Controlled Substance Advisory Committee

Self-Report

2024 Full Review Cycle

152nd General Assembly

Respectfully submitted to the
Joint Legislative Oversight and Sunset Committee
May 2023

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ABOUT JLOSC AND THE REVIEW PROCESS

The Joint Legislative Oversight and Sunset Committee ("JLOSC" or "Joint Committee") is a bipartisan body comprised of 5 members of the Senate appointed by the President Pro Tempore and 5 members of the House of Representatives appointed by the Speaker of the House.

JLOSC completes periodic reviews of state supported entities such as agencies, commissions, and boards following statutory criteria under 29 Del. Code, Chapter 102. The review's purpose is to determine the public need for the entity and whether the entity is effectively performing to meet the need. The goal of the review is to provide strength and support to entities that are providing a state recognized need.

JLOSC performs its duties with support provided by the Division of Research's dedicated and nonpartisan staff. JLOSC staff completes a performance evaluation of the entity under review and submits a Staff Report to JLOSC which includes analysis, key findings, and recommendations. Recommendations are not finalized until reviewed, discussed, and adopted by JLOSC with an affirmative vote of 7 members. Beginning in February 2024, JLOSC staff will schedule a presentation meeting for each entity under review to present to JLOSC. For additional review information, please visit the Committee's website at https://legis.delaware.gov/Committee/Sunset.

ABOUT THIS SELF-REPORT

The JLOSC statute requires the entity under review to supply information and materials to facilitate a legislative oversight and sunset review. Additionally, the entity under review has the burden of showing, through the statutory review criteria, that there is a genuine public need and that the entity is meeting that need.

JLOSC staff supplies each entity under review with a Self-Report template and instructions. All questions appearing in this Self-Report are from the JLOSC staff created *JLOSC Performance Review Questionnaire* ("questionnaire") and are the similar for each entity under review. All questions appearing in the questionnaire use statutory review criteria. Throughout the questionnaire, the use of the broad term "entity" refers to the entity under review, which may be a board, committee, commission, or council. The entity under review supplies review information by submitting all requested review documents and completing this Self-Report. The entity under review is responsible for the contents of the Self-Report and for forwarding all updates, corrections, and requested documents to JLOSC staff in a timely manner during the entire review period.

JLOSC staff will not edit or modify the information received in this Self-Report and only checks for completeness and adherence to instructions. JLOSC members will receive completed Self-Reports and updates directly from their staff. The Committee's website will include electronic copies of all Self-Reports and any updates received from entities under review. JLOSC analysts are the point of contact throughout all reviews. All questions and comments regarding JLOSC, and reviews should be submitted to Sunset@Delaware.gov.

JLOSC PERFORMANCE REVIEW QUESTIONNAIRE

SECTION 1: ENTITY HISTORY, PURPOSE, AND FUNCTIONS

Section 1-A. Please provide a summary of the entity's history. Highlight any key events.

The Controlled Substance Advisory Committee (CSAC) conducted meetings and operated without statutory regulations between 2010 and 2013 but was expressly created legislatively pursuant to SB 59 w/SA 2 which passed the 147th General Assembly and was enacted August 6, 2013. The CSAC falls under Subchapter III, Chapter 47, Title 16 of the Delaware Code: "Regulation of Manufacture, Distribution and Dispensing of Controlled Substances." Specifically, 24 Del. C. §4731(b) provides that: "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."

During the first years of the Committee meeting, discussions included issues such as scheduling bath salts, drug diversion, tamper resistant prescription requirements, drug disposal activities and statutory or regulation amendments specific to security, diversion, and practitioner dispensing. Below are some key changes that were implemented since the inception of the Committee:

1. The regulation and discipline of practitioners who failed to comply with procedures and guidelines pertaining to prescribing of controlled substances and who posed a threat to public safety and welfare.

2. The creation of regulation changes to identify a patient both when presenting and picking up controlled substance prescriptions to assist in an increase with diversion or fraud and unauthorized individuals picking up medications, law enforcement identification, and ultimate prosecution. In addition, changes were added to include requirements for security camera systems in pharmacy drive-thru for drop off and pick up of prescriptions with clear images of faces and license plates.

3. In June 2010, the electronic transmission of controlled substance prescriptions was approved. Electronic prescribing was a method in which practitioners could accurately transmit prescriptions, including controlled substances, in a more efficient and safe manner. January 1, 2021, an act went into effect requiring podiatrists, dentists, doctors, nurses, and optometrists who issue prescriptions to utilize e-prescribing except under certain circumstances.

4. An official launch of the prescription monitoring program (PMP) took place on August 21, 2012. The purpose of the PMP is to reduce misuse of controlled substances in Delaware and to promote improved professional practice and patient care. SB 59 of the 147th

General Assembly added new requirements to Title 16, Chapter 47 that all prescribers and Delaware pharmacies holding a controlled substance registration (CSR) be registered with the PMP by January 1, 2014, in addition to fixing several other issues with statutory language.

5. The addition of Regulation 9.0 Safe Prescribing of Opioid Analgesics to the Uniform Controlled Substance Act in January 2017. Regulation 9.1 Preamble states, “This Section provides requirements for the prescribing of opioid analgesics in order to address potential prescription drug overdose, abuse, and diversion and encourage the proper and ethical treatment of pain. Pursuant to the requirements of this Section, the practitioner can meet the goal of addressing drug overdose, abuse and diversion while ensuring patient access to safe and effective pain care.”

6. The introduction of language in 2013 to prohibit non-pharmacy practitioners from dispensing controlled substances beyond a 72-hour emergency supply and requiring practitioners who dispense the permitted quantity to enter the data into the prescription monitoring program.

7. The introduction of tamper resistant prescription pads and implemented in 2012 which would prevent unauthorized copying, erasure or modification, and counterfeit prescription forms. This program was implemented to assist with theft of prescription blanks and the increase in forged or modified prescriptions. All practitioners receive a security code as authorization to order approved tamper resistant prescription pads. A list of approved prescription pad vendors is available on the Division’s website.

8. The Committee reviewed and provided recommendations to the Secretary of State regarding multiple drugs over time for consideration in scheduling these drugs as controlled substances. These substances have a high potential for abuse and were scheduled as controlled substances through the emergency regulation process, and eventually incorporated into the law. Substances that were discussed included bath salts in 2011, extended-release hydrocodone, Zohydro, in 2014, “Pinky” or synthetic opioid U-47700 in 2016, and xylazine in 2023.

Section 1-B. What are the main functions of this entity? Does this entity issue any advisory or policy opinions? If so, where can they be found?

Per Regulation 1.1 “The Controlled Substance Advisory Committee (hereafter designated as "the Committee") has a primary objective to promote, preserve and protect the public health, safety and welfare by regulating and monitoring controlled substance use and abuse through a program of registration, inspection, investigation and education. The Committee regulates by registering prescribers, dispensers, manufactures, distributors, clinics, researchers and other controlled substance registrants (i.e. – dog handler). Among its functions, the Committee issues and renews licenses; and makes recommendations to the Secretary of State of new or amended controlled substance regulations and disciplinary actions of registrants who violate the law. (16 Del. C. §4700 to the end)”

The Committee makes recommendations to the Secretary of State regarding licensure and regulation of practitioners and facilities who prescribe, store, and/or dispense controlled

substances in Delaware. The Committee also promulgates regulations to be incorporated in the Uniform Controlled Substance Act Regulations.

The Committee does not issue any advisory or policy opinions.

Section 1-C. What condition(s), situation(s), and/or problem(s) existed prior to the creation of this entity that directly led to its creation? Please provide specific examples.

The CDC reports that "from 1999–2020, more than 564,000 people died from an overdose involving any opioid, including prescription and illicit opioids" The increase in opioid overdose deaths appeared in three waves: in the 1990's there was increased prescribing of prescription opioids, in 2010 there was a rise in overdose deaths involving heroin, and in 2013 there was a significant increase if overdose deaths involving synthetic opioids, specifically those involving illicitly manufactured fentanyl.

The overprescribing of controlled substances by all practitioners, not just pain management practitioners, lead to the increase of opioid dependence and drug addiction across the nation. The need for an entity to create regulations around controlled substances dispensing, prescribing, and distributing, the ability to monitor prescribing practices, and the potential to discipline licensees when practicing unlawfully and willingly while endangering public safety was very necessary.

Section 1-D. To what extent has the existence and functioning of this entity alleviated each of these condition(s), situation(s), and/or problem(s) described in question "1-C" above? Please provide specific examples.

Regulations have been updated by the Committee concerning safeguards around prescribing opioids as mentioned in Section 1-A (#5). In addition, the Committee also can make recommendations to the Secretary of State to update regulations on an emergency basis in scheduling substances that present a risk to the public safety, such as mentioned in Section 1-A (#8).

The Committee reviews hearing officer recommendations or consent agreements that are the result of certain practitioners violating the Uniform Controlled Substance Act and/or regulations. Upon reviewing these recommendations, the Committee then makes final recommendations to the Secretary of State to enforce disciplinary, monetary, or educational sanctions on these healthcare licensees. Discipline could include:

- probation, suspension, or revocation of their CSR license
- letters of reprimand that remain on the practitioner's license file
- monetary penalties not to exceed $1,000 per violation
- required continuing education completion relating to the practitioner's violation such as ethical courses, prescribing of opioids, or charting processes

The Committee also has the ability to monitor licensees who have regained their CSR privileges, such as providing random quarterly patient chart audits performed by other practitioners, to ensure the licensee stays in compliance. A specific example of this type of monitoring discipline would be, "During the period of probation, Dr. ___ shall arrange, at his own expense, for his charting to be audited at random on at least a quarterly basis by someone approved by the Committee, who shall file quarterly monitoring reports with the Director of the Office of Controlled Substances. At least three charts shall be audited during each quarterly audit, and the quarterly

reports must summarize Dr.___'s charting practices." This sanction was a result of the practitioner treating patients and failing to meet basic requirements designed to ensure appropriate patient care while guarding against abuse and diversion of controlled substances.

Section 1-E. Would the condition(s), situation(s), and/or problem(s) described in question "1-C" above recur or worsen, in the absence of the entity?

Yes, overprescribing of controlled substances may recur or worsen without the work of the CSAC. The Committee and Secretary of State specifically regulate controlled substance prescribing, dispensing, and distributing, which may involve a distinct level of discipline beyond the discipline imposed on underlying professional license.

Section 1-F. Are there any recent condition(s), situation(s), and/or problem(s) that further justify the need for the entity's existence?

There are ongoing complaints against practitioners across the various healthcare professions who are in violation of laws and regulations in relation to their prescribing, dispensing, or distribution practices of controlled substances which may pose a risk to public safety. Below are specific examples of practitioners or pharmacies who engaged in inappropriate conduct that resulted in disciplinary actions over the past few years:

1. A practitioner "repeatedly prescribed controlled substances to patients without obtaining informed consent for treatment with controlled substances or discussing the risks and benefits of the use of such controlled substances; without either utilizing or enforcing treatment agreements; without conducting meaningful initial evaluations or examinations; without attempting to obtain prior treatment records; without adjusting drug therapies to meet the individual patient needs; without referring these patients for any diagnostic imaging; and without responding to red flags for medication abuse or diversion; failing to keep accurate, complete, and accessible patient records that included: medical histories; physical examinations; diagnostic, therapeutic, and laboratory results; treatment objectives; discussion of risks and benefits; informed consents; the medications presc1ibed including the date, type, dose, and quantity prescribed; patient agreements or contracts; and periodic reviews with interim histories, physical examinations, assessments of progress, and medication plans."

2. A pharmacy "failed to maintain effective controls against diversion of controlled substances into other than legitimate medical, scientific or industrial channels." As this pharmacy's "lax approach to storage, control and dispensing of controlled substances in conjunction with the failure to complete required inventories led to the conclusion that the continued operation of the pharmacy is inconsistent with the public interest."

3. A practitioner exploited a patient with a history of substance abuse who was on long-term treatment for drug addiction by making an assessment that the patient was opioid-dependent without a diagnosis or physical findings. The practitioner then dispensed various controlled substance to this patient in exchange for sexual favors, and the patient feared that refusing the practitioner's advances and requests or demands for sexual favors would lead to termination of their relationship and access to controlled substances. The patient also showed positive urine drug screenings for prescribed medication in addition to other controlled substances that were not prescribed. Prescribing to this patient continued, which reenforced the patient's drug addiction with no consideration to her safety or wellbeing.

4. A practitioner overprescribed controlled substances to patients without proper medical examination, maintaining proper records, and establishing an underlying medical need for medication. Even though the practitioner lacked training, education, and knowledge to manage chronic pain patients they did not refer the patients to an appropriate pain management practitioner. In addition, this practitioner knew "the patients for whom he prescribes controlled substances were addicts, criminals, and/or street drug dealers who sell the drugs he prescribes." This licensee was suspended from practice but "continued his pain management practice under a suspended CSR; misled nurse practitioners into prescribing controlled substances without meeting face to face with patients; and failed to supervise the medical practice he was supposed to be managing;" in addition to prescribing controlled substances for himself. This practitioner's failure to comply with procedures and guidelines pertaining to prescribing of controlled substances posed a threat to public safety and welfare. This practitioner was eventually sentenced to 20 years in prison in 2022, for his conviction by a federal jury in July 2021 for 13 counts of unlawful drug distribution and maintaining a drug-involved premises.

