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To: GACEC Policy and Law
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From: Disabilities Law Program
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Consistent with council requests, DLP is providing an analysis of certain proposed and final regulations appearing in the December 2019 issue of the Delaware Register of Regulations. **Please note that one of the final regulations, regarding DOE's supportive instruction, may require Council action well before the close of the month, due to new, substantive changes made in the final version.**

Proposed Regulations

1. Proposed DOE Regulation on Family Educational Rights and Privacy Act (FERPA), 23 Del. Register of Regulations 416 (December 1, 2019)

The Delaware Department of Education ("DOE") proposes to amend 14 DE Admin. Code 251. This regulation adopts the federal Family Educational Rights and Privacy Act ("FERPA") standards, and requires school districts, charter schools and private schools to enact educational record policies that are compliant with FERPA.

The proposed amendment updates the names of the federal offices that are responsible for fielding complaints and conducting investigations of alleged FERPA violations. The Student Privacy Policy Office (SPPO) was previously known as the Family Policy Compliance Office (FPCO), and the regulation updates the name. The regulation also adds reference to the Office of the Chief Privacy Officer, of which SPPO is one division. While the new information added is correct, the proposed regulation removes the language that more clearly explains the functions of these offices, which is that people may file complaints alleging FERPA violations and SPPO will investigate and review these complaints.

Councils may wish to suggest that DOE leave in the sentence explaining that SPPO will investigate and review alleged FERPA violation complaints that are filed with its office. Councils may wish to make an additional, minor comment, that the zip code listed on SPPO's website (20202-5920) differs from the zip code stated in the proposed regulation (20202-4605).

2. Proposed DOE Regulation on Tobacco and Smoking Policy, 23 Del. Register of Regulations 419 (December 1, 2019)

The Delaware Department of Education ("DOE") proposes to amend 14 DE Admin. Code 877 to require school districts and charter schools to expand policies banning the use and distribution of tobacco products. The expanded ban would include a prohibition on "smoking," and will also prohibit activities such as vaping.



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The proposed regulation might prohibit utilizing medical marijuana through smoking on school grounds and property. The Delaware Medical Marijuana Act (16 Del. C. 49A) already prohibits smoking medical marijuana in a public place and using medical marijuana on school grounds, except for a limited exception involving medical marijuana oil. Medical marijuana oil can be administered in different forms, one of which is through smoking. Councils may wish to ask for an inclusion that these policies do not limit any treatment rights that may be afforded under 16 Del. C. 49A and are not designed to limit students' access to medical treatment as prescribed by their doctor.

3. Proposed DMMA Action Regarding Drug Utilization Review, 23 Del. Register of Regulations 427 (December 1, 2019)

DMMA is proposing to amend the Title XIX Medicaid State Plan regarding the Drug Utilization Review (DUR), specifically updating provisions included in the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) (P.L. 115-271). Under the SUPPORT Act, all states with a Medicaid program that includes a drug benefit are required to have a DUR program that assures that prescriptions for outpatient drugs are appropriate, medically necessary, and not likely to result in adverse medical outcomes. DMM previously published proposed changes for DUR in the September 1, 2019 issue of the Delaware Register of Regulations (23 DE Reg. 184). DMMA is now republishing the proposed DUR changes, to provide additional public notice and comment due to substantive changes. While the previous proposal appeared consistent with federal regulations, the republished proposal may no longer comply with federal requirements.

In the previous publication, Section 5 "Provision of Section 1004 of the SUPPORT ACT" included four sections: (a) Claim Review Limitations; (b) Programs to monitor antipsychotic medications to children; (c) Fraud and abuse identification, and; (d) Managed Care Organization (MCO) Requirements. As written in the September proposal, these sections complied with federal requirements. In the December proposal, sections (a), (b), and (c) remain consistent with the September publication.

