SPONSOR: Sen. Bushweller & Rep. Mitchell & Rep. Walker
Sens. Ennis, Henry; Reps. Bolden, Heffernan, Jaques, Dukes

DELAWARE STATE SENATE
147th GENERAL ASSEMBLY

SENATE BILL NO. 59

AN ACT TO AMEND TITLE 16 OF THE DELAWARE CODE RELATING TO THE REGULATION OF THE MANUFACTURE, DISTRIBUTION AND DISPENSING OF CONTROLLED SUBSTANCES, AND THE DELAWARE PRESCRIPTION MONITORING PROGRAM.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF DELAWARE:

Section 1. Amend Title 16, Chapter 47 of the Delaware Code by making deletions as shown by strike through and insertions as shown by underlining as follows:

§ 4731. Rules; fees; Controlled Substance Advisory Committee.

(a) The Secretary may promulgate rules and charge reasonable fees relating to the registration and control of the manufacture, distribution and dispensing of controlled substances within this State.

(b) The Secretary shall appoint a council to act in an advisory capacity to the Secretary and other state agencies on all matters relating to this chapter. The advisory council shall be named the Controlled Substance Advisory Committee and may serve as the Secretary's designee in any hearing under this chapter.

§ 4732. Registration requirements; exemptions; inspections.

(a) Any pharmacy, distributor, manufacturer, practitioner, researcher or ~~under the classification of "~~Other Controlled Substance Registrant~~s,"~~ who has or proposes to engage in activities accordingly within this State must obtain biennially a registration issued by the Secretary in accordance with the Secretary's rules.

(b) Any pharmacy, distributor, manufacturer, researcher or ~~classified under "~~Other Controlled Substance Registrant~~s" are~~ is limited to those substances to the extent authorized by their registration and in conformity with the other provisions of this subchapter.

(c) The following persons need not register and may lawfully possess controlled substances under this chapter:

(1) Any agent or employee of any registered manufacturer, distributor or dispenser of any controlled substance if the agent or employee is acting in the usual course of the agent's or employee's business or employment;

(2) A common or contract carrier or warehouseperson, or any employee thereof, whose possession of any controlled substance is in the usual course of business or employment; and

(3) An ultimate user or a person in possession of any controlled substance pursuant to a lawful order of a practitioner or in lawful possession of a Schedule V substance.

(d) The Secretary may waive by rule the requirement for registration of certain manufacturers, distributors or dispensers if the Secretary finds it consistent with the public ~~health and safety~~ interest.

(e) A separate registration is required at each principal place of business or professional practice where the applicant, including Other Controlled Substance Registrants, manufactures, distributes, dispenses or conducts research with controlled substances. ~~(Includes classification of "Other Controlled Substance Registrants").~~

(f) The Secretary or the Secretary's representative may inspect the establishment of any registrant or applicant for registration in accordance with the Secretary's rules.

(g) Every registrant under this chapter shall be required to report any change of professional or business address in such a manner as the Secretary may require by ~~regulation~~ rule.

§ 4733. Registration; rights of registrants.

(a) The Secretary shall register an applicant as a pharmacy, distributor, manufacturer, practitioner, researcher or ~~under the classification, "~~Other Controlled Substance Registrants~~"~~ for purposes of manufacturing, distributing or dispensing, some or all of the controlled substances included in ~~§§ 4714, 4716, 4718, 4720 and 4722~~ Schedules I-V who has an active Federal DEA registration and relevant underlying professional license in the State of Delaware 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 ~~includes~~ 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; ~~and~~

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

(8) Any other factors relevant to ~~and consistent with~~ the public ~~health and safety~~ interest.

(b) Registration under subsection (a) does not entitle a registrant to manufacture, research and distribute controlled substances ~~including the classification of "Other Controlled Substance Registrants"~~ in Schedule I or II other than those specified in the registration.

(c) Practitioners must be registered to dispense any controlled substances or to conduct research with controlled substances in Schedules II through V if they are authorized to dispense or conduct research under the law of this State. The Secretary need not require separate registration under this subchapter for practitioners engaging in research with nonnarcotic controlled substances in Schedules II through V where the registrant is already registered under this subchapter in another capacity. Practitioners registered under federal law to conduct research with Schedule I substances may conduct research with Schedule I substances within this State upon furnishing the Secretary evidence of that federal registration.

(d) Compliance by manufacturers and distributors with the federal law respecting registration (excluding fees) entitles them to be registered under this chapter.

