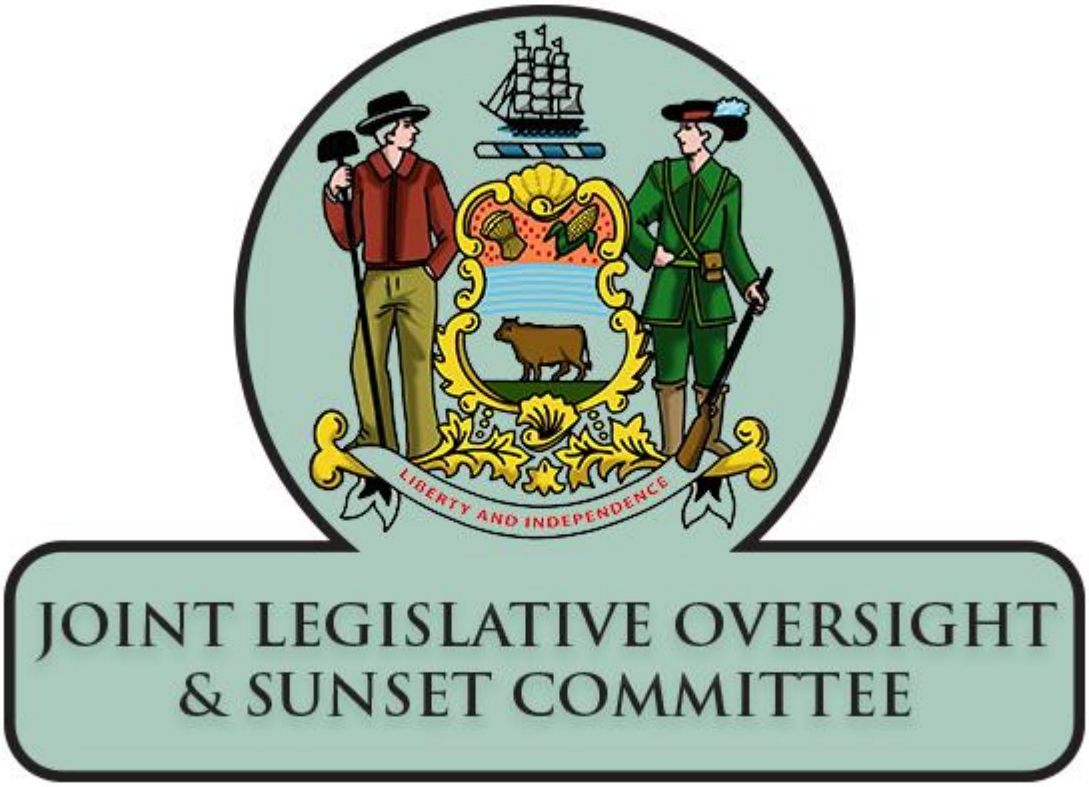
Staff Findings and Recommendations Report

Controlled Substance Advisory Committee

153rd General Assembly, 1st session



Respectfully submitted to the
Joint Legislative Oversight and Sunset Committee
March 2025

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Special thanks: We appreciate the aid provided by Controlled Substance Advisory Committee staff in conducting this review.

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ABOUT THIS REPORT

This is a staff findings and recommendations report ("staff report") drafted by Division of Legislative Services staff on the sunset and oversight review ("review") of the Controlled Substance Advisory Committee ("Committee").

The Joint Legislative Oversight and Sunset Committee ("JLOSC") is a bipartisan 10-member legislative body which performs periodic legislative review of state entities. The purpose of the oversight and sunset review is to assess genuine public need and entity performance. JLOSC performs its duties with support provided by the dedicated and nonpartisan staff of Division of Legislative Services. The Division of Legislative Services is a nonpartisan and confidential reference bureau for the General Assembly and supplies many services including staff support for JLOSC.

JLOSC staff completes a performance evaluation of the entity under review and provides a staff report to JLOSC which includes research, analysis, key findings, and recommendations. During the review process, the following is not assumed:

- There is a genuine public need for the entity under review.
- That the entity is satisfactorily and effectively meeting a public need.

Rather, the entity under review has the burden of showing, through the statutory criteria for review included in their self-report and analyst requested supplemental documentation, that there is a genuine public need, and that the entity is meeting that need.

JLOSC selected the Committee for review on March 2, 2023. During the review process the Committee supplied information by completing a self-report which included a performance review questionnaire.[1]

JLOSC staff compiled the following findings and recommendations after completing a performance evaluation. Staff used national evaluation standards while conducting the performance evaluation. These standards require planning and performing the evaluation to obtain sufficient evidence to provide a reasonable basis for the findings and conclusions based on the review criteria. Staff believe the evidence obtained provides a reasonable basis for their findings and conclusions. Additionally, the Objectives, Scope, and Methodology section discusses the fieldwork procedures used while conducting the research and developing the findings and recommendations presented in this report.

The staff report includes recommendations for JLOSC review and discussion. JLOSC does not follow their staff's recommendations by obligation. They convene publicly to review and discuss the staff report and finalize recommendations only after discussing and adopting with an affirmative vote from 7 members.

[1] Self-reports available on the Committee's website, https://legis.delaware.gov/Committee/Sunset.

JLOSC is authorized by statute to recommend 1 or more of the following:[2]

- Continuation of the entity as is.
- Termination of the entity.
- Termination of any program within the entity.
- Consolidation, merger, or transfer of the entity or the entity's functions to another entity.
- Termination of the entity unless certain conditions are met or modifications are made, by legislation or otherwise within a specified period.
- Budget appropriation limits for the entity.
- Legislation which JLOSC considers necessary to carry out its decision to continue or terminate the entity.