The Committee consistently reviews changes in controlled substance Federal Law and amends State laws or regulations accordingly to mirror or reiterate Federal language, if appropriate. An example of this would be updates to state regulation language in March 2022, which defined the expiration and partial filling of controlled substance prescriptions to mirror the Comprehensive Addition and Recovery (CARA) Act of 2016. Most recently, the DEA established a registration category for emergency medical services (EMS) and the Committee will need to amend the statute or regulations, particularly considering recent concerns with handling and possible diversion of controlled substances by county EMS.

There are also occasional issues involving substances being used as or added to illicit drugs that require discussion and consideration by the Committee to suggest scheduling these substances as controlled substances to the Secretary of State, such as xylazine, which is discussed in Section 13-A.

Section 1-G. Are there any functions of this entity that are outdated and no longer needed? If so, please explain and provide examples.

All functions of this Committee are still within date and needed.

SECTION 2: MISSION, GOALS, OBJECTIVES, & AUTHORITY

Section 2-A. What is the mission of this entity? Does the enabling legislation accurately reflect the mission?

The mission of the CSAC is to promote, preserve and protect public health, safety, and welfare by regulating and monitoring use and abuse of controlled substances.

Yes, the Committee meets this objective by as stated below in Title 24, Committee Rule 1.1:
"The Controlled Substance Advisory Committee (hereafter designated as "the Committee") has a primary objective to promote, preserve and protect the public health, safety, and welfare by regulating and monitoring controlled substance use and abuse through a program of registration, inspection, investigation, and education. The Committee regulates by registering prescribers, dispensers, manufactures, distributors, clinics, researchers, and other controlled substance

registrants (i.e. – dog handler). Among its functions, the Committee issues and renews licenses; and makes recommendations to the Secretary of State of new or amended controlled substance regulations and disciplinary actions of registrants who violate the law. (16 Del. C. §4700 to the end)"

The mission of the Division of Professional Regulation (Division) is to ensure protection of the public's health, safety, and welfare. Our services benefit the citizens of Delaware, professional licensees, license applicants, other state and national agencies, and private organizations.

Section 2-B. Please identify and explain the entity's goals and objectives, in order of priority.

The primary objective of the Committee, to which all other objectives and purposes are secondary, is to promote public health, safety, and welfare, and to protect the general public from unprofessional, improper, unauthorized, or unqualified practice with controlled substances across all healthcare professions.

The secondary objective of the Committee is to license and regulate practitioners and facilities that prescribe, store, or dispense controlled substances based on the minimum criteria for licensure.

In meeting its objectives, the Committee shall address the ongoing opioid epidemic in Delaware; shall develop standards assuring professional competence when prescribing and dispensing controlled substances; shall monitor complaints brought against practitioners or facilities regulated by the Committee; shall adjudicate at formal hearings resulting in appropriate recommendations to the Secretary of State; shall promulgate rules and regulations; and shall impose sanctions where necessary against practitioners or facilities.

Section 2-C. Please describe the internal performance evaluation system that the entity uses to measure the attainment of its goals and objectives.

The Committee does not have an internal process to evaluate its performance.

The Division conducts formal and informal performance reviews of staff that provide staff support to the Committee. In addition, the Division develops performance measures through the strategic planning process to evaluate and monitor the progress and performance of its services to the boards and commissions. The Division conducts surveys for new licensees, licensees during renewal, licensees involved in the complaint process and new board members who complete board member orientation. The results are reviewed by the Division's senior leadership team to identify opportunities to improve processes and performance.

Section 2-D. Does the entity collect any data sets? If so, please identify and explain.

No data sets are collected by the Committee.

Section 2-E. Does the entity conduct any research? If so, please explain and provide the location of research reports (if produced).

No, the Committee does not conduct any research.

Section 2-F. Has the State Auditor or any other external organization recently audited or evaluated the entity or any of its programs? Please identify some of the major conclusions and/or recommendations. Provide links to all reports.

The Committee has never been audited by the State Auditor or another external organization.

Section 2-G. In general, how do other states carry out similar functions?

In Delaware a practitioner must have both a State and Federal CSR to prescribe, store, dispense, or distribute controlled substances in and to Delaware patients. The Committee licenses and regulates these licensees. There are currently 25 states or territories that require both a State and Federal registration to practice with controlled substances. The surrounding jurisdictions that require both registrations include Maryland, New Jersey, and Washington DC. The other 28 jurisdictions require only a federal DEA registration, which includes neighboring states Pennsylvania and Virginia, but still possess controlled substance laws and regulations.

The **State of Maryland** Office of Controlled Substances Administration (OCSA) is under the Department of Health. They are similar in that each practitioner must hold both a State and Federal CSR, must be registered with the Prescription Drug Monitoring Program (PDMP), demonstrate proof of professional licensure in good standing, and produce any disciplinary action or supporting documentation, if appropriate, for licensure consideration. Per their website "The OCSA enforces the Controlled Dangerous Substance (CDS) Act and ensures the availability of drugs for legitimate medical and scientific purposes. OCSA also issues CDS permits to practitioners, researchers, and establishments that administer, prescribe, dispense, distribute, manufacture, conduct research and conduct chemical analysis of CDS." https://health.maryland.gov/ocsa/Pages/home.ASPX

The **State of New Jersey's** Drug Control Unit is within the Department of Law and Public Safety, "for the purpose of assisting in the enforcement of those provisions of the New Jersey Controlled Dangerous Substances (CDS) Act which relate to persons who, or firms that, manufacture, prescribe, distribute, dispense or conduct research or analysis utilizing controlled substances. *The purpose of the Unit is to:* register practitioners, pharmacies and non-professional licensees that prescribe, administer, manufacture, distribute, dispense or conduct research or analysis utilizing controlled substances; authorize the destruction of expired controlled substances (practitioner office use); and review the New Jersey Prescription Blank (NJPB) Incident Reports filed by practitioners and healthcare facilities. *The Unit protects the public by:* requiring that all CDS registrants renew their registration annually; investigating and prosecuting any CDS registrant who has violated the Controlled Dangerous Substances Act and its accompanying rules; and reviewing reports by pharmacies of stolen or lost controlled substances." https://www.njconsumeraffairs.gov/dcu/Pages/default.aspx

Washington DC's controlled substance drug registration is through the Health Regulation and Licensing Administration (HRLA) and The Pharmacy & Pharmaceutical Control Division (PPCD). "The PPCD licenses and regulates pharmacies, pharmaceutical manufacturers, pharmaceutical distributors, and suppliers. They also administer the District's controlled substances registration program, which registers health professionals, pharmacies, and health facilities that receive, dispense, and prescribe controlled substances in the District of Columbia. Facilities regulated include institutional and retail pharmacies, pharmaceutical manufacturers, distributors, and suppliers." https://dchealth.dc.gov/node/185862

The **Commonwealth of Pennsylvania** regulated controlled substances through their Department of Health and their Drugs, Devices, and Cosmetics Program, but they do not require a State CSR, only a federal DEA registration.
https://www.health.pa.gov/topics/disease/Opioids/Pages/Prescribers-Providers.aspx
https://www.health.pa.gov/topics/programs/Pages/Drugs-Devices-and-Cosmetics.aspx

Section 2-H. Are the entity's functions similar or overlapping of other state or federal entities? If so, discuss how the entity coordinates its services with other state or federal bodies sharing similar objectives. Please explain why the functions are best placed within this entity or why they should be placed elsewhere.

The Committee is inclusive and overlaps with other Division professional boards who are comprised of healthcare professionals that prescribe or dispense controlled substances, which are represented by the members appointed to the Committee. This includes the following professional boards: Board of Medical Licensure and Discipline, Board of Nursing, Board of Pharmacy, Board of Veterinary Medicine, Board of Podiatry, Board of Dentistry and Dental Hygiene, and Board of Examiners in Optometry.

Organizing the Committee as a separate entity outside of other professional boards, to issue and regulate licensees, promulgate rules and regulations, and to make recommendations to the Secretary of State is imperative as this spans across multiple healthcare professions and there is a need for continuity across all these professions. This Committee also provides a centralized entity to discuss the use of controlled substances in a variety of healthcare settings to create an overall climate of the controlled substance situation in the State.

The Committee also overlaps with the Federal Drug Enforcement Agency (DEA), in that both the State and Federal entities issue and regulate CSRs, and a licensee must have both registrations to prescribe, store, dispense, or distribute controlled substances in and to Delaware patients. There are currently 25 states or territories that require both a State and Federal CSR to practice with controlled substances. The surrounding jurisdictions that require both registrations include Maryland, New Jersey, and Washington DC. The other 28 jurisdictions require only a federal DEA registration.

SECTION 3: ACCOMPLISHMENTS

Section 3-A. List and briefly explain the entity's most significant accomplishments.

1. The regulation and discipline of practitioners who failed to comply with procedures and guidelines pertaining to prescribing of controlled substances and who posed a threat to public safety and welfare. Specifically, practitioners such as Dr. Patrick Titus who is now serving a 20-year sentence in prison based on his actions and conviction by a federal jury in July 2021 for 13 counts of unlawful drug distribution and maintaining a drug-involved premises.

2. The creation of regulation changes to identify a patient both when presenting and picking up controlled substance prescriptions to assist in an increase with diversion or fraud and unauthorized individuals picking up medications, law enforcement identification, and ultimate prosecution. In addition, changes were added to include requirements for security

camera systems in pharmacy drive-thru for drop off and pick up of prescriptions with clear images of faces and license plates.

3. In June 2010, the electronic transmission of controlled substance prescriptions was approved. Electronic prescribing was a method in which practitioners could accurately transmit prescriptions, including controlled substances, in a more efficient and safe manner. January 1, 2021, an act went into effect requiring podiatrists, dentists, doctors, nurses, and optometrists who issue prescriptions to utilize e-prescribing except under certain circumstances.

4. The addition of Regulation 18.0 "Use of Controlled Substances for the Treatment of Pain: Purpose" into the Board of Medical Licensure and Discipline regulations within Title 24 in February 2012.

5. An official launch of the prescription monitoring program (PMP) took place on August 21, 2012. The purpose of the PMP is to reduce misuse of controlled substances in Delaware and to promote improved professional practice and patient care. SB 59, 147th General Assembly added new requirement to Chapter 47, Title 16 that all prescribers holding a CSR be registered with the PMP by January 1, 2014. All Delaware pharmacies holding a CSR must be registered with the PMP by January 1, 2014, in addition to fixing several other issues with statutory language.

6. The addition of Regulation 9.0 Safe Prescribing of Opioid Analgesics to the Uniform Controlled Substance Act in January 2017. Regulation 9.1 Preamble states, "This Section provides requirements for the prescribing of opioid analgesics in order to address potential prescription drug overdose, abuse, and diversion and encourage the proper and ethical treatment of pain. Pursuant to the requirements of this Section, the practitioner can meet the goal of addressing drug overdose, abuse and diversion while ensuring patient access to safe and effective pain care."

7. The introduction of language in 2013 to prohibit non-pharmacy practitioners from dispensing controlled substances beyond a 72-hour emergency supply and requiring practitioners who dispense the permitted quantity to enter the data into the prescription monitoring program.

8. The introduction of tamper resistant prescription pads and implemented in 2012 which would prevent unauthorized copying, erasure or modification, and counterfeit prescription forms. This program was implemented to assist with theft of prescription blanks and the increase in forged or modified prescriptions. All practitioners receive a security code as authorization to order approved tamper resistant prescription pads. A list of approved prescription pad vendors is available on the Division's website.

9. The Committee reviewed and provided recommendations to the Secretary of State regarding multiple drugs over time for consideration in scheduling these drugs as controlled substances. These substances have a high potential for abuse as controlled substances, were scheduled as emergency regulations, and eventually incorporated into the law. Substances that were discussed included bath salts in 2011, extended-release hydrocodone, Zohydro, in 2014, "Pinky" or synthetic opioid U-47700 in 2016, and xylazine in 2023.

SECTION 4: CHALLENGES

Section 4-A. List and briefly explain 3 to 4 challenges the entity is currently facing.

- The Committee has had significant difficulty in filling vacant member positions as these positions are voluntary and considered upon referral by the respective professional boards. The dental representative and public representative have been especially hard to fill over the past few years. In addition, the turnover rate for members is very low because these dedicated members continue to serve without official appointments by the Secretary of State's Office.

- Ensuring that the veterinarians are properly licensed if storing, prescribing, dispensing, or distributing controlled substances at their place of business. There has been confusion in the past about who is required to have a CSR license in a veterinarian clinic and if the clinic itself needs to be licensed if they are storing, dispensing, administering, or distributing. Clarifying language needs to be developed to ensure all entities are properly licensed, if appropriate.

- Recently there has been a lower volume of complaints received that would possibly lead to disciplinary orders reviewed by the Committee, which may be a temporary after effect of the COVID-19 pandemic. However, this might also mean that the practitioner prescribing habits are improving because of tools put in place such as the prescription monitoring program, academic detailing by Division of Public Health, and the overall practitioner awareness and caution of prescribing controlled substances in the appropriate situation upon thorough evaluation of a patient.