However, section (d) "Managed Care Organization (MCO) Requirements," is not included in the December DUR publication. This Section previously stated "effective October 2019, DMMA contracts require MCOs to comply with the drug reviews included in the SUPPORT Act. Our MCO partners are employing the same review processes and limits as our fee-for-service program."

Federal regulation requires that the MCO operate a drug utilization review program that complies with the requirements described in the SUPPORT Act, "as if such requirement applied to the [MCO] instead of the State."¹ It is unclear why this requirement was not included in the republished proposal. Councils may wish to highlight this discrepancy and seek an explanation for the removal of section (d) "Managed Care Organization (MCO) Requirements."

¹ 42 C.F.R. §438.3(s)(4)

4. Proposed DHSS Regulation Regarding Authorization and Regulation of Medicaid/CHIP Accountable Care Organizations, 23 Del. Register of Regulations 428 (December 1, 2019)

DHSS/DMMA is proposing to amend the DSS Manual to set standards for the authorization and regulation of Medicaid/CHIP Accountable Care Organizations (ACOs). ACOs are groups of doctors, hospitals, and other health providers who voluntarily agree to form partnerships to provide coordinated care and share accountability for the outcomes and cost of care. ACOs receive financial rewards for keeping patients healthy and are meant to deliver higher quality care more efficiently. An increasing number of states are implementing ACOs in an effort to improve health outcomes while reducing costs. Delaware is moving to establish a Medicaid/CHIP ACO program in which DMMA will authorize certain ACOs to contract directly with Medicaid/CHIP MCOs and operate as part of their provider networks. Beneficiaries will not be required to use providers within an ACO.

This is an important and complicated regulation that requires a level of review that could not be completed before the Policy & Law meeting. The public benefits unit of Community Legal Aid Society, Inc. (CLASI) will be providing an analysis and comments on this proposed regulation prior to the close of the comment period, but after the Policy & Law meeting. Specifically, DMMA has outlined basic standards that ACOs will have to meet, but CLASI will further analyze whether stronger state oversight is advisable or necessary. For example, DMMA may need to include additional language in the regulations about data transparency and what metrics the state will use to assess ACO performance. Councils may wish to review CLASI's public benefits unit comments once available, and at that time determine whether or not to endorse those comments.

5. Proposed DPH Regulation Regarding Medical Marijuana, 23 Del. Register of Regulations 433 (December 1, 2019)

The Delaware Office of Medical Marijuana, Division of Public Health, and Department of Health and Social Services proposes to amend 16 DE Admin. Code 4470 which comprise the regulations governing the State of Delaware Medical Marijuana Code [hereinafter the Code]. The proposed amendment seeks to establish requirements for Safety Compliance facilities, detail provisions and limitations for producing edible marijuana products, outline compliance and enforcement procedures, outline random sampling procedures, establish the formation of a Compassionate Use patient card, and add definitions and technical corrections.

Many of the proposed changes do not substantively impact individuals with disabilities, so this review will focus specifically on relevant changes to definitions, the addition of the "compassionate use card" and its requirements, the process for adding debilitating medical conditions, and the "no animals/pets" restriction in the kitchen of a Marijuana Infused Food Establishment.

The first major relevant definitional change is with the term "debilitating medical condition." DHSS proposes to amend this definition to include terminal illness, seizure disorder, glaucoma, chronic debilitating migraines, and new daily persistent headache. According to the

National Center for Complementary and Integrative Health, cannabis and cannabinoids are also helpful in treating anxiety, inflammatory bowel disease, irritable bowel syndrome, movement disorders due to Tourette Syndrome, and sleep problems. (<https://nccih.nih.gov/health/marijuana-cannabinoids#hed11>). Councils may wish to encourage DHSS to consider adding these additional health conditions to its definition of “debilitating medical condition.”