The information contained in this report, along with the previously published self-report, which includes background information from the entity under review help JLOSC in conducting a review of the entity.[3] The "JLOSC Staff Observations and Analysis" section of this report has information to support the staff's findings and recommendations.

Next Steps

JLOSC will hold a public hearing for each entity under full review to present to JLOSC and accept public comment on the scope of the review.[4]

JLOSC will review all information received, including the findings and recommendations presented in this staff report. Recommendations are adopted after review, discussion, and an affirmative vote of 7 JLOSC members. JLOSC is not bound by recommendations presented by staff and are free to change, reject, or create new recommendations. Once JLOSC adopts recommendations, the review moves to the implementation phase which may include drafting legislation.

[2] 29 *Del. C.* § 10214(a).
[3] Self-report is accessible on JLOSC's website, https://legis.delaware.gov/Committee/Sunset.
[4] Public meeting notices found on JLOSC's website and the State of Delaware's Public Meeting Calendar.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

A performance evaluation conducted as required under JLOSC statute and based on the following review criteria:

1. If the agency is a licensing agency, the extent to which the agency has permitted qualified applicants to be licensed.
2. The extent to which the agency has served the public interests.
3. The extent to which the agency has recommended statutory changes, and whether those changes directly benefit the public or whether those changes primarily benefit the agency or other entities and are of only indirect benefit to the public.
4. Review the implementation of recommendations contained in the final reports presented to the General Assembly and the Governor during previous legislative sessions.

Scope

This review covers a 3-year performance period except where noted.

Review Criteria #1[4]

If the agency is a licensing agency, the extent to which the agency has allowed qualified applicants to be licensed.

Methodology for Review Criteria #1

The Committee is a not a licensing agency but provides the Secretary of State ("Secretary") with advice on issuing registrations for controlled substances. Statutory criteria #1 is applicable to this review. This review looked at processes that the Division of Professional Regulation ("DPR") and the Committee use.

Review Criteria #2

The extent to which the agency serves public need.

Methodology for Review Criteria #2

As described in the fieldwork section of this report, this review explored the main duties and responsibilities listed in the statute that governs the Committee's work: Chapter 47 of Title 16 (Uniform Controlled Substances Act), except where noted. This report includes findings and recommendations pertaining to the main statutory duties.

Review Criteria #3

The extent to which the agency has recommended statutory changes, and whether those changes directly benefit the public or primarily benefit the agency or other entities and are of only indirect benefit to the public.

Methodology for Review Criteria #3

The Committee submitted its self-report in May 2023, which included the Committee's recommendations for improvement. It recommended updating Chapter 47 to shift the

[4] Review Criteria in this staff report is an aggregation of the criteria established in § 12011(b), Title 29.

Review Criteria #4

Review the implementation of recommendations contained in the final reports presented to the General Assembly and the Governor during earlier legislative sessions.

Methodology for Review Criteria #4

This is the first JLOSC review of the Committee. Statutory criteria number 4 is not applicable to this review.

Fieldwork completed

During this review, JLOSC staff completed review of the following:

- Reviewed all information that Committee staff supplied in April 2024, including:
  - Self-report.
  - Meeting minutes.
  - Current Committee membership.
  - Committee staffing.
  - Process of registration and investigation of complaints.
  - Spreadsheet of controlled substance registry applications received and issued past 5 years, 2018-2023.
  - Spreadsheet of received controlled substance registry complaints received and closed past 5 years, 2018-2023.
  - Uniform Controlled Substance Act regulations.
- Current regulations.
- All available public documents such as Committee and Department of Health and Social Services ("DHSS") websites, available news articles.
- Current Committee statute, Chapter 47, Title 16, the Uniform Controlled Substances Act, referred to throughout this report as "Chapter 47".
- Related legislation.
- Committee's overall performance as it relates to current statute.
- Committee meeting minutes available on the public meeting calendar January 2020 – December 2024.
- Attended various Committee meetings.
- Drug Enforcement Administration registration requirements.
- Center for Disease Control and Prevention information pertaining to controlled substances.
- Similar processes and committees in other states.

REVIEW BACKGROUND

The Committee was established in 2013 to advise the Secretary on issuing and renewing controlled substance registrations.[5] The Committee advises the Secretary on regulating prescribers and facilities, including dispensers, manufacturers, distributors, clinics, researchers, and other entities involved in managing controlled substances. Additionally, the Committee recommends to the Secretary regulations and disciplinary actions related to prescribing, storing, and dispensing controlled substances. The Committee can recommend regulation updates, including making emergency changes to scheduling substances that present a risk to public safety.

Practitioners must obtain a state-issued controlled substance registration to prescribe, and facilities must obtain registration to store or dispense controlled substances.[6] Both practitioners and facilities must also possess a controlled substance registration from the Drug Enforcement Administration ("DEA"). The Committee oversees all aspects of prescribing, storing, distributing, and dispensing controlled substances in Delaware. As of the self-report submission, 7 of the 9 committee positions are filled. JLOSC began its review of the Committee in March 2023. The entity completed and returned its self-report in June 2023, and JLOSC staff conducted research and drafted this findings and recommendations report.

[5] Senate Bill No. 59, as amended by Senate Amendment No. 2, 145th General Assembly, enacted in August 2013.