- The CSR license continuing education (CE) requirements, 2 hours per renewal cycle, can be difficult to discern for licensees from the mandatory training course that is required upon initial licensure. This mandatory course can only be used once as part of the licensees first renewal period CE requirements, as it only counts for 1 hour of credit. Licensees commonly try to complete the mandatory course again and report as part of their renewal CE requirements, which is not accurate as new courses need to be completed for each renewal.

SECTION 5: OPPORTUNITIES FOR IMPROVEMENT

Section 5-A. List and briefly explain several opportunities for improvement. Please prioritize.

- The Committee would like the opportunity to update language in the Uniform Controlled Substance Act to become more cohesive with Title 24 professional Boards. In addition, there has been discussion about the possibility of converting this Committee to a Board, which may be beneficial in several ways for members, licensees, and the public.

- Since the COVID-19 pandemic certain barriers to patient access and prescribing of medication have been identified and improved through the increase in telehealth services. HB-334 from the 151st General Assembly, was signed on October 21, 2022,

which “permits health-care providers who are licensed in a state other than Delaware to deliver health-care services by telehealth and telemedicine only if a health-care provider-patient relationship has been established in accordance with § 6003 of Title 24.” Language updates are needed in the UCSA to include “telehealth registration” and “privilege to practice.” This would allow practitioners with telehealth registrations to obtain CSR licensure and prescribe controlled substances to Delaware patients after the DEA extension of COVID-19 PHE full set of telemedicine flexibilities for prescribing controlled substance medications ends November 11, 2023.

- The Committee has recently been notified of an increase in drug diversion by emergency medical service (EMS) providers and that there might be a need to license and regulate these healthcare professionals with CSRs, who handle controlled substances regularly.

- Updates are needed for the mandatory ONE-hour, two-part course pertaining to safe prescribing and distributing of controlled substances, treatment of pain, and recognizing and treating opioid use disorder, that must be completed for CSR licensure. This course was last updated in 2019 and some of the information is now outdated. There has also been a request to add pediatric prescribing and information into the training as well by the Division of Public Health.

    - Per UCSA Regulation 3.1.2 All practitioners who obtain new registration under Title 16, Chapter 47 after July 1, 2013, must attest to completion of a one-hour education course on Delaware law, regulation and programs, acceptable to the Secretary, pertaining to the prescribing and distribution of controlled substances within the first year of obtaining registration in order to qualify for continued registration.

Section 5-B. In the past 5 years, has the entity recommended any changes to the Legislature, Governor’s Office, or agency to improve the entity’s operations? If so, please explain and provide the outcome or status.

No recommendations have been provided to improve the Committee’s operations.

SECTION 6: COMPOSITION & STAFFING

Membership:
Section 6-A. How is entity membership defined? Please explain and provide the section(s). Examples include statute, regulations, or by-laws.

Per Title 24, Committee Rule 1.2 “The Committee shall consist of 9 members: one physician, one dentist, one podiatrist, one veterinarian, one nurse practitioner, two pharmacists, one physician assistant and one public member. The Secretary of State will be provided recommendations for appointments to the Committee from the associated licensing Boards. Members shall have engaged in the prescribing, dispensing, or storing of controlled substances for at least 5 years except for the public member. All Committee members will be appointed by the Secretary of State or their designee.”

Section 6-B. Are there special qualifications for membership?

Per Title 24, Committee Rule 1.2 “Committee members shall have engaged in the prescribing, dispensing, or storing of controlled substances for at least 5 years except for the public member.” The Committee member must also have an active and in good standing professional license in the State of Delaware pertaining to their specific representative role.

Section 6-C. Who has member appointment authority? Where is this defined?

Per Title 24, Committee Rule 1.2 the Secretary of State or their designee has the authority to appoint professional members to the Committee that have been recommended by their associated professional Boards.

Section 6-D. What is the designated term of office for entity members? Where is this defined?

Per Title 24, Committee Rule 1.3 “A member of the Committee may not serve more than 3 full, consecutive 3-year terms, which is not diminished by serving an unexpired term. Upon serving 3 full, consecutive 3-year terms, a former member is eligible for reappointment to the Committee no earlier than 1 year after the expiration of the last term served on the Committee by the former member.”

Section 6-E. How many members currently serve on this entity? Are there any vacancies? If so, indicate the length of time each vacancy has existed and the reason(s) why. Has the entity or support staff advised the Governor’s Office or appointing authority of the vacancies?

There are currently seven members serving on the Committee with vacancies in the dental representative and public representative positions. The dental representative position has been vacant since January 2022 because this representative was unable to attend the meetings as scheduled. Outreach was attempted by the Division Director and Director of Office of Controlled Substances (OCS) multiple times requesting the Board of Dentistry to recommend another representative. In addition, the Division reached out to dentists of interest recommended by Committee members to no avail.

The public representative position has been vacant since April 13, 2023, as the public member passed away unexpectedly. This specific public member was appointed on June 27, 2022, with the position being vacant from November 2018 to June 2022. The public position has been difficult to fill because of its voluntary nature, and Committee appointment is through recommendations to the Secretary of State, as opposed to the Governor’s Office application process.

The Secretary of State’s office was notified of both vacancies at the time of availability, and their office requested that Division provide any presented recommendations for consideration.

Section 6-F. Can this entity create subcommittees or task forces? If "yes" please address the following questions:

1. **Describe the process and cite the entity document (statute, regulations, or by-laws) that permit this.**

   The statute and regulations do not address the formation of subcommittees; however, the Committee formed the Regulatory Subcommittee and Legislative Subcommittee, with all meetings conducted publicly and meeting minutes were produced and made available to the public.

2. **Provide a brief history on how many have been created in the past 5 years and indicate where meeting documents can be found.**

   In the past five years, since 2018, there have been no new subcommittees formed or meetings conducted. The legislative and regulatory subcommittee report items remained on the agendas with no new information discussed for those items. These subcommittees were created in previous years to address and improve the current regulatory language at that time and to create more inclusive regulation of controlled substances and prescribing in response to the ongoing opioid crisis.

3. **Were meetings open and noticed to the public? If so, indicate where notices were published.**

   Yes, they were open and noticed to the public through the Delaware Public Meeting Calendar at least 7 days before the meeting.
   https://publicmeetings.delaware.gov/#/

4. **If final reports were issued, please provide their location.**

   All meeting minutes were provided for public view through the Delaware Public Meeting Calendar attached to the specific meeting date.
   https://publicmeetings.delaware.gov/#/

5. **If there are current subcommittees or task forces currently meeting and conducting business; include information on membership, duties, and where meeting notices and documents can be found.**

   There are no subcommittees or task forces currently meeting.

Section 6-G. Include a current membership roster with this Self-Report. This is a separate request from the list of supporting documents included in the Self-Report instructions. This current membership roster must indicate the following for each member:

- **First and last name, and their city and state of residence.**
- **Position held (i.e., Chair, President, Co-Chair, Secretary, etc.).**
- **Professional or public member.**
- **Their profession or occupation.**
- **Original appointment date, expiration date, and number of terms served.**

To satisfy this current membership roster request, please complete one of the following:

- **Complete the included table below.**
- **Delete the included table below, build a new table, and place in this section.**
- **Delete the included table below and attach a document to the Self-Report and label in the appendices section.**

Title 24, Committee Rule 1.3 A member of the Committee may not serve more than 3 full, consecutive 3-year terms, which is not diminished by serving an unexpired term. Upon serving 3 full, consecutive 3-year terms, a former member is eligible for reappointment to the Committee no earlier than 1 year after the expiration of the last term served on the Committee by the former member. A Committee member whose appointment has expired remains eligible to participate in Committee proceedings until replaced.

Member's Name and City and State of residence.	Position Held	Professional or Public Member	Profession or Occupation	Original Appointment Date	Appointment Expiration Date	Number of Terms Served
Linda Ciavarelli, DPM *Wilmington, DE*	Chair	professional	Podiatrist	April 19, 2018	April 19, 2021, Reappointment Pending	1
Joseph M. Parise, DO *Dover, DE*	Vice-Chair	professional	Doctor	December 18, 2017	December 21, 2021 Reappointment Pending	1
Herb E. Von Goerres, RPh *Lewes, DE*		professional	Pharmacist	August 2013	Carry-over; no reappointment	3
Cheri R. Briggs, Pharm D *Newark, DE*		professional	Pharmacist	October 13, 2020	October 13, 2023	1
Jo Ann Baker, DNP, RN, FNP-C *Camden-Wyoming, DE*		professional	Nurse Practitioner	August 2013	Carry-over; no reappointment	3
Kirsten Opalach, PA-C *Dover, DE*		professional	Physician Assistant	February 14, 2018	February 1, 2021 Reappointment Pending	1
Erin G. Whaley, DVM *Lewes, DE*		professional	Veterinarian	November 18, 2022	November 18, 2025	1
Dental Representative- **VACANT**		professional				
Public Representative- **VACANT**		public				

Meeting Frequency:

Section 6-H. How frequent are meetings held? Is meeting frequency defined anywhere such as the statute or by-laws? If so, provide document name and section information.

Historically meetings were scheduled every other month and 5 to 6 meetings were conducted a year; however, at the Committee's meeting on May 25, 2022, they decided to decrease meeting frequency to quarterly. Since that decision the Committee has conducted 3 meetings year to date, with one meeting scheduled as an ad hoc meeting to discuss a practitioner's ability to satisfy a disciplinary order.

Per Title 24, Committee Rule 1.4 "The Committee shall hold regularly scheduled meetings at least four times a calendar year and at other times the Committee considers necessary at the request of a majority of the members. A president and vice-president shall be elected by the members annually. Each officer shall serve for 1 year and shall not succeed himself or herself for more than 2 consecutive terms."

Section 6-I. Can the entity hold special or emergency meetings? If so, describe the protocol involved in requesting and holding a special or emergency meeting.

Yes, the Committee can schedule and conduct a meeting at other times as deemed necessary per Title 24, Committee Rule 1.4. "The Committee shall hold regularly scheduled meetings at least four times a calendar year and at other times the Committee considers necessary at the request of a majority of the members…"

Various dates of availability would be provided to the Committee members and the date that the majority of the members could attend to meet a quorum would be scheduled on the Delaware Public Meeting Calendar at least 7 days before the meeting date.

The Committee may also conduct a meeting to review and consider drafted emergency regulations per Title 24, Committee Rule 10.3 Emergency Regulations. "If the Secretary of State, upon the recommendation of the Committee, finds that an imminent peril to the public health, safety or welfare requires adoption of a regulation upon fewer than twenty (20) days' notice and states in writing the reasons for that finding, the Secretary of State may proceed without prior notice or hearing or upon any abbreviated notice and hearing the Secretary finds practicable, to adopt an emergency regulation. Such rules will be effective for a period not longer than 120 days, but the adoption of an identical rule under the procedures discussed above is not precluded."

In addition to Title 29, Chapter 101. Administrative Procedures
"§ 10119. Emergency regulations.
If an agency determines that an imminent peril to the public health, safety or welfare requires the adoption, amendment or repeal of a regulation with less than the notice required by § 10115, the following rules shall apply:
(1) The agency may proceed to act without prior notice or hearing or upon any abbreviated notice and hearing that it finds practicable;
(2) The order adopting, amending or repealing a regulation shall state, in writing, the reasons for the agency's determination that such emergency action is necessary;
(3) The order effecting such action may be effective for a period of not longer than 120 days and may be renewed once for a period not exceeding 60 days;

(4) When such an order is issued without any of the public procedures otherwise required or authorized by this chapter, the agency shall state as part of the order that it will receive, consider and respond to petitions by any interested person for the reconsideration or revision thereof; and (5) The agency shall submit a copy of the emergency order to the Registrar for publication in the next issue of the Register of Regulations."

Various dates of availability would be provided to the Committee members and the date that a majority of the members could attend to meet quorum would be posted on the Delaware Public Meeting Calendar as soon as a meeting date was agreed upon. This emergency meeting does not require a 7-day prior to meeting posting on the Delaware Public Meeting calendar but does need to include specific language to inform the public of the emergency meeting purpose and that there is an imminent peril to the public health, safety or welfare

Meeting Order and Quorum:
Section 6-J. For meeting order, does the entity follow Mason's Manual of Legislative Procedure or Roberts' Rules of Order? Is this defined in statute, regulation, or by-laws?

No, the Committee does not follow these procedures while conducting meetings. Meeting order is not expressly incorporated, but generally follow Roberts Rules of Order.

Section 6-K. How is meeting quorum defined and where is the definition located?

The Committee is to consist of 9 members with the presence of 5 members constituting a quorum or majority. Per Title 24, Committee Rule 1.7 "A majority of the members shall constitute a quorum for the purpose of transacting business and no action shall be taken without the affirmative vote of a majority of the quorum. No disciplinary action may be recommended to the Secretary without the affirmative vote of a majority of the members of the Committee."

Member Removal:
Section 6-L. Is there a mechanism for member removal? If so, how are members removed and who has the authority to remove a member? Using the process described, has there ever been an instance of member removal, and if so, briefly describe the nature of events that led to the member removal.