DHSS is also proposing to add an additional subsection under the “debilitating medical condition” definition that describes the qualifying conditions for individuals under the age of 18. It reads:

2.0(c) Pediatric qualifying conditions are limited to any of the following related to a terminal illness: pain, anxiety, or depression; seizure disorder; severe debilitating autism; or a chronic or debilitating disease or medical condition where they have failed treatment involving one or more of the following symptoms: cachexia or wasting syndrome; intractable nausea; severe, painful and persistent muscle spasms; and chronic debilitating migraines and new daily persistent headache that are refractory to conventional treatment and interventions;

For clarity, Councils may wish to recommend that DHSS consider using subsection headings to divide each qualifying condition. It would then read:

2.0(c) Pediatric qualifying conditions are limited to

- (1) any of the following related to a terminal illness: pain, anxiety, or depression;
- (2) seizure disorder; severe debilitating autism; ~~or~~, chronic debilitating migraines and new daily persistent headache that are refractory to conventional treatment and interventions; or
- (3) a chronic or debilitating disease or medical condition where they have failed treatment involving one or more of the following symptoms: cachexia or wasting syndrome; intractable nausea; severe, painful and persistent muscle spasms; ~~or~~; ~~and chronic debilitating migraines and new daily persistent headache that are refractory to conventional treatment and interventions;~~

Alternatively, DHSS could use the same format and division as used in the proposed amended 3.3.3:

2.0(c) Pediatric qualifying conditions are limited to

- (1) any of the following related to a terminal illness: pain, anxiety or depression;
or
- (2) intractable epilepsy or seizure disorder;
- (3) a chronic or debilitating disease or medical condition where the patient has failed treatment involving 1 one or more of the following symptoms: cachexia or wasting syndrome; intractable nausea; seizures; severe, painful and persistent muscle spasms. spasms; or chronic debilitating migraines and new daily persistent headache that are refractory to conventional treatment and interventions; or
- (4) severe debilitating autism.

The second major definitional change involves the proposed amendment to the definition of “physician.” DHSS is proposing to remove the requirement that a physician be a licensed psychiatrist if the debilitating medical condition is post-traumatic stress disorder (PTSD) and expand the options for pediatric physicians to include pediatric psychiatrist and developmental pediatrician. Removing the requirement that a licensed physician be a psychiatrist for PTSD expands the number of doctors/physicians that can recommend medical marijuana treatment for patients, in line with the expansion of pediatric psychiatrists.

The third relevant definitional change involves the addition of the term “terminal illness” which includes language similar to the federal definition used for Medicare and Medicaid services. The biggest difference between the two definitions is that the proposed definition gives a life-expectancy of 12 months whereas the federal definition gives a life expectancy of 6 months. Councils may wish to support the proposed amendment as is, giving more individuals access to medical marijuana. Alternatively, councils may wish to recommend that the definition for terminally ill or “terminal illness” use the same language used by the federal government. (42 CFR § 418.3).

The next major change involves the addition of the “compassionate use card.” (Section 3.4) The requirements for the compassionate use card are more expansive and cumbersome than those used for the regular registry card because the compassionate use card allows a physician to certify a patient for the card for a medical condition that is not currently covered by the Act. 3.4.2 includes the requirement for physicians to re-evaluate the treatment for different medical conditions at different rates including every 15 days for the first 90 days and then every 30 days for substance use disorder, every 30 days for mental health disorders, every 30 days for the first 90 days and then every 90 days for autoimmune disease, and every 30 days for any other conditions. Councils may wish to support this proposed amendment as is or recommend longer intervals of re-evaluation given how cumbersome these timeframes may be.

In addition, DHSS proposes to make the denial of an application or renewal for a compassionate use card not subject to judicial review. (5.4.4.1). Presently, the denial of an application or renewal for registry identification cards is subject to judicial review in the Superior Court. Councils may wish to recommend DHSS remove section 5.4.4.1 which would allow denials of applications or renewals for compassionate use cards be subject to judicial review.