[6] Practitioner registration required for physicians, dentists, veterinarians, podiatrists, physician assistants, advanced practice registered nurses, and optometrists. Facilities storing or dispensing controlled substances require a facility registration.

REVIEW CRITERIA OBSERVATIONS

Criteria #1 Observations:

Criteria #1 evaluates the extent to which an agency fulfills its licensing responsibilities by enabling qualified applicants to obtain licensure. The Committee is a not a licensing agency but provides the Secretary with advice on issuing registrations for controlled substances. Statutory criteria #1 is applicable to this review.

This review looked at processes that DPR, the Office of Controlled Substances, and the Committee use to process applications to either issue or deny controlled substance registrations. Also reviewed were processes used to ensure qualified applicants maintain registration by investigating registration complaints and issuing recommendations for discipline. The Office of Controlled Substances is discussed in this report because it provides primary staff support to the Committee. Lastly, education requirements are discussed in this report because the requirements apply to initial registrations as well as renewals.

Registration Requirements and Process

In Delaware, 7 practitioner types must apply and hold a controlled substance registration, along with a separate practitioner license and a DEA license, to prescribe controlled substances. The 7 practitioner types are: physicians, dentists, veterinarians, podiatrists, physician assistants, advanced practice registered nurses, and optometrists. Facilities that store or dispense controlled substances in Delaware must also register, including pharmacies, hospital or clinic pharmacies, provider pharmacies, distributors, manufacturers, and research or laboratory facilities.

The Committee explained in its self-report that applicants complete the application process through DPR's licensing system, DELPROS. The director of the Office of Controlled Substances receives, credentials, and issues applications within 1 to 2 weeks from the date of receipt in the order they are received. Deficient applicants are contacted to resolve any missing information. If the application is for an in-state pharmacy or facility, a pharmacy compliance officer conducts an on-site inspection to ensure compliance with licensure laws and regulations. Once the director reviews the information submitted with the application and confirms it meets the requirements, the registration is issued, and the system automatically sends an email directly to the applicant. During the review period, the director processed 4,286 applications for controlled substance registrations from both practitioners and facilities. The average time from application submission to issuance was about 13 days.[7]

Denial, Suspension, Revocation, and Investigation of Controlled Substance Registration

During the review period, the Committee advised to deny 3 applications.[8] The Secretary may deny an application for registration if it does not meet public interest criteria, such as having effective controls against substance diversion, complying with laws, providing accurate application materials, and holding valid professional licensure free of prior

[7] Calculated from DPR-supplied spreadsheet of received and licensed applications in active status, total of 3,861. Spreadsheet also included statuses for cancelled, closed, expired, terminated, and withdrawn applications. Twenty-one applications had been recently received and not issued.

[8] Review of meeting minutes 2020-2024.

discipline.[9] The Secretary can deny, suspend, or revoke a registration if the registrant's DEA registration or professional license is suspended or revoked, or if the registrant fails to meet required continuing education requirements set by the Secretary. The Secretary evaluates these factors and can also deny applications if the DEA registration or state licensure is suspended, revoked, or if mandatory education requirements are unmet.

Before denial, the Director notifies the applicant with the reasons for a potential denial and offers an opportunity for a hearing. The Committee serves as the Secretary's designee during hearings. The Committee submits its recommendations to the Secretary, who makes the final decision. If the Secretary denies, suspends, or revokes the registration, the findings are shared in writing and the decision stands unless the applicant or registrant appeals.

The Committee also advises the Secretary on discipline resulting from registry investigations. By statute, DPR receives and investigates all complaints.[10] During the review period, the office received 24 complaints: 2 complaints closed with discipline, 7 were referred to the Attorney General's office, 7 closed without discipline, 2 remain under review, and 6 were rejected.

The Office of Controlled Substances, the Division of Professional Regulation, and the Committee

The intersection of the Office of Controlled Substances, DPR, and the Committee is not plainly provided by statute, but all 3 entities have a role in regulating and monitoring controlled substances. The Office of Controlled Substances, like the Committee, is governed by Chapter 47 and, also like the Committee, its purpose or administration is not defined. The Office's primary role relates to the Prescription Monitoring Program ("PMP"), also under Chapter 47. Chapter 47 does not, however, expressly create the Office, nor does it specify where the Office should be administratively placed.

DPR's main purpose is to be responsible for "the administrative, ministerial, budgetary, clerical, and exclusive investigative functions" of a specified list of committees and boards that license, investigate, and discipline many professions.[11] DPR houses the Committee and provides staff through the Office of Controlled Substances, but neither Chapter 47 nor DPR's governing statute explicitly connect the Committee with DPR or the Office of Controlled Substances.[12] Instead, Chapter 47 establishes the requirements for the Committee to review and advise the Secretary on applications for controlled substances registration, a role that is typical to a profession under DPR.[13]

The statutory connections among the Office of Controlled Substances, DPR, and the Committee are confusing to parse through; regulations clarify the relationship and the Committee's duties, and DPR's website contains all controlled substance registration information.

[9] 16 *Del. C.* § 4733.
[10] 16 *Del. C.* § 4735.
[11] 29 *Del. C.* § 8735.
[12] DPR is an agency under the Department of State.
[13] *See* Title 24 generally.

Adding to the organizational confusion, the Office of Controlled Substances' website presence is limited.[14] The DPR website for the PMP names the Office of Controlled Substances as the office managing the program.[15] The link for the Office, however, directs users to the *Committee's* section of the DPR website, and does not include the Office in the headings or text.