§ 4734. Denial, ~~R~~revocation and suspension of registration; Order to show cause proceedings before the Secretary

(a) A registration under § 4733 of this title ~~as a pharmacy, distributor, manufacturer, practitioner, researcher or under the classification of "Other Controlled Substance Registrants"~~ may be denied, suspended or revoked by the Secretary upon a finding that ~~continued registration would be inconsistent with the public interest. In determining the public interest, the Secretary shall consider the following factors:~~ 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.

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

~~(2) Compliance with applicable state and local law including such events as a practitioner losing their license to practice or a drug detection animal trainer not obtaining or maintaining formal training and continuing education;~~

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

~~(4) The existence in the registrant's establishment of effective controls against diversion;~~

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

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

~~(7) Any other factors relevant to and consistent with the public health and safety.~~

~~(b) The Secretary may limit revocation or suspension of a registration to the particular controlled substance with respect to which grounds for revocation or suspension exist.~~

~~(c) 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 therefor 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.~~

~~(d) The Secretary shall promptly notify the Administration of all orders suspending or revoking registration and all forfeitures of controlled substances.~~

~~§ 4735. Order to show cause and subpoenas; judicial review.~~

~~(a)~~(b) Before denying, suspending or revoking a registration ~~or refusing a renewal of registration~~, the Secretary shall serve upon the applicant or registrant an order to show cause why registration should not be denied, suspended or revoked ~~or suspended or why the renewal should not be refused~~. 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 ~~less~~ more than 30 days after the date of service of the order~~, but in the case of a denial or renewal of registration the show cause order shall be served not later than 30 days before the expiration of the registration. These proceedings shall be conducted in accordance with the procedures established by the Secretary without regard to any criminal prosecution or other proceeding~~. Proceedings to refuse renewal of registration shall not abate the existing registration which shall remain in effect pending the outcome of the administrative hearing.

~~(b) The Secretary may suspend, without an order to show cause, any registration simultaneously with the institution of proceedings under § 4734 or where renewal of registration is refused, if the Secretary finds that there is an imminent danger to the public health or safety which warrants this action. The suspension shall continue in effect until the conclusion of the proceedings, including judicial review thereof, unless sooner withdrawn by the Secretary or dissolved by a court of competent jurisdiction.~~

~~(c) Any person complained against under this subchapter may appear personally or by counsel at the hearing and produce any competent evidence in the person's behalf in answer to the alleged violation. The Secretary shall be authorized to administer oaths, examine witnesses and issue, in the name of the Department of Health and Social Services, 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.~~

~~(d) Any party in interest aggrieved by a decision of the Secretary to deny, suspend, revoke or refuse to renew registration under this subchapter may appeal such decision to Superior Court. Such appeal shall be on the record and the~~

~~only question before said Court shall be whether the Secretary abused the Secretary's discretion. When notified of an appeal under this section, the Secretary shall forward to Superior Court a certified and complete copy of the written transcripts or taped voice records 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.~~

§ 4735. Investigations; written complaints; grounds for limitation, suspension or revocation of registration.

(a) All complaints shall be received and investigated by the Division of Professional Regulation in accordance with 29 *Del. C.* § 8735, and the Division of Professional Regulation shall be responsible for issuing a final written report at the conclusion of its investigation.

(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.

~~§ 4736. Authority of Secretary to impose fines.~~

~~(a) Whenever the Secretary has found a registrant to be guilty of a violation of this chapter or of rules adopted pursuant to this chapter, the Secretary shall, in addition to the power and authority granted the Secretary in this chapter, have the power to impose a fine on the registrant for such violation and require that such fine be paid, with the sanction that the person's registration may be suspended until the fine is paid. No fine imposed by the Secretary may exceed $500.~~

~~(b) Prior to the imposition of any fine, the Secretary shall hold an investigation and hearing after notice to the registrant or the registrant's attorney. A fine shall be imposed by the Secretary only upon finding that:~~

~~(1) The public welfare and morals would not be impaired by the imposition of such fine; and~~

~~(2) Payment of the sum of money will achieve the desired disciplinary purposes.~~

~~(c) The Secretary shall not impose a fine on a registrant whose registration has been revoked by the Secretary for such violation. The power and authority of the Secretary to impose such fines is not to be affected by any other proceeding, civil or criminal, concerning the same violation, nor shall the imposition of such fine preclude the Secretary from imposing other sanctions short of revocation.~~

~~(d) Any person so fined may appeal to the Superior Court for a trial de novo, provided the appeal is taken within 15 days of the time of the decision of the Secretary.~~

~~§ 4737. Records of registrants.~~

~~Persons registered to manufacture, distribute or dispense controlled substances under this chapter shall keep records and maintain inventories in conformance with the record-keeping and inventory requirements of federal law and with any additional rules the Secretary issues.~~

~~§ 4738. Order forms.~~

~~Controlled substances in Schedules I and II shall be distributed by a registrant to another registrant only pursuant to an order form. Compliance with federal law respecting order forms shall be deemed compliance with this section.~~

§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. 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 or taped voice records 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 therefore.