Although not presently being amended, Councils may wish to request DHSS consider amending section 6.0 which details the procedure for the addition of debilitating medical conditions, or otherwise address the lack of published information on denied conditions. Presently, there is only a database for the medical conditions that are approved to be added as a debilitating medical condition, and not a database for those that have been denied. Given that DHSS considers a petition to add a new debilitating medical condition to have “merit” if, among other requirements, the particular medical condition has not been the subject of a petition in the preceding two years. If DHSS also includes information on those petitions that were denied, the date, and the reasoning in the same location as those that have been approved, it would provide consumers and Delawareans with additional information and could prevent the spending of additional staff hours on petitions.

Lastly, in DHSS's proposed addition of the regulations and procedures for Marijuana Infused Food Establishment, section 15.3.1 states "No animals/pets shall be permitted in the kitchen area of a Marijuana Infused Food Establishment during the preparation, packaging, or handling of any marijuana infused products. Under the Americans with Disabilities Act, individuals who utilize service dogs are afforded certain protections under law. Guidance by the Food and Drug Administration explains that in the context of food service:

Decisions regarding a food employee or applicant with a disability who needs to use a service animal should be made on a case-by-case basis. An employer must comply with health and safety requirements, but is obligated to consider whether there is a reasonable accommodation that can be made.

(pg. 537; <https://www.fda.gov/media/87140/download>). There may be situations where an employee could have their service dog at work, with precautions in place to prevent handling of the animal during food prep duties. Councils may wish to support this amendment, but request that DHSS change 15.3.1 to include similar language as the FDA guidance, such as:

Decisions regarding a Marijuana Infused Food Establishment employee's use of a service animal should be determined by the employer on a case-by-case basis, considering both health and safety requirements and whether there is a reasonable accommodation that can be made.

In summation, Councils may wish to support this amendment with the below recommendations:

1. adding anxiety, inflammatory bowel disease, irritable bowel syndrome, movement disorders due to Tourette Syndrome, and sleep problems to the definition of "debilitating medical condition";
2. adding subsections to the pediatric qualifying conditions under section 2.0;
3. amending 6.0 to include the posting of conditions subject to denied petitions (with the denial date and reason), or otherwise developing a means to make that information publicly available; and
4. amending 15.3.1 to include a determination on a case-by-case basis of the use of service animals by Marijuana Infused Food Establishment employees.

Final Regulations

1. Final DDOE Regulation for 23 Del. Register of Regulations, 452 (December 1, 2019).

The now finalized changes to 14 DE Admin. Code 930 modifies the definition of supportive instruction and the accompanying eligibility criteria. The DDOE proposed regulation makes it explicit that supportive instruction is available for students experiencing a mental health condition by adding the terms "mental illness" and "mental health conditions." Certification of such conditions may be provided by a "licensed clinical mental health provider (such as a Licensed Clinical Social Worker, psychiatric nurse practitioner, psychologist, or psychiatrist)."

Previously Councils endorsed the proposed regulation but recommended that the DDOE consider broadening the categories of medical professionals who have authority to certify that a child has a mental health condition under this regulation, such as pediatricians or family medicine doctors, and their associated advanced practice nurses or physicians' assistants. Councils made this recommendation because often these physicians and medical professionals are a child's sole provider. Additionally, accessing specialized mental health services in a timely fashion can be difficult, given the shortage in Delaware. The DDOE responded to the Council's comments that "the proposed language has appropriately expanded the medical professionals eligible to certify absences due to a mental illness or mental health condition." Councils may wish to raise the expansion of such eligible medical professionals in future comments on DDOE policies.