The Secretary of State has the ability to remove a Committee member based on lack of meeting attendance as noted in Title 24, Committee Rule 1.8 "Any member who fails to attend 3 consecutive meetings, or who fails to attend at least half of all regular business meetings during any calendar year, shall automatically upon such occurrence be deemed to have resigned from office and a replacement shall be appointed by the Secretary of State."

This rule does not provide the ability to remove a member based on malfeasance or other misconduct and language should be added as a regulatory change to be consistent with other profession Boards. An example of this language is provided from Title 24, Chapter 25 § 2503. Board of Pharmacy "(f) The Governor shall suspend or remove a member of the Board for the member's misfeasance, nonfeasance, malfeasance, misconduct, incompetency, or neglect of duty. A member subject to a disciplinary hearing must be disqualified from Board business until the charge is adjudicated or the matter is otherwise concluded. A Board member may appeal to the Superior Court a suspension or removal initiated pursuant to this subsection."

The Division's Director's Office communicates with the Secretary of State concerning any vacancies for this Committee as well as communicating with the appropriate professional Boards that would recommend a practitioner to fill a vacant position. In addition, Committee members receive attendance letters from the Division Director's Office when attendance is a concern. Members are appointed by the Secretary of State, or their designee, and the appointment and replacement process is administered by the Division's Office of Controlled Substances.

Yes, Eric Spencer, a dental representative, was sent a letter on January 11, 2022, by past Division Director, Geoffrey Christ, stating "I am writing to emphasize the importance of your role as the Dental Representative on the Controlled Substance Advisory Committee. Your position is critical in serving and protecting the citizens of the State of Delaware. It has come to my attention that you have missed the last 5 meetings. If personal or professional obligations are preventing you from fulfilling your commitment, please submit a letter of resignation to my office. Please respond to our office by January 18, 2022, with your intent to continue serving, or a copy of your letter of resignation that you have mailed to the Division office." Dr. Spencer responded that he thoroughly enjoyed his time on the Committee, but his work schedule could no longer afford him time on Wednesday mornings to attend scheduled meetings. He requested an afternoon time slotted meeting; however, the Committee was unwilling to change the dates and times of their scheduled meetings.

Member Compensation:
Section 6-M. Are members compensated? If so, how are they compensated?

Members of the committee are not compensated for meeting attendance or travel expenses.

Member Training and Handling Conflicts of Interest:
Section 6-N. Are members offered any special training opportunities? Is training required or voluntary?

Pursuant to 29 Del. C. §8735, the Division of Professional Regulation shall provide at least once every fiscal year training to board/commission members appointed to the regulatory boards/commissions. The training shall outline the legal responsibilities of board/commission members to protect the health, safety and welfare of the general public. This training is a requirement upon appointment as a board/commission member.

In January of 2013, the Division purchased an annual subscription for Online Board Member training offered by the Council on Licensure Enforcement and Regulation (CLEAR) and have continued to renew this subscription each year. In addition to the CLEAR online training, the Division provides an orientation to newly appointed board/council members and provides them with a resource manuals and access to Simbli e-Boards for meeting agenda access and training.

Section 6-O. Has a Deputy Attorney General ("DAG") reviewed the provisions of the Public Integrity Act with entity members to ensure that they are in compliance with the provisions in the law? If so, what is the frequency of this review?

The Committee's DAG has not, but she will review this with the members at their next scheduled meeting in July 2023. The Division provides new committee members copies of Public Integrity laws during the board/committee member orientation. The Public Integrity Act should be expressly incorporated into the statute.

Section 6-P. Please explain how entity members avoid conflicts of interest.

The Committee's DAG advises committee members of potential conflicts. The Division provides new committee members copies of Public Integrity laws during the board member orientation.

Section 6-Q. Has the Public Integrity Commission ("PIC") provided training or clarification to members or issued any advisory opinions on entity activities? If so, please explain the details. Provide a link to the information or attach relevant information to this report.

No.

Support Staff:
Section 6-R. Is there dedicated support staff *directly* assisting the entity? If so, what state agency, office, or department supplies the support staff?

- **If this question is applicable answer all questions in this section.**
- **If not applicable, state that no support staff exists for question Section 6-R and explain how duties are divided among entity members, skip to questions Section 6-Y, Section 6-Z, and Section 6-AB below.**

Yes, the OCS through the Division.

Section 6-S. How many employees are employed by the state agency, office, or department supplying support staff? (skip if not applicable)

The Division employs 64 employees, including merit and contractual positions.

Section 6-T. Does the state agency, office, or department supplying support staff offer internships? If so, do interns provide support services to the entity? (skip if not applicable)

Internships are not offered by the Division or OCS.

Section 6-U. What is the size of the support staff *directly* assisting the entity? How many are merit, appointed, exempt, temporary, casual seasonal, or contract employees? For contract employees indicate who holds the employment contract. Highlight support staff responsibilities, indicate who performs each and the percent of staff time spent on each responsibility. (skip if not applicable)

The Division is organized by Service Teams who provide administrative support to a group of professions and trades. The Service Team responsible for the CSAC also supports ten other professional boards. There are four state employees (three merit employees and one exempt employee) and two contractual employees that provide credentialing, licensing, and board liaison services to all boards within the Service Team. The Director of this Service Team also supervises two other merit employees, a Pharmacist Administrator who has the responsibility of managing the Prescription Monitoring Program, and a Pharmacy Compliance Officer who completes all routine and opening facility inspections for the professions of pharmacy and controlled substances.

The contractual employer is Goodwill. There are currently two contractual administrative positions for this Service Team.

The Division has an investigative unit that handles complaints for all 35 professional boards and commissions. There are currently fourteen investigators, of which three are contractual investigators.

The Committee's direct support staff include the Director of OCS who credentials and issues all facility and individual CSR licenses. In addition, the Director serves as the board liaison for the Committee by answering controlled substance inquiries from practitioners, new applicants, and the public; regulating and monitoring disciplined licensees; creating agendas and drafting meeting minutes; and researching pertinent topics of discussion for the meetings. These responsibilities are allotted about 35% of the Director's time as this individual also holds the position of Executive Secretary of the Board of Pharmacy and assists with other professions in support of the Service Team. Her other responsibilities include but not limited to answering questions, credentialing applications, monitoring state and federal changes, confirming application alignment with statute and regulations, and managing the team's performance. Because of employee shortages the Teams Administrative Specialist III should have the responsibility of board liaison, but she is currently supporting 4 other profession boards, including cosmetology, massage, diet and nutrition, and chiropractors.

Both the Pharmacy Administrator (PMP Administrator) and the Pharmacy Compliance Officer are requested by the Committee to provide a report at each meeting to support discussion and awareness of what is occurring in the healthcare community regarding controlled substances.

Section 6-V. Who supervises the support staff *directly* assisting the entity? (skip if not applicable)

The Director of the OCS, who also serves as the Director of the Board of Pharmacy and one of the Division's Service Team, supervises the administrative specialist III who serves as the Committee's "Board Liaison." The Division's Director, currently there is an Acting Director, supervises the OCS Director.

Section 6-W. How is the support staff *directly* assisting the entity recruited and hired? Is there an orientation session for new hires? (skip if not applicable)

Staff is hired through the State of Delaware Merit System competitive hiring process, which is coordinated through the Department of State's Human Resources Office and the Office of Management and Budget, Human Resources Management Office.

Specifically, when a position becomes vacant, statewide recruitment is handled through the Office of Management and Budget who evaluates applicants to determine if minimum qualifications are met and prepares the referral lists of qualified persons for interview consideration by the Division of Professional Regulation. There are specific positions, such as administrative and accounting positions that require justification and prior approval by the Office of Management and Budget to fill. Both the Department of State Human Resources Office and the Division of Professional Regulation conducts an orientation and on the job training for new hires.

Contractual employees are hired through the State of Delaware temporary employment services contract. The Division conducts orientation and on the job training for contractual employees.

Section 6-X. What training opportunities are available to support staff *directly* assisting the entity? (skip if not applicable)

Training opportunities for staff are available through in-house training along with the Deputy Attorney Generals from the Department of Justice, and other programs offered by the Office of Management & Budget, Human Resources Management, national conferences and committees. Participation in the State's Supervisory Development and Career Enrichment Programs is another option. Out-of-state travel costs are closely monitored by management for all discretionary spending.

Section 6-Y. Is the effectiveness of the entity hindered by a lack of staff assistance or dedicated support staff? Please explain. What steps, if any, have been taken to address any staffing issues? (all entities under review answer this question)

The effectiveness of the Committee has not been directly affected by the lack of staff at the Division. Based on the current workforce climate the Division has about 10 positions to fill out of a total of 64 positions, with one open position on the Service Team that directly supports the Committee. Covering for these vacant positions does take additional time and effort for the remaining Service Team members, but this should be a temporary situation.

Historically staffing issues in the past have resulted in the steps below:

In 2011, the Division hired two new hearing officers and a paralegal as mandated by legislation to implement a hearing officer process to expedite the adjudication of complaints made against professionals.

In 2013, the Division's senior leadership team considered and approved a proposal from the administrative staff, after completing the LEAN Thinking initiative. The main goal was to significantly reduce the amount of time it takes to complete the credentialing and licensing processes.

In 2014, the Division's senior leadership team considered a similar proposal by the investigative staff, after they had completed the LEAN Thinking initiative. The main goal was to implement changes that would result in streamlining the intake and processing of investigations and reducing any backlog investigations, by realigning tasks and eliminating unnecessary processing steps to increase their effectiveness.

In June 2020, the Division implemented a new online licensing system and portal, through the software vendor Salesforce, called the Delaware Professional Regulation Online Services (DELPROS). The online licensing portal provides clear instructions to guide applicants and licensees through a simpler and more efficient application process, in addition to allowing these individuals to submit service or change requests through their individual portal. This licensing portal has eliminated many paper-based documents the Division is receiving and mailing, in addition to creating a more efficient, universal place for licenses, documentation, questions, and communications with applicants and licensees to be stored. The licensing system and portal continue to allow for electronic renewal processing.

Section 6-Z. Please identify, list, and briefly describe any executive orders, interagency agreements, management directives, administrative circulars, or like documents that directly impact the functioning of the entity. (all entities under review answer this question)

There are none currently.

Section 6-AB. Does the entity have legal counsel? If so, provide attorney's name and firm if not a state supplied DAG.

Yes, the Committee has a Deputy Attorney General and her name is Eileen Kelly.

SECTION 7: FREEDOM OF INFORMATION ACT ("FOIA") & OPEN MEETING LAW COMPLIANCE

Section 7-A. How does the entity respond to FOIA requests?

All FOIA requests are handled by the Deputy Director of the Division in coordination with the Division's Deputy Attorney General and the Department of State's FOIA Coordinator pursuant to 29 Del. Q. §10001. Senate Bill 231 w/SA 1 became effective August 1, 2012, regarding the handling of FOIA requests.

Section 7-B. When and where are the meeting notices and agendas posted?

Meeting agendas and notices are posted online through the State of Delaware Public Meeting Calendar. Meeting agendas are posted seven (7) days prior to the meeting date in accordance with the Administrative Procedures Act. Meeting agendas may be amended within 24 hours of the meeting date.

Section 7-C. Are meeting minutes regularly transcribed? When and where can the public obtain copies of meeting minutes?

Meeting minutes are drafted for each Committee meeting and are maintained electronically in the Committee office. Minutes are prepared for approval by the Committee at their next regularly scheduled meeting. Final approved minutes are posted to the Delaware Public Meeting Calendar within five (5) business days after the meeting in accordance with the Freedom of Information Act. The public may download copies of the approved meeting minutes online or request a hard copy by contacting the Division. Senate Bill 320 w/HA 1 and SA 1 became effective June 26, 2014, which requires minutes to be available for those boards that meet four or less times per year to be electronically posted and marked as draft minutes within 20 business days after the conclusion of each meeting. The CSAC meets at least 4 times a year or at the request of a majority of the members.

Section 7-D. Are meetings recorded? If so, indicate whether it's an audio or video recording and is the recording posted online for the public? If the recordings are not posted online, are instructions provided to the public on how to request recordings?

Meetings are recorded via conference room recording equipment or Microsoft Teams when public hearings are conducted to allow for the production of transcripts when needed. These meetings

are recorded in an audio and/or video format depending on the type of recorder used. Currently the Committee meets in a hybrid manner with members joining both in-person and virtually through Microsoft Teams, as approved by the Committee Chair and pursuant to 29 Del. C., Section 10006A.

Section 7-E. Within the past 3 calendar years, has the entity conducted executive sessions or other closed meetings? If yes, please indicate the date of each and the nature of the meeting. Are minutes of executive sessions or other closed meetings available to the public?

No executive sessions or closed meetings have been conducting during this time.

Section 7-F. Has the entity ever received any complaints that it was violating FOIA? If so, please list and include the result of the hearing or the review.

There have been no complaints of FOIA violations.

SECTION 8: ADMINISTRATIVE PROCEDURES ACT COMPLIANCE

Section 8-A. Does the entity promulgate rules and regulations in accordance with the Administrative Procedures Act?

Yes, the Committee promulgates rules and regulations in accordance with the Administrative Procedures Act.

Section 8-B. Has a DAG assigned to this entity or other legal counsel reviewed the current rules and regulations for compliance with the governing statute?