Mandatory Education Requirements for Initial Registry and Renewal

All practitioners applying for an initial controlled substance registration must complete a mandatory 1-hour, 2-part course. For each renewal, registrants must attest to completing 2 hours of continuing education on topics such as controlled substance prescribing practices, chronic pain treatment, opioid risks, abuse detection, and related subjects. Statutes and regulations mandate these education requirements.

The DPR website explains the mandatory course requirement, stating that the "Division of Professional Regulation (Office of Controlled Substances) offers the only approved course" and that "completion of this Mandatory Course is no longer accepted as continuing education credit."[16] The website provides the approved course as a 2-part file, which applicants must download from a Dropbox link. The registration requirement states that applicants must attest to completing the training, as the system does not issue a completion certificate. Committee noted in its self-report that the 2019 course, the most recent year available, is outdated.

A review of the course videos revealed outdated content, including a slide referring to a process of claiming continuing education credits by completing a post-test, a practice that the Committee discontinued. Some language in the course examples could be considered stigmatizing and the regulations discussed in the course have been changed since the course was published. At the end of the second training webinar video, a slide titled "Find regulations and other valuable resources online" lists the Help Is Here website.[17] This website offers the training webinar directly, but its text contains the following outdated information, contradicting the details on the Committee's website:

- The website states that the webinar must be completed every 2 years for license renewal, which conflicts with the current renewal process and continuing education requirements.
- The accreditation statement on the website mentions that the Committee no longer provides continuing education for this webinar. Other professional boards may have stopped accepting this webinar for credit since the completion certificate and post-test were discontinued.
- The website provides links to 5 training videos under PMP registration, but those videos are no longer active.
- The document for opioid prescription guidelines for healthcare providers, last updated in February 2017, is outdated. The Committee updated its regulations in 2018 and 2022, and the CDC updated its prescribing guidelines in 2022.

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[14] *See* https://dpr.delaware.gov/boards/controlledsubstances, last accessed March 13, 2025.
[15] PMP website available at https://dpr.delaware.gov/boards/pmp, last accessed March 13, 2025.
[16] DPR mandatory course website available at https://dpr.delaware.gov/boards/controlledsubstances/mandatory_course.
[17] Provided link is HelpIsHereDE.com/Provider, last accessed March 13, 2025. DHSS hosts Help Is Here Delaware, providing information for the public and providers on treatment and prevention strategies for mental illness and addiction in Delaware. It is unknown why this resource marked as "valuable" is not provided directly on the Committee's website for applicants and registrants.

- The regulations document provided is the December 15, 2016, final order for regulations, which became effective on April 1, 2017. The website does not provide a link to the current regulations which have been modified twice since the final order.

The Help Is Here website offers resources that the Committee's website does not, such as information and sample agreements for the required signed consent and treatment agreements.[18] It is unclear whether this information is current.

In its self-report, the Committee acknowledged the confusion and challenges surrounding continuing education requirements. As of the January 2024 meeting, 64 licensees were selected for audit during the renewal cycle. Once DPR staff reviews all documentation, it will notify and schedule non-compliant licensees for a Rule to Show Cause hearing, which may lead to discipline.

It is unclear whether the Committee has reviewed its current education requirements to assess any overlap with the updated DEA registration requirement. As of June 2023, the DEA mandated a new one-time, 8-hour training course on treating and managing patients with opioid or other substance use disorders.[19] Practitioners must affirm completion of this course when registering or renewing their DEA registration. Veterinarians are exempt from this requirement. All practitioners, including veterinarians, holding a controlled substance registration in Delaware must also obtain and maintain DEA registration.

Criteria #2 Observations:

Criteria #2 assesses how effectively an agency has served the public interest. This review explored the main duties and responsibilities listed in Chapter 47 and made the following observations regarding Committee composition, education, research, communication, outreach, emergency regulation and drug scheduling, prescription monitoring program, public reporting, and data transparency

Committee Composition, Duties, and Function

As previously noted, Chapter 47 is brief in its formation of the Committee.[20] The Committee's regulations further define it as 9-members consisting of professionals and public members appointed by the Secretary, that hold regular quarterly meetings.[21] However, the Committee's role is advisory in nature, and its connection to broader enforcement and registration processes is not outlined in statute. The Committee holds hearings on behalf of the Secretary but can only provide advice on disciplinary actions; the Secretary makes all final decisions.

Education and Research

The Committee does not conduct research and stopped including reports from the medical examiner, DEA, substance abuse, law enforcement, and regulatory sources after its May 2021 meeting. There does not appear to be a standard set of reports or materials

[18] Controlled substance registry statute and regulations provide requirements for consent and treatment agreements.
[19] DEA Medication Assisted Treatment website available at https://deadiversion.usdoj.gov/pubs/docs/MATE_training.html, last accessed March 13, 2025.
[20] 16 *Del. C.* § 4731(b).
[21] Uniform Controlled Substances Act Regulations-1.2, 1.4 of Title 24 of the Delaware Administrative Code.

the Committee reviews since removing these reports from agendas. The Committee receives information from DPR staff and sporadic articles from Committee members.

The Secretary is tasked with carrying out educational programs to prevent and deter misuse and abuse of controlled substances.[22] However, the Secretary does not appear to engage in education or research activities directly; rather, DHSS carries out the educational programs, such as prevention toolkits. The Committee does not provide advice to the Secretary on educational programs.