Additionally, in the final regulation, DDOE provided clarification on supportive instruction provided to preschool students, as some districts provide preschool for non-IEP students. Specifically, the regulation now provides that for students with a disability, "the district shall provide supportive instruction each week of eligibility in an amount recommended by the student's individualized education program (IEP) team." Finally, for pre-school students without a disability districts may, but are not required to provide supportive instruction. There is no minimum number of hours each week of eligibility." These provisions neglect to address the possibility that preschool students may require accommodations under 504 plans, which may take the form of supportive instruction. This lack of clarity could cause children with disabilities who are protected under Section 504 of the Rehabilitation Act to not have equal access to preschool services. **The Councils may wish to consider quickly (in advance of the end of the month), and strongly, recommending that DDOE republish this regulation for comment, after addressing and providing clarification on this issue.**

2. Final DHCC Regulations for the Health Insurance Individual Market Stabilization Reinsurance Program, 23 Del. Register of Regulations 455 (December 1, 2019).

House Bill No. 193, which was signed by Governor Carney on June 20, 2019, created the Health Insurance Individual Market Stabilization Reinsurance Program and Fund. The act amends 16 *Del. C.* §9903 and 18 *Del. C.* §§8701, 8702, and 8703. The program will start January 1, 2020. The Delaware Health care Commission (DHCC), which will administer the program, issued these regulations to implement the act passed by the General Assembly. The purpose of the act is to provide reinsurance to health insurance companies that offer individual health benefit plans. Reinsurance in its simplest terms is insurance for insurers. It is a reimbursement system that protects insurers from very high claims, and involves a third party paying part of the company's claims once they pass a certain amount. The act attempts to stabilize insurance rates and premiums in the individual markets while providing more available and more affordable choices for consumers seeking health insurance.

The act and regulations create a fund with monies from the federal government under the Affordable Care Act (ACA) (pass through savings from the 1332 waiver), monies from the federal government for reinsurance, and monies from a 2.75% assessment on insurance carrier's premium tax liability. The fund will be used to provide payments to reinsurance carriers whose claims costs exceed the threshold benefit amount set by the Executive Director of the DHCC.

According to Delaware's 1332 waiver proposal, the state is planning on covering 75% of claims that are between \$65,000 and \$215,000. Councils endorsed the Regulations with the recommendation that DHCC consider covering more claims at a higher threshold. DHCC responded that "Commission staff worked extensively with nationally renowned actuaries to develop a proposal that would be the most appropriate for Delaware's individual health insurance market in calendar year 2020." They went on to note that DHCC will be able to review and set thresholds each year of the program, and will consider the comments of the Councils during future reviews. The Councils may wish to reiterate in the future their encouragement that DHCC review and consider lowering thresholds in coming years.

3. Final DMMA Regulation Regarding Telehealth Services Originating Site Fees, 23 Del. Register of Regulations 461 (December 1, 2019)

DMMA is amending the Title XIX Medicaid State Plan regarding telehealth services, specifically adding facilities to which originating sites fees can be paid. Telehealth seeks to improve a patient's health by permitting two-way real time interactive communication between the patient and the physician or practitioner at a distant site. Centers for Medicare and Medicaid Services (CMS) note that telehealth is a cost-effective alternative to the more traditional face-to-face way of providing medical care and that states can choose to cover under Medicaid.

Telehealth is an innovative method for health care delivery. Including Federally Qualified Health Centers and School Based Wellness Centers among facilities to which originating sites can be paid will increase access to telehealth. Councils previously endorsed this initiative; further comment is not necessary.

4. Final DMMA Regulation Regarding Obesity Drugs, 23 Del. Register of Regulations 464 (December 1, 2019)

Via this regulation, DMMA clarifies its policy related to drugs indicated for the treatment of obesity. The regulation clarifies that Delaware will cover drugs indicated for the treatment of obesity to address weight loss with co-morbid conditions with prior authorization. Delaware is a founding member of My Healthy Weight, an initiative committed to working with providers and beneficiaries to increase utilization of standardized benefits, to encourage the collection of obesity metrics, and seeks to provide individuals with consistent coverage related to obesity services. Consistent with this effort, Councils previously supported this regulation; no further comment is necessary.