Yes, the Committee's DAG has reviewed the current rules and regulations for compliance with the governing statute.

Section 8-C. Is the entity considering any changes to its current rules and regulations? If "yes" please address the following questions:

Yes, the Committee is considering an emergency regulation change to schedule xylazine as a schedule III-controlled substance as it has been determined that this medication is an imminent peril to public health, safety, and welfare.

1. **What is the status and nature of the planned changes?**

   The Committee conducted an emergency CSAC meeting on May 5, 2023, to discuss and consider drafted emergency regulation. The Committee approved drafted language for the Secretary of State's consideration, and if approved by the Secretary the order effecting such action may be effective for a period of no longer than 120 days and may be renewed once for a period not exceeding 60 days per Title 29, Del. C. § 10119(3).

2. **Have the proposed changes been reviewed and approved by the entity's DAG or other legal counsel?**

   The regulation changes are currently being reviewed by the Secretary of State's Office for modifications and/or approval.

3. **Have the proposed changes and the public hearing date been published in the Register of Regulations?**

   No, this will not occur until the Committee and the Secretary of State have approved the drafted regulation changes. Once approved the emergency order will be sent to the Registrar for publication in the next issue of the Register of Regulations per Title 29, Del. C. § 10119 (5).

SECTION 9: COMPLAINT AND DISCIPLINARY PROCESS

Section 9-A. Does the entity receive and review complaints from the public? If so, please describe in detail the complaint process used. Include how complaints are filed, who investigates complaints, and how long investigations proceed.

The Division's Investigative Unit has a staff of fourteen Investigators who provide investigative support to all 35 boards and commissions within the Division of Professional Regulation.

Complaints may be submitted to the Division in multiple ways. The Investigative Unit maintains a web-based complaint portal which is available 24 hours a day. Complaints may also be submitted via a pre-printed form for those without Internet access. To assure public safety, all efforts are made to assist those individuals who are submitting their concerns by filing a complaint. It is not unusual for an investigator to guide an individual through the submission process. Complaints will also be accepted in free text written font. Once a complaint has been received it is reviewed by the Investigative Supervisor or his/her designee to determine if there is sufficient evidence to initiate a case file. After the initial review, the case may be "accepted," "rejected" or "temporarily accepted with additional required follow-up needed."

Accepted cases are placed in a queue for assignment to an available investigator. The Complainant and the Respondent are both notified of the open investigation. In all cases, the Investigator has the availability of a board member expert to consult with. Cases are assigned based upon priority (imminent public safety issues), then as received. After the Division investigates the complaint, if it is determined that a complaint has merit and the facts can be substantiated, the investigation is then forwarded to the Attorney General's Office for possible prosecution. Complaints that are unable to be substantiated or do not rise to the level of a violation of law or rule are closed at the Division level. The Division Director or his/her designee has the authority to subpoena investigative material and witnesses. Investigations involve evidence gathering, witness interviews and rare undercover operations. The management of complaints is defined by statute pursuant to 29 Del. C. §8735(h).

All complaints are worked in the order received or the priority, imminent public safety issue, of the complaint. Complaints are assigned to an Investigator and asked to be completed within

90-120 days. Various factors will determine the length of time to conclude an investigation such as subpoena response, contacting and communicating with witnesses, or consulting with Board contacts. The Division is an umbrella agency that provides regulatory oversight of 35 Boards and 54 professions. There were approximately 1000 complaints total received in 2022. Currently our Investigative Unit is about a year behind and processing complaints from 2022.

Section 9-B. What are some of the most common complaints received by the entity? Please identify where the complaints originate (i.e., public, media, Attorney General's Office, consumer groups, etc.).

Some of the most common complaints received by the Investigative Division include practitioner intoxication from substance abuse at workplace, drug diversion by licensees from their workplace, over prescribing of controlled substances to patients, poor prescribing practices of controlled substances, demonstrating poor patient record-keeping, having relationships with patients involving controlled substances or prescriptions as fee for serves.

The complaints originate from the Divisions web-based complaint portal, which is available 24 hours a day to the public; self-reporting of discipline by licensees; National Practitioner Data Bank (NPDB) Alerts regarding practitioner's licenses disciplined in other states. Many controlled substance complaints from 2020 until the present have been filed by our Division staff; however, we have received complaints from the public and employers as well. Some complaints will be submitted by an investigator when a controlled substance violation was determined in addition to the main profession of the licensee (medical, nurse practitioner, pharmacist).

Section 9-C. Have any complaints been filed with the Attorney General's Office? If so, have they been resolved?

Yes, complaints have been filed with the Attorney General's Office and all of them have been resolved and been presented to the Committee for consideration and recommendations to the Secretary of State. The Investigative Unit also has received referrals from the Attorney General's Office to file a complaint and those are input as complaints in the name of the Division.

Section 9-D. Are there any Delaware Attorney General's Opinions that affect the functioning of the entity? If so, please provide the date and number.

No, there are no Delaware Attorney General's opinions that affect the function of the Committee.

Section 9-E. Are there any recent judicial decisions (state or federal) that directly affect the functioning of the entity?

No, there are no recent judicial decisions (state or federal) that directly affect the functioning of this Committee.

Section 9-F. What specific disciplinary actions are taken by the entity as a result of complaint investigations? (i.e., license revocation, license suspension, formal reprimand, penalty, etc.).

Currently, by statute, disciplinary sanctions are limited to suspension, revocation and a maximum fine of $1,000 per violation. The Secretary of State may also limit prescribing or access to certain scheduled controlled substances. The possible sanctions must be updated to provide for probation, letters of reprimand, additional continuing education, increased monetary fines, and random auditing of patient charts.

A licensee may also be required to enroll in the Delaware Professional's Health Monitoring Program, through Uprise Health, to help licensees with substance use and mental health issues to recover and continue working safely while supporting both public and workplace safety. Licensees are eligible for this monitoring program if the individual has a Delaware license or certification. Licensees also must not have committed an offense, other than the status of being chemically dependent or impaired, that would constitute grounds for discipline under applicable laws governing the profession. Currently, there is no explicit reference to the DPHMP in the Committee's statute and that needs to be updated.
Website Access: https://www.delawaremonitoring.com/

Section 9-G. Please describe in detail the process used for determining appropriate disciplinary actions taken against individuals licensed, employed, or monitored by the entity. Include the appeals process, if applicable.

Typically, a case comes to the Committee through a hearing officer recommendation or consent agreement from the Attorney General's Office, although the Committee is authorized to hold hearings and has done so, primarily for applicant cases. The Committee reviews the recommendation provided, and then makes a final recommendation to the Secretary of State for review and consideration. The Final Order, subject to appeal to the Superior Court, consists of the hearing officer recommendation, the Committee's recommendation, and the Secretary's Order.

Section 9-H. If applicable, provide the following complaint data for calendar years 2020, 2021, 2022, 2023 (to date):

	Calendar Year 2020	Calendar Year 2021	Calendar Year 2022	Current Calendar Year 2023
Total Number of Complaints Received by the Entity	10	6	8	1
Total Number of Complaints Investigated	9	4	4	0
Total Number of Complaints Found Valid	2	0	4	0
Total Number of Complaints Forwarded to the Attorney General	3	2	4	0
Total Number of Complaints Resulting in Disciplinary Action	2	6	0	0
Not Assigned / not investigated	0	0	1	1

SECTION 10: PRIOR JLOSC REVIEW

Section 10-A. Has JLOSC previously reviewed this entity? If so, provide the year(s) of review and list all JLOSC final recommendations, indicate whether the entity is complying or non-compliant with each recommendation, and explain all areas of non-compliance.

This committee has not been previously reviewed by JLOSC.

SECTION 11: PUBLIC INFORMATION

Section 11-A. How does the entity communicate information with the public? Does the entity use a website and/or social media platform(s)? If so, please list each method of communication and supply the applicable web address, handle, or username.

The Committee communicates with the public via the Delaware Public Meeting Calendar by the Director of the OCS posting all meeting agendas at least seven (7) days prior to the meeting and posting all approved meeting minutes for the previous meeting within five (5) days of their approval by the Committee.

The Division also has a website specifically for Controlled Substances: https://dpr.delaware.gov/boards/controlledsubstances/ that includes access to all Committee meetings, licensure fees and requirements, continuing education and renewal requirements, and access to State and Federal statute and regulations.

The Committee and the Division also communicate with licensees via email through the DELPROS licensing system to notify of license issuances, license renewal periods, and/or timely alerts to all CSR licensees, such as a regulation change that would affect multiple professions. An example of this type of email alert would be a regulation change, such as in March 2022, when Regulation 4.7 was changed to mirror the already promulgated federal law regarding the expiration and partial filling of controlled substance prescriptions. Alerts may also be sent out to licensees if a reported DEA registration number has been used by an unauthorized individual or patient to prevent any other fraudulent prescriptions to be filled.

Section 11-B. What information or educational resources are made available to the public relating to the entity's activities? Examples include newsletters, guidelines, rules and regulations, policy briefs, or other similar documents. Please indicate the method and frequency of distribution for each and identify the target group(s).

All educational resources can be accessed through the Division website for Controlled Substances. The Committee does not distribute newsletters or guidelines to licensees or the public. All rules and regulation changes are published in the Delaware Register of Regulations and once promulgated are included in the full version of the Uniform Controlled Substance Act Regulations, which is accessible through the Division's Controlled Substances website.

Section 11-C. Does the entity actively engage with the public and solicit feedback? If so, please explain. If the entity has conducted surveys, please list all surveys conducted within the past 5 years and indicate where the public can find survey results.

No, the Committee does not actively engage with the public and solicit feedback.

Section 11-D. Does the entity have by-laws? If so, are they available for the public (include location) and what was the last date of revision?

No, the Committee does not have by-laws.

Section 11-E. Please complete the following 3 charts (add or delete cells as needed) with the most current information regarding interest groups, national organizations, and industry or trade publications as described in each chart heading.

Interest Groups **(Groups affected by entity actions or represent others served by or affected by entity actions)**		
Group or Association Name/Contact Person	**Internet Address**	**Phone Number**
Board of Medical Licensure and Discipline	https://dpr.delaware.gov/boards/medicalpractice/	302-744-4500
Board of Pharmacy	https://dpr.delaware.gov/boards/pharmacy/	302-744-4500
Board of Nursing	https://dpr.delaware.gov/boards/nursing/	302-744-4500
Board of Podiatry	https://dpr.delaware.gov/boards/podiatry/	302-744-4500
Board of Dentistry and Dental Hygiene	https://dpr.delaware.gov/boards/dental/	302-744-4500
Board of Veterinary Medicine	https://dpr.delaware.gov/boards/veterinarymedicine/	302-744-4500
Board of Examiners in Optometry	https://dpr.delaware.gov/boards/optometry/	302-744-4500

National Organizations or other State Agencies **(Serve as an information clearinghouse or regularly interact with the entity)**		
Group or Association Name/Contact Person	**Internet Address**	**Phone Number**
NASCSA- National Association of State Controlled Substances Authorities	https://www.nascsa.org/	(617)-347-1455
NPDB- National Practitioner Data Bank	https://www.npdb.hrsa.gov/	(800)-767-6732
DEA- Drug Enforcement Agency	https://www.deadiversion.usdoj.gov/drugreg/	(800)-882-9539
DPH-Division of Public Health My Healthy Community	https://dhss.delaware.gov/dhss/dph/index.html My Health Community Link	(302) 744-4700
DSAMH-Division of Substance Abuse & Mental Health Help is Here	https://dhss.delaware.gov/dsamh/ https://www.helpisherede.com/	(302) 255-9399

Industry or Trade Publications		
Group or Association Name/Contact Person	**Internet Address**	**Phone Number**
N/A		

SECTION 12: ENACTED LEGISLATION IMPACTING THE ENTITY-

Section 12-A. Did legislation establish the entity? If so, what year and by what legislative bill was the entity established?

Yes, the Committee was formed in 2010 and was operating for a period before legislation established the Committee in 2013 per SB 59 from the 147th General Assembly
§ 4731. Rules; fees; Controlled Substance Advisory Committee.

(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.

Section 12-B. Please list all legislation and other acts that have made substantive amendments to the entity's enabling legislation. Please indicate the bill number and date of enactment for each.

The CSAC was expressly created legislatively pursuant to SB 59 w/SA 2 which passed the 147th General Assembly and was enacted August 6, 2013. The CSAC falls under Subchapter III, Chapter 47, Title 16 of the Delaware Code: "Regulation of Manufacture, Distribution and Dispensing of Controlled Substances." Specifically, 24 Del. C. §4731(b) provides that: "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 following legislative amendments impacted Subchapter III, Chapter 47, Title 16 of the Delaware Code.

- SB 226 w/SA 1 and 2 and HA 1, 3, 4, 5, 6 & 8 passed the126th General Assembly and was enacted on June 13, 1972. This Bill amended the Uniform Controlled Substances Act, Chapter 47 of Title 16 of the Delaware Code, by adding Subchapter III, Regulation and Manufacture, Distribution and Dispensing of Controlled Substances.