The Committee's own educational outreach efforts, such as providing guidance to professionals in the controlled substances field, are minimal. The Committee occasionally sends out materials to professionals. For example, the CDC updated its *2016 CDC Clinical Practice Guideline for Prescribing Opioids for Pain* ("CDC prescribing guidelines") in 2022. The CDC prescribing guidelines assist healthcare providers with patient care, but the Committee has not ensured these updates are accessible through its platform. Additionally, although the DHSS Help Is Here website provides resources for providers, this website is not effectively linked to the Committee's platform, resulting in the dissemination of outdated materials, including the 2016 CDC prescribing guidelines.[23]

In addition to the DHSS Help Is Here website, there are many established committees and state initiatives aimed at state drug awareness and prevention programs, such as the Drug Overdose Fatality Review Commission, also created under Chapter 47. However, the Committee does not have frequent interaction or collaboration with many of these public bodies, including the Drug Overdose Fatality Review Commission.

Emergency Regulation and Drug Scheduling

During the period of review the Committee recommended one drug, xylazine, to the Secretary for emergency reclassification. Xylazine emerged as a significant drug of concern due to its growing presence in illicit drug supplies, often unknowingly consumed when mixed with other substances. Used and approved as a veterinary drug, xylazine is not approved for human use. Its unique dangers include the inability to reverse an overdose with naloxone (commonly known as "Narcan"). Moreover, users frequently develop severe skin wounds that, if left untreated, can lead to amputations or even death. The withdrawal symptoms of xylazine also present distinctive challenges for users who discontinue use and the hospital and rehabilitation systems who provide treatment. These withdrawal symptoms often manifesting as irritability, anxiety, dysphoria, and mental health issues like hallucinations. Prolonged use of the drug is also associated with conditions such as psychosis and a decline in memory, focus, and decision-making abilities.

Xylazine was the subject of an emergency meeting that the Committee held on May 5, 2023. Following the meeting, the Secretary reclassified xylazine as a schedule III-controlled substance, a decision later codified through legislative action.[24] Emergency

[22] 16 *Del. C.* § 4787.
[23] 2016 CDC prescribing guidelines referenced on "a prescription for change in Delaware" section of Help Is Here website available at https://www.helpisherede.com/health-care-providers, last accessed March 13, 2025. Guidelines for Prescribing Opioids Establish a Clear Decision-Making Process (last updated February 2017) available at https://www.helpisherede.com/health-care-providers/safe-prescribing, last accessed March 13, 2025.
[24] Senate Bill No. 189, as amended by Senate Amendment No. 1, 152nd General Assembly, enacted August 2023.

action was prompted by growing evidence of the drug's harmful effects and its increasing abuse potential. However, despite the Committee's involvement in this process, no educational materials or public health campaigns were initiated or coordinated with DHSS to raise awareness of the public health risks associated with xylazine and to provide overdose prevention and harm reduction strategies.[25] Other states to reclassify xylazine, like Ohio and Pennsylvania, have issued fact sheets and guidance for healthcare providers and the public on xylazine.[26]

Prescription Monitoring Program

Delaware's PMP was also established under Chapter 47, along with a PMP advisory committee that provides guidance to the Office of Controlled Substances on PMP maintenance.[27] However, the committee met only 6 times, last meeting in February 2020, leaving its current role uncertain. Since the PMP advisory committee ceased meeting, the Committee has continued to receive PMP updates from the PMP program manager.

Registration for the PMP is mandatory within 90 days of obtaining a controlled substance registration for all practitioners, excluding veterinarians, and pharmacists dispensing controlled substances. Optional registration is available for specific professionals, such as prescribers, authorized delegates, substance abuse counselors, and the Chief Medical Examiner or a designated physician investigating deaths.

Despite this mandatory PMP registry requirement for practitioners with controlled substance registration, the Committee's website does not prominently feature the obligation under individual practitioner registration sections, and instead directs users to legal and regulatory links.[28] Further, the main PMP website also omits visible mention of the requirement, except in the "register" section.

The Committee has not been provided with data on compliance with the 90-day registration rule. During a May 2022 meeting, it was noted that PMP accounts are automatically deactivated upon practitioner license or DEA registry expiration, but this measure does not address compliance when the registration holder initially obtains registration.

Public Reporting and Data Transparency

The Uniform Controlled Substance Act requires both the Department of Justice ("DOJ") and the Office of Controlled Substances to issue reports.[29] The Committee does not have a role in these reports.

The DOJ is responsible for compiling and publishing an annual report detailing various aspects of seizures, including property type, currency, demographic data, and case outcomes.[30]

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[25] In 2023, Delaware launched the first harm reduction test strip to detect both fentanyl and xylazine in various substances, but websites dedicated to overdose prevention and harm reduction do not include education on xylazine.

[26] Ohio and Pennsylvania both rescheduled Xylazine.

[27] Senate Bill No. 235, as amended by Senate Amendment No. 2, 145th General Assembly, enacted July 2010.

[28] The mandatory PMP registry is covered in the mandatory 1 hour 2-part training course for initial registration.

[29] 16 *Del. C.* § 4788 and 4798(o).

[30] 16 *Del. C.* § 4788.

The Office of Controlled Substances is tasked with evaluating the PMP to determine its cost-benefits and impacts on controlled substance abuse and prescribing practices.[31] The Office must submit a report of its findings annually to the General Assembly.

Although outside the scope of this review, there are indications that the 2 reports are either outdated or not publicly available in the format outlined by statute. The Committee is not involved in the creation or distribution of these reports, and it does not appear that the Committee has consistently used the reports to inform the Committee's decisions or the public about controlled substances issues.