§ 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.

§ 4738. Records of registrants; Order forms

(a) Persons registered to prescribe, manufacture, distribute or dispense controlled substances under this chapter shall keep records and maintain inventories in conformance with the record-keeping and inventory requirements of federal and state law and with any rules the Secretary issues.

(b) Controlled substances in Schedules I and II shall be distributed by a registrant to another registrant only pursuant to an order form. Compliance with federal law respecting order forms shall be deemed compliance with this section.

§ 4739. Prescriptions.

(a) Except when dispensed directly by a practitioner other than a pharmacy to an ultimate user, no controlled substance in Schedule II may be dispensed without the written prescription of a practitioner.

(b) In emergency situations, as defined by rule of the Secretary, Schedule II drugs may be dispensed upon oral prescription of a practitioner, reduced promptly to writing and filed by the pharmacy. Prescriptions shall be retained in conformity with the requirements of ~~§ 4737~~this chapter. No prescription for a Schedule II substance may be refilled.

(c) Except when dispensed directly by a practitioner other than a pharmacy to an ultimate user, a controlled substance included in Schedule III or IV which is a prescription drug shall not be dispensed without a written or oral prescription of a practitioner. The prescription shall not be filled or refilled more than 6 months after the date thereof or be refilled more than 5 times, unless renewed by the practitioner.

(d) A controlled substance included in Schedule V shall not be distributed or dispensed other than for a medical purpose.

Section 2. Amend § 4798(b), Title 16 of the Delaware Code by making insertions as shown by underlining and deletions as shown by strike through as follows:

(b) Definitions. –

(1) "Administer" or "administration" means the direct application of a drug to the body of a patient by injection, inhalation, ingestion, or any other means.

(2) "Chemical dependency professional" means a person who uses addiction counseling methods to assist an individual or group to develop an understanding of alcohol and drug dependency problems, define goals, and plan action reflecting the individual's or group's interest, abilities and needs as affected by addiction problems

~~(2)~~ (3)"Controlled substance" means any substance or drug defined, enumerated or included in this chapter and Title 21, Code of Federal Regulations.

~~(3)~~ (4)"Dispense" or "dispensing" means the interpretation, evaluation, and implementation of a prescription drug or, including the preparation and delivery of a drug to a patient or patient's agent in a suitable container appropriately labeled for subsequent administration to, or use by, a patient.

~~(4)~~ (5) "Dispenser" means a person authorized by this State to dispense or distribute to the ultimate user any controlled substance or drug monitored by the program, but shall not include any of the following: a licensed health care facility pharmacy that dispenses or distributes any controlled substance or drug monitored by the program for the purposes of inpatient care, emergency department care for the immediate use of a controlled substance or when dispensing up to a 72-hour supply of a controlled substance or a drug of concern monitored by the program at the time of discharge from such a facility.

~~(5)~~ (6) "Distribute" or "distribution" means the delivery of a drug other than by administering or dispensing.

~~(6)~~ (7)"Drug" means any of the following:

a. Any substance recognized as a drug in the official compendium, or supplement thereto, designated by the Office of Controlled Substances for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans.

b. Any substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease or pain in humans.

c. Any substance other than food intended to affect the structure or any function of the body of humans.

~~(7)~~ (8)"Drugs of concern" means drugs other than controlled substances as defined by rule which demonstrate a potential for abuse or diversion.

(9) "Licensed professional counselor of mental health" means an individual licensed as a professional counselor of mental health who publicly offers to render to individuals, groups, organizations or the general public a service involving the application of clinical counseling principles, methods or procedures and the diagnosis and treatment of mental and emotional disorders to assist individuals in achieving more effective personal and social adjustment.

~~(8)~~ (10) "Patient" means the person who is the ultimate user of a controlled substance or drug monitored by the program for whom a prescription is issued and for whom a controlled substance or drug is dispensed.

