiting discrimination in the areas of medical treatment;
- the use of value assessments (assessments/tools that discount the value of life extension on the basis of disability);
- web, mobile, and kiosk accessibility; and
- requirements for accessible medical equipment, to afford "an opportunity to participate in or benefit from health care programs and activities that is equal to the opportunity afforded others."

The proposed rule also updates the definition of disability and other provisions for consistency with statutory amendments to the Rehabilitation Act, enactment of the Americans with Disabilities Act and the Americans with Disabilities Amendments Act of 2008, the Affordable Care Act, as well as Supreme Court and other significant court cases.

The proposed regulation further clarifies the obligation to provide services in the most integrated setting.[15]

A number of national organizations who are part of the Consortium for Constituents with Disabilities (CCD; https://www.c-c-d.org/index.php) will be doing a single set of comments on these HHS 504 regulations. We expect those comments to be available in early November.

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[15] **§84.76 Integration.**
(a) Application. This provision applies to programs or activities that receive Federal financial assistance from the Department and to recipients that operate such programs or activities.
(b) Discriminatory action prohibited. A recipient shall administer a program or activity in the most integrated setting appropriate to the needs of a qualified person with a disability. Administering a program or activity in a manner that results in unnecessary segregation of persons with disabilities constitutes discrimination under this section.
(c) Segregated setting. A segregated setting is one in which people with disabilities are unnecessarily separated from people without disabilities. Segregated settings are populated exclusively or primarily with individuals with disabilities, and may be characterized by regimentation in daily activities; lack of privacy or autonomy; and policies limiting visitors or limiting individuals' ability to engage freely in community activities and to manage their own activities of daily living.
(d) Specific prohibitions. The general prohibition in paragraph (b) of this section includes but is not limited to the following specific prohibitions, to the extent that such action results in unnecessary segregation, or serious risk of such segregation, of persons with disabilities.
(1) Establishing or applying policies or practices that limit or condition individuals with disabilities' access to the most integrated setting appropriate to their needs;
(2) Providing greater benefits or benefits under more favorable terms in segregated settings than in integrated settings;
(3) Establishing or applying more restrictive rules and requirements for individuals with disabilities in integrated settings than for individuals with disabilities in segregated settings; or
(4) Failure to provide community- based services that results in institutionalization or serious risk of institutionalization. This category includes, but is not limited to planning, service system design, funding, or service implementation practices that result in institutionalization or serious risk of institutionalization. Individuals with disabilities need not wait until the harm of institutionalization or segregation occurs to assert their right to avoid unnecessary segregation.
(e) Fundamental alteration. A recipient may establish a defense to the application of this section if it can demonstrate that a requested modification would fundamentally alter the nature of its program or activity.