The Office of Controlled Substances' PMP program manager does, however, collaborate with DHSS to make data from the PMP publicly accessible through the My Healthy Community website, as highlighted by the PMP program manager during Committee discussions.[32]

Criteria #3 Observations:

Criteria #3 evaluates whether an agency has proposed statutory changes that directly benefit the public or primarily serve the agency or other entities with only indirect public benefit. The Committee submitted its self-report in May 2023, which included the Committee's recommendations for improvement. It recommended updating Chapter 47 to shift the Committee from being only advisory to operating similarly to other professions under Title 24 (Professions and Occupations) and converting the Committee into a licensing board to benefit members, licensees, and the public. The Committee also noted a desire to update registration requirements to include emergency medical service ("EMS") providers who handle controlled substances.

Statutory Modifications Regarding Committee Conversion

The Committee's statutory history is unique. The Committee does not have a statute typical of a public body, which would include the specifics of membership and provisions guiding the administration and operations of the Committee. Rather, § 4731 of Title 16 states, in its entirety:

> § 4731. Rules; fees; Controlled Substance Advisory Committee.
>
> (a) The Secretary may promulgate rules and charge reasonable fees relating to the registration and control of the manufacture, distribution and dispensing of controlled substances within this State.
>
> (b) The Secretary shall appoint a council to act in an advisory capacity to the Secretary and other state agencies on all matters relating to this chapter. The advisory council shall be named the Controlled Substance Advisory Committee and may serve as the Secretary's designee in any hearing under this chapter.

The Committee's duties are established by statute as the Secretary's duties, which the Secretary may – and does – delegate to the Committee. Many of the Committee's duties are promulgated through regulation rather than in statute. This review examines the

[31] 16 *Del. C.* § 4798(o).
[32] PMP data available under the data section for "Mental Health & Substance Use." My Healthy Community is a Delaware Environmental Public Health Tracking Network hosted by DHSS and available at: https://myhealthycommunity.dhss.delaware.gov/home.

current processes used by DPR staff and the Committee in advising the Secretary on the monitoring and regulation of the controlled substance registry. These processes include providing guidance on registry applications, renewals, disciplinary actions, regulations, and emergency regulation updates to schedule substances that pose risks to public safety.

The Committee operates under the guidance and support of DPR staff, which also supports the Office of Controlled Substances. DPR provides regulatory oversight and staff support for over 50 professions and occupations under Title 24. For these professions, the Secretary holds emergency powers, such as temporarily suspending licensure, to protect public health, safety, and welfare.

As previously noted, the Committee is loosely established under Chapter 47 and further defined through regulations. However, statutory authority limits the Committee to an advisory role, unlike other DPR-regulated professions, which have broader authority and responsibilities. Currently, the Committee's statute relies entirely on the Secretary for all aspects of the registration process, which is outdated.

This review demonstrates that the Committee, along with DPR staff, has the ability to effectively regulate and monitor the controlled substance registry in Delaware. If legislative changes redefined the Committee's role from advisory to that of a licensing board, it should model itself on Title 24 licensing boards while continuing to advise the Secretary on emergency regulation updates related to scheduling substances that pose public safety risks. This would ensure consistency with the emergency powers the Secretary holds for other professions regulated by DPR.

Updated DEA Requirements Regarding EMS Providers

The Committee submitted in their self-report a desire to review and update registration requirements to include emergency medical service ("EMS") providers who handle controlled substances. The Committee noted with concern receiving notification of increased drug diversion by EMS providers. The federal Controlled Substances Act was recently updated in 2017 by the Protecting Patient Access to Emergency Medications Act,[33] to add EMS guidance at the federal level and to standardize and improve EMS processes and patient care. The changes include several items regarding standing orders, storage of controlled substances, restocking EMS vehicles at hospitals, maintenance of controlled substance records, liability of EMS agencies, and DEA registration for EMS agencies. The DEA registration for EMS agencies piece has been in development for several years to receive public comment and study impact to EMS agencies. The DEA registration has 2 key factors: that EMS agencies serving multiple states must maintain DEA registrations in each state and hospital-based EMS agencies can use the hospital's DEA registration and do not need to register separately. The DEA finalized regulations in 2024, and their website does not currently include an application form for EMS registrations. Some states have started the process of reviewing DEA regulation changes and registration requirements effecting EMS agencies. At time of this review few states were observed to process state-level EMS agency registration for controlled substances.[34]

[33] *See* The Protecting Patient Access to Emergency Medications Act of 2017, Public Law 115-83, which amends the federal Controlled Substances Act at 21 U.S.C. § 823.

[34] New Mexico has required EMS facility registration since 1999.

JLOSC STAFF OBSERVATIONS AND ANALYSIS

Staff reviewed the Committee's current statute, structure, and processes, and noted the following:

1. Staff support, administrative location, and duties of the Office of Controlled Substances and Committee should be clarified in statute.

2. Overlapping and often unclear continuing education requirements can place an undue burden on registrants and may be perceived as redundant. The Committee should strive to balance the need for continuing education with the administrative challenges of managing these requirements. It should also evaluate the continuing education courses required for a practitioner's primary professional license alongside the newer DEA registration education mandates.
    - As of June 2023, the DEA requires practitioners (veterinarians are exempt) to complete a one-time, 8-hour course—exceeding Delaware's initial registration education requirements—and this could be considered equivalent to the continuing education required for 4 controlled substance registry renewals.
    - Controlled substance registry holders are also subject to audits to verify compliance with continuing education requirements. During the last renewal cycle, DPR audited 64 renewals, with deficiencies resulting in hearings and disciplinary actions. This auditing process demands staff resources from DPR and its hearing officer unit, further increasing the burden on both registrants and the regulatory agency.