- SB 583 w/SA 2 passed the 128th General Assembly and was enacted on July 21, 1976. This Bill amended Subchapter III, Chapter 47 of Title 16 of the Delaware Code by striking §4734(a) in its entirety and replacing it with a list of factors to be considered by the Secretary of State in determining whether suspension or revocation of a CSR was warranted. A new section 4736 was added to give the Secretary of State the

authority to impose a maximum fine of $500 as a sanction for violation of Subchapter III.

- HB 510 passed the 133rd General Assembly and was enacted on July 9, 1986. This Bill amended Subchapter III, Chapter 47 of Title 16 of the Delaware Code by adding a new subsection (g) to Section 4732 requiring registrants to report any change of address to the Secretary of State.

- SB 221 w/SA 1 passed the 138th General Assembly and was enacted on July 10, 1995. This Bill gender neutralized designations in the Delaware Code.

- HB 515 passed the 139th General Assembly and was enacted on June 16, 1998. This Bill amended Subchapter III, Chapter 47 of Title 16 of the Delaware Code by adding definitions for "Other Controlled Substance Registrants," "Prescribe," and "Researcher" and amending certain language for clarity.

- SS 1 for SB 110 w/SA 1 passed the 143rd General Assembly and was enacted on June 14, 2005. This Bill amended Subchapter III, Chapter 47 of Title 16 of the Delaware Code by adding section 4740 pertaining to the sale of pseudoephedrine or ephedrine to provide that such products may be sold or dispensed only from behind a checkout counter.

- SB 119 w/SA 1 passed the 147th General Assembly and was enacted on July 3, 2013. This Bill amended Subchapter III, Chapter 47 of Title 16 of the Delaware Code by adding section 4739A providing that, except for pharmacies and researchers, practitioners were prohibited from dispensing controlled substances beyond the amount deemed medically necessary for a 72-hour supply.

- SB 59 w/SA 2 passed the 147th General Assembly and was enacted on August 6, 2013, with an effective date of March 1, 2014. This Bill, which amended Subchapter III, Chapter 47 of Title 16 of the Delaware Code, expressly gave the Secretary of State the authority to appoint the Controlled Substance Advisory Committee. Specifically, 24 Del. C. §4731(b) provides that: "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." This Bill also amended section 4733, relating to registration, to add the discipline of any professional license in any jurisdiction as grounds for denial of an application for registration. This Bill further amended the language pertaining to proceedings related to revocation or suspension of a registration to specify that complaints will be received and investigated by the Division of Professional Regulation. The potential fine for violation of practice requirements was increased to $1,000 per violation. A provision was added to provide that upon suspension or revocation of a registration, all controlled substances owned or possessed by the registrant may be placed under seal with the requirement that the DEA be notified promptly. This Bill also added provisions pertaining to the hearing process and created a temporary suspension process.

- HB 130 passed the 147th General Assembly and was enacted on August 27, 2013. This Bill amended section 4740 of Subchapter III, Chapter 47 of Title 16 of the Delaware Code pertaining to the sale of pseudoephedrine and ephedrine to require the submission of certain information to the National Precursor Log Exchange System.

- SB 59 w/SA 2 passed the 147th General Assembly and was enacted on August 6, 2013, with an effective date of March 1, 2014. This Bill amended Subchapter III, Chapter 47 of Title 16 of the Delaware Code by expressly giving the Secretary of State the authority to appoint the Controlled Substance Advisory Committee. Specifically, 24 Del. C. §4731(b) provides that: "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." This Bill also amends section 4733, relating to registration to add the discipline of any professional license in any jurisdiction as grounds for denial of a registration. This Bill further amends the language pertaining to proceedings related to revocation or suspension of a registration to specify that complaints will be received and investigated by the Division of Professional Regulation. The potential fine for violation of practice requirements was increased to $1,000 per violation. A provision was added to provide that upon suspension or revocation of a registration, all controlled substances owned or possessed by the registration may be placed under seal with the requirement that the DEA be notified promptly. The bill also added provisions pertaining to the hearing process and created a temporary suspension process.

- HB 154 w/HA 2 passed the 147th General Assembly and was enacted on February 14, 2014. This Bill amended section 4732, Subchapter VI, Chapter 47 of Title 16 of the Delaware Code by adding subsection (h), which provided that, as a condition of biennial renewal of registration, the registrant must complete continuing professional education concerning prescribing, distributing, dispensing or delivery of controlled substances and the detection and recognition of the symptoms or impairment and dependency resulting from the abusive or illegal use of controlled substances.

- HS 1 for HB 218 passed the 147th General Assembly and was enacted on August 12, 2014. This Bill added subsection (e) to section 4739 of Subchapter III, Chapter 47 of Title 16 of the Delaware Code to provide that an ultimate user shall be permitted to prohibit or limit another person from receiving a prescription on the ultimate user's behalf from a pharmacy.

- SB 8 passed the 148th General Assembly and was enacted on April 2, 2015. This bill amended section 4739A of Subchapter III, Chapter 47, Title 16 of the Delaware Code to exempt opioid treatment programs and veterinarians from the 72-hour supply limitation.

- HB 329 passed the 148th General Assembly on June 16, 2016. This Bill amended Subchapter III, Chapter 47 of Title 16 of the Delaware Code by adding limitations to the sale of dextromethorphan.

- HB 331 w/HA 1 as amended by HA 1 to HA No. 1 passed the 149th General Assembly on September 4, 2018. This Bill amended Subchapter III, Chapter 47 of Title 16 of the Delaware Code by adding provisions relating to the use, distribution and education pertaining to benzodiazepines.

- SB 225 w/SA 1 and SA 2 passed the 149th General Assembly on September 10, 2018. This Bill amended Subchapter III, Chapter 47 of Title 16 of the Delaware Code by adding continuing education on the risks of using opioids as a requirement for registration renewal.

Section 12-C. Please identify, list, and briefly describe any federal laws or regulations that guide or otherwise directly affect the functions, responsibilities, and operations of the entity.

There are no federal laws and regulations directly impacting the Committee.

SECTION 13: PENDING & PROPOSED LEGISLATION

Section 13-A. Please list any currently proposed legislation (state and federal) that, if passed, will directly impact the functions or operations of the entity. Please indicate any bills that the entity is supporting or opposed.

Recently discovered data and information about xylazine, a non-opioid sedative, analgesic and muscle relaxant approved exclusively for veterinary use in the US, has demonstrated a significant rise in abuse potential with the highest prevalence documented in the Northeast region of the US. Its inclusion in illicit drugs has led to growing evidence of harmful effects in humans including toxicity, severe skin ulcers, and overdose; with resulting overdoses not reversed by naloxone as a non-opioid.

The Committee recommended to the Secretary of State the promulgation of an emergency order to schedule this substance as a schedule-III controlled substance in Delaware. An emergency regulation to schedule xylazine as a schedule III-controlled substance has been drafted and approved by the Committee as of May 5, 2023. It is currently being reviewed and considered by the Secretary of State. If approved, this emergency regulation will be effective for 120 days from the date of execution in accordance with the requirements of Title 29 Del. C. §10119(3).

There is no other proposed or pending legislation that the Committee is aware of currently.

SECTION 14: FISCAL INFORMATION –

Section 14-A. Complete the following chart to provide the entity's actual revenue for fiscal years 2021 and 2022 and budgeted revenue for fiscal year 2023. Also indicate the source of funds (i.e., general fund, federal funds, special funds, etc.).

Revenue:

Fiscal Year	Source of Funds	Amount
FY2023 (budgeted)*		
	General Funds	$0.00
	Federal Funds**	$605,658
	Special Funds*	$1,590,000
	TOTAL:	**$2,195,658**
FY2022 (actual)		
	General Funds	$0.00
	Federal Funds**	$607,236
	Special Funds*	$408,239
	TOTAL:	**$1,015,475**
FY2021 (actual)		
	General Funds	$0.00
	Federal Funds**	$600,526
	Special Funds*	$2,713,952
	TOTAL:	**$3,314,478**

*Special funds - this amount is an estimate of the applications the Division will receive in FY23. We are unable to determine how many licensees will request additional services from the Division.
**Federal Funds - the revenues are actuals of funding provided by the grant received.

Section 14-B. If the entity receives federal funds, including grants, please indicate the following:

- **Total amount of federal funds.**
  - $1,813,419 (total for 3 fiscal years outlined above)
- **Type of federal fund.**
  - Centers for Disease Control (CDC), Overdose Data to Action Grant, through MOU with DHSS/Public Health
- **State/Federal Match Ratio.** N/A
- **State Share of Dollars.** N/A
- **Federal Share of Dollars.** N/A

Section 14-C. Does the entity collect any fees or fines? Provide information on any fines or fees collected by the entity. Modify chart rows as needed.

Description of Fine or Fee	Current Fine or Fee $$	Number of Persons or Entities Paying Fine or Fee	Fine or Fee Revenue $$	Where is the Fine or Fee Revenue Deposited? (i.e., general fund, special fund)
Practitioner & Facility CSR	$200	7423	Fee	Special Fund
Hosp/Clinic CSR	$300	89	Fee	Special Fund
Distributor CSR	$1200	270	Fee	Special Fund
License Verification	$35	9	Fee	Special Fund
Roster	$45	35	Fee	Special Fund
Fines	Varying	0	Fine	General Fund

The information above was populated on 5/4/2023. Fees referenced above were effective 7/1/2022.

Section 14-D. Has the entity conducted a financial analysis to determine if the current fees are sufficient to cover the cost of the administrative activity related to each? Do the current fees or fines need to be updated or revised? Please explain, indicating whether the fees or charges can be changed directly by the entity or if legislative approval is required.

The Division of Professional Regulation conducts a fee setting analysis biennially for all professions. This analysis was completed June of 2022 for fees effective July 1, 2022 – June 30, 2024. The next analysis will be done in May/June 2024. The Division has authority to establish a change the fee as approved by the Secretary of State pursuant to 29 Del. C. §8735(d).

Section 14-E. Complete the following chart to provide the entity's actual expenditures for fiscal years 2021 and 2022 and budgeted expenditures for fiscal year 2023. Also indicate the source of expenditures (i.e., general fund, federal fund, special fund, etc.).

Expenditures:

Fiscal Year	Source of Funds	Amount
FY2023 (budgeted)		
	General Funds	$0.00
	Federal Funds	$0.00
	Special Funds*	$0.00
	TOTAL:	**$0.00**
FY2022 (actual)		
	General Funds	$0.00
	Federal Funds	$607,236
	Special Funds**	$147,168.75
	TOTAL:	**$757,404.75**
FY2021 (actual)		
	General Funds	$0.00
	Federal Funds	$600,525
	Special Funds**	$146,263.41
	TOTAL:	**$746,788.41**

*The Division is unable to provide expenditure information for Special Funds, on a per board/commission basis. The budget for the Division of Professional regulation encompasses all boards and commissions. Federal funds expenditures are predetermined and set by the grant prior to receiving funding.

**This amount is the direct expenses and overhead costs for the Controlled Substance Advisory Committee. The overhead costs are apportioned by the percentage of licensees to the total number of licenses in the Division of Professional Regulation; this is done biennially during the fee setting analysis. The Federal Expenses are the actual costs associated with the Federal Funding.

Section 14-F. Provide a detailed breakdown of fiscal year 2023 budgeted expenses. Modify chart rows as needed.
Breakdown of fiscal year 2023 budgeted expenses:

Line Item	Source(s)	Amount of Expenditures
See explanation above		
		TOTAL

Section 14-G. Within the last three fiscal years, have there been any external factors that have positively or negatively impacted the entity's revenue or expenditures?

Revenue was significantly higher in FY21 because of the biennial renewal of all licensees.

SECTION 15: LICENSING PROCESS

Section 15 of the Self-Report may not be applicable. This section will apply if the entity reviews applications and/or issues licenses. If unsure, please contact JLOSC staff.

- **If this section is applicable, answer all questions in Section 15.**
- **If this section is not applicable, write below that the entity does not review applications or issue licenses, and skip to Section 16.**

Section 15-A. Please list each of the licenses, certificates, or approval notices issued by the entity and include the following information:

- **Indicate how many are currently licensed, and whether an individual or institution receives the license.**

Number of Active CSR licenses as of April 30, 2023:

Type of License	License Type	Count of Active Licenses
Practitioner/Individual	Physician Assistant CSR	787
Practitioner/Individual	Physician CSR	4,135
Practitioner/Individual	Advanced Practice RN CSR	1,756
Practitioner/Individual	Dentist CSR	460
Practitioner/Individual	Veterinarian CSR	279
Practitioner/Individual	Optometrist CSR	34
Practitioner/Individual	Podiatrist CSR	80
Facility	Pharmacy CSR	701
Facility	Distributor/Manufacturer CSR	294
Facility	Hospital/Clinic CSR	96
Facility	Research/Laboratory CSR	35
Facility	Other CSR	2
Facility	Provider Pharmacy Facility CSR	2
	Sub Total: Practitioner/Individual	**7,531**
	Sub Total: Facilities	**1,130**
	Total Practitioner and Facilities	**8,661**

- **Standard date of and requirements for renewal.**

All active CSRs must be renewed every two years before the expiration date of June 30 of ODD years. During renewal, you are asked to attest to completing the two hours of continuing education (CE) in the areas of controlled substance prescribing practices, treatment of chronic pain, or other topics related to prescribing controlled substances.