~~(9)~~ (11)"Prescriber" means a licensed health care professional with the authority to write and issue prescriptions, except it shall not include:

a. A prescriber or other authorized person who administers such controlled substance or drug upon the lawful order of a prescriber.

b. A prescriber or other authorized person who, in providing emergency patient care in a healthcare facility, causes the administration of a controlled substance for immediate relief of symptoms arising from an acute condition.

c. A prescriber or other authorized person who ~~prescribes~~ dispenses up to a 72-hour supply of a controlled substance for on call services or emergency care.

d. A veterinarian who prescribes for the purpose of providing veterinary services.

~~(10)~~ (12)"Prescription monitoring information" means data submitted to and maintained by the prescription monitoring program established under this section.

~~(11)~~ (13)"Prescription Monitoring Program" or "PMP" means the electronic program established by this section.

(c) The Office of Controlled Substances shall establish and maintain a PMP program to monitor the prescribing and dispensing of all Schedule II, III, IV and V controlled substances by prescribers in this State, and to research the prescribing and dispensing of drugs of concern. The PMP shall not interfere with the legal use of a controlled substance or drug of concern. The PMP shall be:

(1) Used to provide information to prescribers, dispensers, and patients to help avoid the illegal use of controlled substances;

(2) Used to assist law enforcement to investigate illegal activity related to the prescribing, dispensing and consumption of controlled substances or drugs of concern; and

(3) Designed to minimize inconvenience to patients and prescribing medical practitioners while effectuating the collection and storage of prescription monitoring information.

(d) A dispenser shall submit the required information regarding each prescription dispensed for a controlled substance, in accordance with the transmission methods and frequency established by regulation issued by the Office of Controlled Substances. When needed for bona fide research purposes and in accordance with applicable regulation, the Office of Controlled Substances may require a dispenser to submit the required information regarding each prescription dispensed for a drug of concern, but in no event should dispensers be required to submit such information any more frequently than that required for controlled substances. The following information shall be submitted for each prescription:

(1) Pharmacy name;

(2) Dispenser DEA registration number;

(3) Date drug was dispensed;

(4) Prescription number;

(5) Whether prescription is new or a refill;

(6) NDC code for drug dispensed;

(7) Quantity dispensed;

(8) Approximate number of days supplied;

(9) Patient name and date of birth;

(10) Patient address;

(11) Prescriber DEA registration number and name;

(12) Date prescription issued by prescriber.

(e) When a dispenser has a reasonable belief that a patient may be seeking a controlled substance listed in Schedule II, III, IV or V for any reason other than the treatment of an existing medical condition, the dispenser shall obtain a patient utilization report regarding the patient for the preceding 12 months from the Prescription Monitoring Program before dispensing the prescription.

~~(e)~~ (f) A prescriber, or other person authorized by the prescriber, shall obtain, before writing a prescription for a controlled substance listed in Schedule II, III, IV or V for a patient, a patient utilization report regarding the patient for the preceding 12 months from the computerized program established by the Office of Controlled Substances when the prescriber has a reasonable belief that the patient may be seeking the controlled substance, in whole or in part, for any

reason other than the treatment of an existing medical condition. The prescriber shall review the patient utilization report to assess whether the prescription for the controlled substance is necessary.

(g) A licensed chemical dependency professional or licensed professional counselor of mental health may obtain a patient utilization report from the Prescription Monitoring Program for patients enrolled in substance abuse treatment programs receiving treatment from, or under the direction of, the chemical dependency professional or professional counselor of mental health,

(h) The Chief Medical Examiner or licensed physician designee may obtain a patient utilization report from the Prescription Monitoring Program for the purpose of investigating the death of an individual.

~~(f)~~ (i)The Office of Controlled Substances may issue a waiver to a prescriber who is unable to access prescription information by electronic means. A prescriber who is unable to access prescription information by electronic means shall obtain a waiver from the OCS on annual basis until such time they can access the prescription information by electronic means.

~~(g)~~(h) Unless a court of competent jurisdiction makes a finding of gross negligence, malice or criminal intent, the Office of Controlled Substances, any other state agency, any prescriber or dispenser, or any person or entity in proper possession of information pursuant to this statute is not subject to civil liability, administrative action or other legal or equitable relief for any of the following acts or omissions:

(1) Furnishing information pursuant to this section.

(2) Receiving, using or relying on, or not using or relying on, information received pursuant to this section.

(3) Information that was not furnished to the Office of Controlled Substances.

(4) Information that was factually incorrect or that was released by the Office of Controlled Substance to the wrong person or entity.