3. The Secretary is tasked with implementing educational programs to prevent and deter the misuse and abuse of controlled substances. However, neither the Secretary nor the Committee appears to directly engage in educational or research activities. Given the existence of numerous established public organizations and state initiatives focused on drug awareness and abuse prevention, it is unnecessary to require the Secretary or Committee to conduct these programs themselves. Instead, the Committee and its staff should collaborate more closely with these organizations to effectively disseminate information on controlled substances. ensure the effective dissemination of information on controlled substances.
    - One of the most significant gaps in the Committee's work is its failure to adequately collaborate and educate to inform the public about the risks associated with substances emerging as concern or recommended for reclassification. While emergency reclassifications are intended to protect the public, they often fall short when it comes to providing information to the public and healthcare professionals.
    - For instance, xylazine was recommended for emergency reclassification due to its significant health risks, but there was limited public outreach or educational material provided either by the Committee or in collaboration with DHSS.

- Both DHSS and DPR websites fail to provide public information on the dangers of xylazine, despite its growing presence in illicit drugs. To address these shortcomings, the Committee should work more closely with DHSS and other prevention initiatives to effectively communicate emergency reclassifications and public health risks from substances of concern.

4. The Drug Overdose Fatality Review Commission is required by statute to make annual recommendations to the Governor and General Assembly regarding practices or conditions which impact the frequency of overdose deaths and measures to reduce the frequency of such overdose deaths.[35] Since this Commission is tasked with reviewing deaths caused by factors such as an overdose of a controlled substance, it would be helpful for the Drug Overdoes Fatality Review Commission to also share their annual recommendations with the Committee.

5. If the PMP advisory committee has disbanded and is no longer holding meetings, it should be removed from Chapter 47 and the duties should be transferred to the Committee, which has taken over receiving frequent reports from the PMP program manager.

6. Reporting requirements for DOJ and the Office of Controlled Substances should be updated to reflect current practices.

7. Chapter 47 establishes the Committee as advisory, with responsibilities that include providing guidance on registry applications, renewals, disciplinary actions, regulations, and emergency updates for scheduling substances that pose risks to public safety. These duties are carried out with support from DPR staff, including the Office of Controlled Substances, which handles all registry applications. To align with current processes and the functions of Title 24 boards, Chapter 47 should be updated to clarify the Committee's role, transition the Committee from advisory status, and retain the Secretary's emergency regulatory and drug scheduling authority.

8. Because the DEA is still developing EMS facility registration for controlled substances, it is recommended that the Committee begin reviewing and comparing the current state processes and procedures for EMS facilities with the federal Protecting Patient Access to Emergency Medications Act. Additionally, the Committee should collaborate with state EMS partners, including the Office of Emergency Medical Services and the State Fire Prevention Commission, to better understand the specific nuances of Delaware's EMS services.

[35] 16 *Del. C.* § 4799C.

JLOSC STAFF FINDINGS AND RECOMMENDATIONS

Finding #1

The Controlled Substance Advisory Committee was established to safeguard public health, safety, and welfare by regulating and monitoring controlled substance use and abuse through registration, inspection, investigation, and education, while issuing licenses and making regulatory recommendations.

Recommendation #1 – Continue.

Continue the Controlled Substance Advisory Committee, subject to further recommendations that JLOSC adopts.

Finding #2

The Controlled Substance Advisory Committee's statute is short and gives broad authority only to advise on applications for controlled substances registration. The Committee has promulgated regulations to provide clarification and has demonstrated the ability to act in a manner more consistent with a licensing board rather than advisory.

Recommendation #2 – Statute Revisions.

JLOSC should consider sponsoring a bill to update Chapter 47 to codify the Committee's purpose, administration, and operations and, using this review as a guide, applying revisions to sections covering topics such as:

- Update Committee duties, staffing, and authority.
    - Include public outreach and education for any drug scheduling activity.
- Clarify Office of Controlled Substance staffing and administrative resources.
- Update Secretary duties regarding educational programs.
- Update reporting requirements for DOJ and Office of Controlled Substance.
- Update continuing education requirements for initial registration and renewal.

JLOSC and DPR staff will work together to develop statutory revisions. JLOSC staff will engage stakeholders as appropriate.

Finding #3

The Controlled Substance Advisory Committee has consistently held public meetings and staff have maintained communication with JLOSC staff throughout the review. JLOSC staff do not believe that monitoring the Board beyond the JLOSC statute's required monitoring[36] is necessary. Additionally, staff do not recommend the Board submit progress reports to comply with any JLOSC adopted recommendations.

Recommendation #3 – Release from Review.

Release the Controlled Substance Advisory Committee from review upon enactment of legislation under Recommendation #2 or further action of JLOSC.

[36] 29 *Del. C.* § 10219.

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April 4, 2025

Joint Legislative Oversight & Sunset Committee
Legislative Council, Division of Research
411 Legislative Avenue
Dover, DE 19901

Dear JLOSC Members and Division of Research Staff:

The Controlled Substance Advisory Committee ("CSAC") sincerely appreciates the work of the Joint Legislative Oversight and Sunset Committee ("JLOSC") Staff and have reviewed their Findings and Recommendations Report ("Report"). Outlined below are the CSAC's comments and clarifications with respect to the Report.