Licensees may file a late renewal application up to one year after the CSR license expiration date and must pay a late fee in addition to the renewal fee. The late period is not a "grace period," and if the licensee fails to renew within one year, the registration will terminate. To resume prescribing, storing, or dispensing in Delaware, the licensee must reapply for registration as a new applicant.

- **Criteria for determining qualifications for licensure.**

The criteria for determining qualifications for licensure are stated per

16 Del. C. § 4733. Registration; rights of registrants.

(a) The Secretary shall register an applicant as a pharmacy, distributor, manufacturer, practitioner, researcher or other controlled substance registrant for purposes of manufacturing, distributing or dispensing, some or all of the controlled substances included in Schedules I-V who has an active, relevant underlying professional license in the State unless the Secretary determines that the issuance of that registration would be inconsistent with the public interest. In determining the public interest, the Secretary shall consider the following factors:

(1) Maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific or industrial channels;

(2) Compliance with applicable federal, state and local law, including but not limited to such requirements as having a license to practice as a practitioner or having documented training and continuing education as a drug detection animal trainer;

(3) Any convictions of the applicant under any federal and state laws relating to any controlled substance;

(4) Past experience in the manufacture or distribution of controlled substances and the existence in the applicant's establishment of effective controls against diversion;

(5) Furnishing by the applicant of false or fraudulent material in any application filed under this chapter;

(6) Suspension or revocation of the applicant's federal registration to manufacture, distribute, prescribe, dispense or research controlled substances as authorized by federal law;

(7) Any professional license disciplined in any jurisdiction; and

(8) Any other factors relevant to the public interest.

In addition to UCSA Regulation 3.1

Registration shall be on a biennial basis upon forms supplied by the Division of Professional Regulation or Secretary of State for that purpose. A separate registration is required at each principal place of business or professional practice where controlled substances are manufactured, distributed, dispensed, or kept for research analysis. Out-of-State registrants who dispense or distribute controlled substances to patients or facilities in Delaware are required to obtain a registration.

3.1.1 All practitioners registered under Title 16, Chapter 47 as of July 1, 2013, must attest to completion of a one-hour education course on Delaware law, regulation and programs, acceptable to the Secretary, pertaining to the prescribing and distribution of controlled substances on or before June 30, 2015, in order to qualify for continued registration.

3.1.2 All practitioners who obtain new registration under Title 16, Chapter 47 after July 1, 2013, must attest to completion of a one-hour education course on Delaware law, regulation and programs, acceptable to the Secretary, pertaining to the prescribing and distribution of controlled substances within the first year of obtaining registration in order to qualify for continued registration.

Each license type has been separated to review specific qualifications for licensure upon credentialing of the submitted applications.

- Practitioner CSR (includes physician, dentist, veterinarian, and podiatrist CSR): In addition to submitting the application and fee in DELPROS, you must:
  - Have an active and in good standing practitioner license in one of the professions listed above that is eligible for issuance of a CSR license.
  - Complete the one-hour Mandatory Course training on Delaware law, regulation and programs on prescribing and distribution of controlled substances and acknowledge that you have completed this required Mandatory Course during the application (Regulation 3.1.2).
  - Attest that the licensee is required to register for the Delaware PMP within 90 days of license issuance. (16 Del. C. § 4798 (u)).
  - After the CSR license is approved and issued, the licensee must apply for a federal DEA registration for Delaware. The licensee must have both a Delaware CSR and DEA registration for Delaware before prescribing controlled substances in Delaware. A DEA registration in another jurisdiction is not sufficient for prescribing controlled substances in Delaware.

- Physician Assistant CSR
  - Have an active and in good standing Physician Assistant license that is eligible for issuance of a CSR license.
  - Must have a main collaborating physician and/or alternate collaborating physician who is licensed in Delaware and in good standing that also holds a CSR license, which is reported on a “Collaborating Physician Form” and uploaded to the application (24 Del. C. § 1770A and § 1771).
  - Complete the one-hour Mandatory Course training on Delaware law, regulation and programs on prescribing and distribution of controlled substances and acknowledge that you have completed this required Mandatory Course during the application (Regulation 3.1.2)
  - Attest that the licensee is required to register for the Delaware PMP within 90 days of license issuance (16 Del. C. § 4798 (u)).
  - After the CSR license is approved and issued, the licensee must apply for a federal DEA registration for Delaware. The licensee must have both a Delaware CSR and DEA registration for Delaware before prescribing controlled substances in Delaware. A DEA registration in another

jurisdiction is not sufficient for prescribing controlled substances in Delaware.

- Advanced Practice Registered Nurse (APRN) CSR
  - Have an active and in good standing APRN license that is eligible for issuance of a CSR license.
  - Complete the one-hour Mandatory Course training on Delaware law, regulation and programs on prescribing and distribution of controlled substances and acknowledge that you have completed this required Mandatory Course during the application (Regulation 3.1.2)
  - Attest that the licensee is required to register for the Delaware PMP within 90 days of license issuance (16 Del. C. § 4798 (u)).
  - After the CSR license is approved and issued, the licensee must apply for a federal DEA registration for Delaware. The licensee must have both a Delaware CSR and DEA registration for Delaware before prescribing controlled substances in Delaware. A DEA registration in another jurisdiction is not sufficient for prescribing controlled substances in Delaware.

- Optometrist CSR
  - Have an active and in good standing optometrist license that is eligible for issuance of a CSR license.
  - Complete the one-hour Mandatory Course training on Delaware law, regulation and programs on prescribing and distribution of controlled substances and acknowledge that you have completed this required Mandatory Course during the application (Regulation 3.1.2).
  - Prescriptive authority for controlled substances is limited to: Schedule II controlled substances containing hydrocodone, up to a maximum 72-hour supply, and Schedules III, IV, and V controlled substances up to a maximum 72-hour supply. (24 Del. C. §2101 (3)).
  - Licensee is not permitted to store or dispense controlled substances.
  - Attest that the licensee is required to register for the Delaware PMP within 90 days of license issuance (16 Del. C. § 4798 (u)).
  - After the CSR license is approved and issued, the licensee must apply for a federal DEA registration for Delaware. The licensee must have both a Delaware CSR and DEA registration for Delaware before prescribing controlled substances in Delaware. A DEA registration in another jurisdiction is not sufficient for prescribing controlled substances in Delaware.

- Facility CSR (includes distributor/manufacturer, hospital/clinic, and research/ laboratory CSR)
  - Have an active and in good standing pharmacy license that is eligible for issuance of a CSR license. These license types include Pharmacy-Wholesale Distributor, Manufacturer, Non-Resident Pharmacy, Hospital Pharmacy, Retail (in-state) Pharmacy. Clinics, research facilities and laboratories do not need a professional license, or pre-requisite license, from the Board of Pharmacy, as they are not dispensing the controlled substances

to patients but do need a CSR depending on the services provided or research performed at the facility.

- All in-state located facilities require an inspection by our Pharmacy Compliance Officer for approval and CSR license issuance. (16 Del. C. §4782(b).)
- Attest that the licensee is required to register for the Delaware PMP within 90 days of license issuance (16 Del. C. § 4798 (u)).
- After the CSR license is approved and issued, the licensee must apply for a federal DEA registration for Delaware. The licensee must have both a Delaware CSR and DEA registration for Delaware before prescribing controlled substances in Delaware. A DEA registration in another jurisdiction is not sufficient for prescribing controlled substances in Delaware.

- **Period for which a license is valid.**

  The full licensure period is two years. However, the initial licensure period may be less than a full licensure cycle depending on when the controlled substance license is issued. All CSR licenses expires June 30th of odd years. CSR licenses are currently in renewal and the current expiration is June 30, 2023. When the licensee renews their CSR, the license expiration is pushed out by 2 years, June 30, 2025.

Section 15-B. Please provide the following data for each license, certificate, or approval notice issued by the entity during calendar years 2020, 2021, 2022, and 2023 (to date). Include additional charts, if necessary:

Please refer to **Appendix A** for a breakdown of all license types.

Section 15-C. Do licenses issued by the entity have reciprocity or endorsement agreements with Delaware? If so, provide a list of all states and jurisdictions that have licensing reciprocity or endorsement agreements with Delaware. Indicate if the entity requires a signed agreement or endorsement from another state or jurisdiction before a Delaware license is issued?

No, licenses issued by the entity do not have reciprocity or endorsement agreements with Delaware. All CSR licenses are issued by initial application.

Application Fees:

Section 15-D. Are any application fees collected by the entity? If so, complete the chart below. Modify chart rows as needed.

Yes, application fees are collected at the time of application submission and at the time of license renewal every two years. Fees are subject to change periodically based on evaluations by the Division per Title 29 Del. C. § 8735(c).

Application Fee Type	Application Fee
Physician CSR	$200
Physician Assistant CSR	$200
Podiatrist CSR	$200
Dentist CSR	$200
Advanced Practice RN CSR	$200
Optometrist CSR	$200
Veterinarian CSR	$200
Researcher/Lab CSR	$200
Pharmacy CSR	$200
Provider Pharmacy CSR	$200
Hospital/Clinic CSR	$300
Distributor/Manufacturer CSR	$1200

Section 15-E. If application fees are collected, when are fees due? Where are fees deposited? What happens if the fee is not paid? Are there any reduced fee options?

An applicant is required to pay the application fee at the time the application is submitted in the DELPROS online licensing system. Fees are deposited into a special fund account, please refer to Section 14. If the fee is not paid, then the DELPROS system will not allow the application to be processed and submitted to the Division for further processing. There are no reduced fee options.

Section 15-F. If application fees are collected, has the entity conducted a financial analysis to determine if the current application fees are sufficient to cover the cost of processing applications? Do the current application fees need to be updated or revised? Please explain, indicating whether the application fees can be changed directly by the entity or if legislative approval is required.

The Division conducts a fee setting analysis biennially for all professions. This analysis was completed June of 2022 for fees effective July 1, 2022 – June 30, 2024. The next analysis will be done in May/June 2024. The Division has authority to establish a change the fee as approved by the Secretary of State pursuant to 29 Del. C. §8735(d).

Application Process:
Section 15-G: Describe the application review process. Include where applications are obtained. Who reviews applications? How are applicants informed of decisions?

The application process is completed through an individual's DELPROS licensing portal by tailoring the application to a specific license type based on wizard questions that the applicant answers.

Applications are credentialed and issued by the OCS Director through our Salesforce DELPROS platform. The applications are listed in the DELPROS system by the date they are submitted, and they are credentialed in the order that we receive the applications. Applications are typically credentialled within about 1 to 2 weeks from submission. If an application is deemed deficient, a validation list will be updated to communicate to the applicant what the deficiencies are, in addition to a deficiency email sent to the applicant communicating how to upload or provide additional documentation that would satisfy their application. This additional documentation can be uploaded directly to the application through an individual's DELPROS Portal, emailed to our customer service email, or mailed directly to the Division.

If the application is for an in-state pharmacy or facility, as listed above, our Pharmacy Compliance Officer must complete an on-site inspection to ensure the facility is in compliance with all rules and regulations to approve for licensure.

Once all information is reviewed and the CSR application has satisfied licensure requirements the license is issued, and an automated license issuance email is sent directly to the individual. This email communication informs the licensee of their license number, expiration date, and how to access their the DELPROS licensing portal to print their license, as the Division no longer mails paper copies of licenses.

Applications that present possible areas of concern are submitted to the Committee for review. The Committee then determines whether to recommend approval to the Secretary of State, or to issue a proposal to deny letter, which advises the applicant of the right to request a hearing. The hearing is conducted before the Committee, which then makes a recommendation of approval or denial to the Secretary of State.

Examinations:
Section 15-H. If there is an examination requirement to obtain a license, address the following questions:

There is no examination required for CSR licensure.

1. **Is the examination written, oral, or both?**
2. **Is a standardized national examination used?**
3. **Who develops and scores the exam?**
4. **Are all aspects of the examination validated?**
5. **Who administers the exam, where is it administered, and how often is the exam given?**
6. **During each of the previous three calendar years, how many persons sat for an exam, and of those, how many successfully passed?**

SECTION 16: RECONSIDERATION, APPEAL, SANCTIONS, REVOCATION

Reconsideration:
Section 16-A: Is there a process for application or entity decision reconsideration (a process prior to a formal appeal, sometimes referred to as an administrative reconsideration)? This could also apply to reconsidering budget decisions made by the entity. If so, please explain.

No, there is not a process for application or entity decision reconsideration. The individual would have to reapply and complete the application, review, and consideration process again, if applicable.

Appeal:
Section 16-B: Can an applicant, group, or individual appeal an entity decision? If so, explain the process for appeal.

Yes, an applicant can appeal to the Superior Court following the steps outlined in Title 29 Del. Code Sec. 10142.

Sanctions:
Section 16-C: Can the entity issue sanctions? If so, explain the sanction process.

The Secretary has the discretion to revoke or suspend a registration or impose a fine up to $1,000 as discipline. The language in the statute references the Secretary holding the hearings, but the Hearing Officers or the Committee preside over hearings:

16 Del. C. § 4731(b): (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.

Rule to Show Cause Hearings:

16 Del. C. § 4734 describes a Rule to Show Cause process which would apply where the underlying professional license was suspended or revoked, or in the case of failure to complete required continuing education. The available sanctions are revocation or suspension.
§ 4734. Denial, revocation and suspension of registration; order to show cause proceedings before the Secretary.