CSAC, Office of Controlled Substances and Division of Professional Regulation

As noted in the Report, the intersection of the CSAC, the Office of Controlled Substances ("OCS") and the Division of Professional Regulation ("DPR") is not clearly delineated by statute. The CSAC acts in an advisory role only. The objective is to establish a licensing entity to regulate controlled substance registrations ("CSR") similar to licensing boards operating under Title 24 of the Delaware Code. Subchapter III, Chapter 47 of Title 16, pertaining to the "Regulation of Manufacture, Distribution and Dispensing of Controlled Substances" will be revised to eliminate the CSAC and expressly create the Office of Controlled Substances as the licensing and regulatory entity for practitioners applying for or holding CSRs. As is currently the case, the OCS will fall under the umbrella of DPR which will provide needed administrative oversight and support. The Secretary of State will retain the authority to schedule drugs on an emergency basis.

Mandatory Education Requirements for Initial Registry and Renewal

All practitioners applying for an initial CSR must complete a mandatory 1-hour, 2-part course which is available on DPR's website. As correctly observed in the Report, this course is outdated. This initial registration requirement will be stricken from the Uniform Controlled Substance Act regulations. Instead, at the time of application, which is accomplished electronically, applicants will be required to attest to familiarity and compliance with all statutory and regulatory requirements applicable to the prescribing and dispensing of controlled substances. For CSR biennial renewal, registrants will be required to complete 2 hours of continuing education in subjects related to controlled substances. As of June 2023, the Drug Enforcement Administration ("DEA") adopted a one-time, 8-hour training requirement on treating and managing patients with opioid or other substance abuse disorders. Practitioners must affirm completion of this course

when registering or renewing their DEA registrations. Uniform Controlled Substance Act regulations will be amended to provide that a registrant who completes the DEA required training may use 2 of the hours to satisfy Delaware continuing education requirements for the CSR renewal period immediately following completion of the requisite hours.

Education and Research

Consistent with Title 24 boards operating under DPR, the CSAC does not generally engage in education outreach or research activities. On occasion, alerts are sent to registrants to advise of law changes, including emergency scheduling of drugs. The Report comments that the "Secretary" is tasked with carrying out educational programs to prevent and deter misuse and abuse of controlled substances, as set forth in 16 *Del. C.* § 4787(a). However, in Section 4787(a), "Secretary" means the Secretary of the Department of Safety and Homeland Security. Therefore, carrying out educational programs is not within the scope of the duties of the Secretary of State and will not fall within the responsibilities of the OCS. 16 *Del. C.* 4701(49). Section 4787(b), providing that the "Secretary shall encourage research on misuse and abuse of controlled substances," does refer to the Secretary of State. However, licensing boards do not engage in or encourage research. Undertaking this type of activity would greatly exceed the powers and duties of a body tasked with regulating a profession. Proposed legislation would strike Section 4787(b).

Emergency Regulation and Drug Scheduling

By regulation, the Secretary of State has the authority to classify a drug as a controlled substance on an emergency basis. Statutory revisions will ensure that the Secretary of State retains this authority. The Report specifically references the emergency scheduling of xylazine in 2023, which was followed by legislation in that the decision to schedule a drug on a permanent basis rests with the General Assembly. The Report further comments that, unlike other states, the CSAC didn't initiate educational materials or public health campaigns to publicize the scheduling of xylazine. To clarify that point, the Secretary of State issued a press release on June 2, 2023 to publicize the scheduling of xylazine. Both the Secretary of State and DPR have the option of issuing press releases on board activities of public interest. However, generally, in Delaware, professional licensing boards do not take on the role of conducting public health campaigns, which would more appropriately rest with the DHSS. Further, meeting notices are published on Delaware's public meeting calendar, and all meetings are public. Interested stakeholders are welcome to provide written information or make public comment at a meeting. Items of public interest may also be added to an agenda for discussion. Upon enactment of legislation creating the OCS as a licensing board, DPR staff will ensure that stakeholder concerns and comments are brought to the attention of OCS members for discussion at a public meeting. Further, as is currently the process, registrants will continue to receive alerts on law changes or developments relevant to their practice and press releases may be issued when appropriate.

Prescription Monitoring Program

The Delaware Prescription Monitoring Act is set forth in Section 4798 of Title 16. DPR has prepared a bill to update Section 4798 to provide clarity and guidance to practitioners and to ensure consistency with legal requirements and practice. At the discretion of the JLOSC, the

proposed bill will be included in the legislation to be drafted in response to the Report. The PMP Advisory Committee, created in Section 4798(v), is defunct, and the relevant statutory language will be stricken accordingly. By statute, registrants are required to register with the PMP within 90 days after issuance of the CSR. They are advised of this requirement in writing at the time that the CSR is issued.

Updated DEA Requirements Regarding EMS Providers

In its Self-Report, the CSAC stated a concern regarding registration of emergency medical service ("EMS") providers who handle controlled substances. The DEA proposed rules to implement this process on a federal level. DEA developments will be monitored closely and there will be discussion as to whether Delaware should create its own registration for EMS providers.

The CSAC is committed to fulfilling and expanding its role of public protection with respect to the registration and control of the manufacture, distribution and dispensing of controlled substances in the State of Delaware. The CSAC will work diligently with the JLOSC to further its objectives. We look forward to the presentation meeting on April 10, 2025.

Respectfully Submitted,

Shauna R. Slaughter

Shauna Slaughter
Director

cc: Charuni Patibanda-Sanchez, Secretary of State
Kris Knight, Chief Deputy Secretary of State
Ruth Dixon, Drug Control Administrator
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