> (a) A registration under § 4733 of this title may be denied, suspended or revoked by the Secretary upon a finding that the registrant's DEA registration or underlying practitioner license has been suspended or revoked, or the registrant has failed to comply with any mandatory continuing education requirements established by the Secretary's rules.
> (b) Before denying, suspending or revoking a registration, the Secretary shall serve upon the applicant or registrant an order to show cause why registration should not be denied, suspended or revoked. The order to show cause shall contain a statement of the basis therefore and shall call upon the applicant or registrant to **appear before the Secretary** at a time and place not more than 30 days after the date of service of the order.

Proceedings to refuse renewal of registration shall not abate the existing registration which shall remain in effect pending the outcome of the administrative hearing.

- The Committee may want to update references to “appearing before the Secretary” in the law, as stated above, and below in Section 4736 “The Secretary shall be authorized to administer oaths, examine witnesses and issue notices...”

Disciplinary Hearings:

Section 4735(b) addresses discipline for any of the violations listed below. Sanctions include suspension, revocation, fine or limiting the prescribing authority.

- The Committee may want to consider amending this language to allow for probation and/or a letter of reprimand, in addition to consider a change to monetary fine limits.

4735 (b) **The Secretary, after due notice and hearing may limit, suspend, fine or revoke the registration of any registrant who**:

(1) Has failed to maintain effective controls against diversion of controlled substances into other than legitimate medical, scientific or industrial channels;
(2) Has failed to comply with applicable federal, state or local law;
(3) Has been convicted under any federal or state law relating to any controlled substances;
(4) Has furnished any false or fraudulent material in any application filed under this chapter;
(5) Has had any federal registration to manufacture, distribute, prescribe, dispense or research controlled substances as authorized by federal law suspended or revoked;
(6) Has violated a provision of this chapter, or violated an order or rule of the Secretary related to controlled substances;
(7) Has been disciplined by a professional licensing board in any jurisdiction; or
(8) Has engaged in any conduct the Secretary finds to be relevant and inconsistent with the public interest.

(c) The Secretary may limit revocation or suspension of a registration to particular controlled substances.
(d) The Secretary may fine any registrant in an amount not to exceed $1,000 per violation of this chapter or the rules promulgated hereunder.
(e) If the Secretary suspends or revokes a registration, all controlled substances owned or possessed by the registrant at the time of suspension or the effective date of the revocation order may be placed under seal. No disposition may be made of substances under seal until the time for taking an appeal has elapsed or until all appeals have been concluded unless a court upon application therefore orders the sale of perishable substances and the deposit of the proceeds of the sale with the court. Upon a revocation order becoming final, all controlled substances may be forfeited to the State.
(f) The Secretary shall promptly notify the Administration of all orders suspending or revoking registration and all forfeitures of controlled substances.

Temporary suspension:

§ 4737. Temporary suspension.

(a) In the event of a formal or informal complaint concerning the activity of a registrant that alleges an imminent danger to the public health, safety or welfare, the Secretary may

temporarily suspend any registration, pending a hearing, by written order. An order temporarily suspending a registration may not be issued unless the registrant or the registrant's attorney received at least 24 hours' written or oral notice before the temporary suspension so that the registrant or the registrant's attorney may file a written response to the proposed suspension. The decision as to whether to issue the temporary order of suspension will be decided on the written submissions. An order of temporary suspension pending a hearing may remain in effect for no longer than 60 days from the date of the issuance of the order unless the temporarily suspended registrant requests a continuance of the hearing date. If the temporarily suspended registrant requests a continuance, the order of temporary suspension remains in effect until the conclusion of all proceedings.

(b) A registrant whose registration has been temporarily suspended pursuant to this section must be notified of the temporary suspension immediately and in writing. Notification consists of a copy of the complaint and the order of temporary suspension pending a hearing personally served upon the registrant or registrant's counsel or sent by certified mail, return receipt requested, to the registrant's last known address. The Secretary will hold a hearing on the complaint giving rise to the temporary suspension within 60 days of the date of the issuance of the order of temporary suspension.

(c) A registrant whose registration has been temporarily suspended pursuant to this section may request an expedited hearing. The Secretary shall schedule the hearing within 15 days of receipt of any expedited hearing request, provided that the request is received within 5 calendar days from the date the registrant received notification of the decision to temporarily suspend the registration.

Hearing process and the right of appeal:

§ 4736. Hearings before the Secretary; subpoenas; judicial review.

(a) Any registrant complained against under this chapter may appear personally or by counsel at the hearing and produce any competent evidence on the registrant's behalf in answer to the complaint. Hearings shall be conducted in accordance with the Administrative Procedures Act [Chapter 101 of Title 29]. The Secretary shall be authorized to administer oaths, examine witnesses and issue notices of hearings or subpoenas requiring the testimony of witnesses and the production of books, records or other documents relevant to any matter involved in such hearing, and subpoenas shall also be issued at the request of the applicant or person complained against. In case of contumacy or refusal to obey a notice of hearing or subpoena under this section, the Superior Court in the county in which the hearing is held shall have jurisdiction, upon application of the Secretary to issue an order requiring such person to appear and testify or produce evidence as the case may require.

(b) Any registrant aggrieved by a decision of the Secretary to deny, suspend, limit, revoke or refuse to renew registration under this chapter may appeal such decision to Superior Court. Such appeal shall be governed by the Administrative Procedures Act. When notified of an appeal under this section, the Secretary shall forward to Superior Court a certified and complete copy of the written transcripts of evidence adduced at the hearing before the Secretary together with a written copy of the Secretary's findings and rulings and the Secretary's reasons therefor.

Revocation:

Section 16-D: Does the entity have a revocation process? If so, explain the process.

Please refer to Section 16-C for details regarding revocation process.

The Office of Controlled Substances, CSAC, and Secretary of State are not mentioned in the Hearing Officer Statute, 29 Del. C. Sec. 8735(a), which lists encompassed boards and commissions. However, the hearing officers have heard controlled substance cases and issued recommendations. This needs to be made explicit that the hearing officers have this authority.

SECTION 17: SELF-REPORT AUTHOR(S)

Section 17-A: Include all Self-Report author(s) and contact information below.

- **All Self-Report author(s) listed below certify the information supplied in this Self-Report is correct to the best of their ability.**
  - **Reminder to entity under review: Any updates or corrections to Self-Report contents and entity information must be submitted to JLOSC staff in a timely manner during the entire period of review.**

- Sarah H. Siok, Director Office of Controlled Substances sarah.siok@delaware.gov
- Shauna Slaughter, Acting Director, Division of Professional Regulation shauna.slaughter@delaware.gov
- Eileen Kelly, Deputy Attorney General Eileen.kelly@delaware.gov

Section 17-B: This Self-Report was submitted to JLOSC staff on:

Thursday, June 1, 2023

APPENDICES

APPENDIX A

Section 15-B. Please provide the following data for each license, certificate, or approval notice issued by the entity during calendar years 2020, 2021, 2022, and 2023 (to date). Include additional charts, if necessary:

These licenses are issued through the Division's Office of Controlled Substances (OCS) with review by the Committee if necessary.

Note the following as you review the tables:

- The number of licenses issued may be less or greater than the total applications approved or received per calendar year. This is because some applications are deficient waiting on some missing documents or application requirements (received in previous year) and was then issued the next calendar year.
- This time period is from January 1, 2020 to May 17, 2023.

Name of license issued by the entity:

Practitioners

1. **License Type Name: Physician Assistant CSR**

	# of License Applications Received	# of License Applications Approved	# of Licenses Issued	# of Licenses Rejected	# of Licenses Revoked	# of Licenses Suspended
Calendar Year 2020	69	72	72	0	0	0
Calendar Year 2021	127	127	127	0	0	0
Calendar Year 2022	127	125	125	0	0	0
Current Calendar Year 2023 (to date)	29	28	28	0	0	0

2. License Type Name: Physician CSR

	# of License Applications Received	# of License Applications Approved	# of Licenses Issued	# of Licenses Rejected	# of Licenses Revoked	# of Licenses Suspended
Calendar Year 2020	264	274	274	0	0	0
Calendar Year 2021	322	318	318	0	0	2
Calendar Year 2022	517	487	487	0	0	0
Current Calendar Year 2023 (to date)	168	154	154	0	0	0

3. License Type Name: Advanced Practice RN CSR

	# of License Applications Received	# of License Applications Approved	# of Licenses Issued	# of Licenses Rejected	# of Licenses Revoked	# of Licenses Suspended
Calendar Year 2020	153	154	154	0	0	0
Calendar Year 2021	212	208	208	0	0	0
Calendar Year 2022	299	286	286	0	0	0
Current Calendar Year 2023 (to date)	96	94	94	0	0	0

4. **License Type Name: Dentist CSR**

	# of License Applications Received	# of License Applications Approved	# of Licenses Issued	# of Licenses Rejected	# of Licenses Revoked	# of Licenses Suspended
Calendar Year 2020	19	19	19	0	0	0
Calendar Year 2021	22	22	22	0	0	0
Calendar Year 2022	35	35	35	0	0	0
Current Calendar Year 2023 (to date)	14	14	14	0	0	0

5. **License Type Name: Veterinarian CSR**

	# of License Applications Received	# of License Applications Approved	# of Licenses Issued	# of Licenses Rejected	# of Licenses Revoked	# of Licenses Suspended
Calendar Year 2020	34	35	35	0	0	0
Calendar Year 2021	33	32	32	0	0	0
Calendar Year 2022	25	25	25	0	0	0
Current Calendar Year 2023 (to date)	14	14	14	0	0	0

6. **License Type Name: Optometrist CSR**

	# of License Applications Received	# of License Applications Approved	# of Licenses Issued	# of Licenses Rejected	# of Licenses Revoked	# of Licenses Suspended
Calendar Year 2020	6	6	6	0	0	0
Calendar Year 2021	2	2	2	0	0	0
Calendar Year 2022	4	4	4	0	0	0
Current Calendar Year 2023 (to date)	0	0	0	0	0	0

7. **License Type Name: Podiatrist CSR**

	# of License Applications Received	# of License Applications Approved	# of Licenses Issued	# of Licenses Rejected	# of Licenses Revoked	# of Licenses Suspended
Calendar Year 2020	4	4	4	0	0	0
Calendar Year 2021	2	2	2	0	0	0
Calendar Year 2022	6	5	5	0	0	0
Current Calendar Year 2023 (to date)	0	0	0	0	0	0

Facilities

1. **License Type Name: Pharmacy CSR**

	# of License Applications Received	# of License Applications Approved	# of Licenses Issued	# of Licenses Rejected	# of Licenses Revoked	# of Licenses Suspended
Calendar Year 2020	56	66	66	0	0	0
Calendar Year 2021	81	81	81	0	0	0
Calendar Year 2022	70	70	70	0	0	0
Current Calendar Year 2023 (to date)	31	29	29	0	0	0

2. **License Type Name: Distributor/Manufacturer CSR**

	# of License Applications Received	# of License Applications Approved	# of Licenses Issued	# of Licenses Rejected	# of Licenses Revoked	# of Licenses Suspended
Calendar Year 2020	21	19	19	0	0	0
Calendar Year 2021	35	35	35	0	0	0
Calendar Year 2022	30	30	30	0	0	0
Current Calendar Year 2023 (to date)	9	8	8	0	0	0

3. **License Type Name: Hospital/Clinic CSR**

	# of License Applications Received	# of License Applications Approved	# of Licenses Issued	# of Licenses Rejected	# of Licenses Revoked	# of Licenses Suspended
Calendar Year 2020	2	2	2	0	0	0
Calendar Year 2021	15	15	15	0	0	0
Calendar Year 2022	6	5	5	0	0	0
Current Calendar Year 2023 (to date)	6	4	4	0	0	0

4. **License Type Name: Research/Laboratory CSR**

	# of License Applications Received	# of License Applications Approved	# of Licenses Issued	# of Licenses Rejected	# of Licenses Revoked	# of Licenses Suspended
Calendar Year 2020	3	2	2	0	0	0
Calendar Year 2021	2	3	3	0	0	0
Calendar Year 2022	1	1	1	0	0	0
Current Calendar Year 2023 (to date)	0	0	0	0	0	0

5. **License Type Name: <u>Other CSR</u> (make sure this is listed above)**

	# of License Applications Received	# of License Applications Approved	# of Licenses Issued	# of Licenses Rejected	# of Licenses Revoked	# of Licenses Suspended
Calendar Year 2020	0	0	0	0	0	0
Calendar Year 2021	0	0	0	0	0	0
Calendar Year 2022	0	0	0	0	0	0
Current Calendar Year 2023 (to date)	0	0	0	0	0	0

6. **License Type Name: Provider Pharmacy Facility CSR**

	# of License Applications Received	# of License Applications Approved	# of Licenses Issued	# of Licenses Rejected	# of Licenses Revoked	# of Licenses Suspended
Calendar Year 2020	0	0	0	0	0	0
Calendar Year 2021	1	1	1	0	0	0
Calendar Year 2022	0	0	0	0	0	0
Current Calendar Year 2023 (to date)	2	2	2	0	0	0