~~(h)~~(i) Prescription information submitted to the PMP is protected health information, not subject to public or open records law, and not subject to disclosure, except as otherwise provided in this section.

~~(i)~~(j) The Office of Controlled Substances shall maintain procedures to ensure that the privacy and confidentiality of patients and patient information collected, recorded, transmitted, and maintained is not disclosed, except as provided for in this section.

(1) If there is reasonable cause to believe a violation of law or breach of professional standards may have occurred, the Office of Controlled Substances shall notify the appropriate law-enforcement or professional licensure, certification, or regulatory agency or entity and shall provide prescription information required for an investigation.

(2) The Office of Controlled Substances may provide data in the prescription monitoring program in the form of a report to the following persons:

a. A prescriber, or other person authorized by the prescriber, or a dispenser, or other person authorized by the dispenser, who requests information and certifies that the requested information is for the purpose of providing medical or pharmaceutical treatment to a bona fide patient;

b. An individual who requests the individual's own prescription monitoring information in accordance with procedures established pursuant to regulations;

c. A designated representative of any Board or Commission pursuant to § 8735(a) of Title 29 responsible for the licensure, regulation, or discipline of prescribers, dispensers or other persons authorized to prescribe, administer, or dispense controlled substances and who is involved in a bona fide specific investigation involving a designated person;

d. A local, state, or federal law-enforcement or prosecutorial official engaged in the administration, investigation, or enforcement of the laws governing controlled substances and who is involved in a bona fide specific drug-related investigation in which a report of suspected criminal activity involving controlled substances by an identified suspect has been made, and provided that such information be relevant and material to such investigation, limited in scope to the extent reasonably practicable in light of the purpose for which the information is sought, and include identifying information only if nonidentifying information could not be used;

e. The Delaware Department of Health and Social Services regarding Medicaid program recipients;

f. A properly convened grand jury pursuant to a subpoena properly issued for the records;

g. Personnel of the Division of Professional Regulation for purposes of administration and enforcement of this section;

h. A licensed chemical dependency professional or licensed professional counselor of mental health who requests information and certifies that the requested information is for a patient enrolled in a substance abuse treatment program receiving treatment from, or under the direction of the chemical dependency professional or professional counselor of mental health.

i. The Chief Medical Examiner or licensed physician designee who requests information and certifies the request is for the purpose of investigating the death of an individual.

~~h.~~ j. Qualified personnel for the purpose of bona fide research or education; however, data elements that would reasonably identify a specific recipient, prescriber or dispenser must be deleted or redacted from such information prior to disclosure; and further provided that, release of the information may be made only pursuant to a written agreement between qualified personnel and the Office of Controlled Substances in order to ensure compliance with this subsection.

~~(j)~~(k) The Division of Professional Regulation may contract with another agency of this State or with a private vendor, as necessary, to ensure the effective operation of the prescription monitoring program. A contractor shall comply with the

provisions regarding confidentiality of prescription information under this section is subject to the penalties specified in this section for any unlawful acts.

~~(k)~~(l) The Office of Controlled Substances may promulgate regulations setting forth the procedures and methods for implementing this section.

~~(l)~~(m) The Office of Controlled Substances shall design and implement an evaluation component to identify cost-benefits of the Prescription Monitoring Program, including its effect on diversion and abuse of controlled substances and drugs of concern, and other information relevant to policy, research and education involving controlled substances and drugs of concern monitored by the Prescription Monitoring Program.

(1) The Office of Controlled Substances shall report to the General Assembly the information obtained pursuant to this subsection on an annual basis.

(2) To the extent such information is made available to the Office of Controlled Substances, the report may include information and data, including surveys, polls, or other data from multi-disciplinary experts and stakeholders, relating to the negative or positive impact of the prescription monitoring program on appropriate prescribing practices of controlled substances and drugs of concern.

(n) The Office of Controlled Substances may exchange prescription information submitted to the PMP through an interstate commission with an authorized member state

.~~(m)~~(o) A dispenser who fails to submit prescription monitoring information to the Office of Controlled Substances PMP as required by this section, or who knowingly submits incorrect prescription information, shall be subject to disciplinary sanction pursuant to ~~Chapter 25 of~~ Title 24.

~~(n)~~(p) A person or persons authorized to have prescription monitoring information pursuant to this section who knowingly discloses this information in violation of this section is guilty of a class G felony and, upon conviction, shall be fined not more than $5,000 nor imprisoned more than 2 years, or both.

~~(o)~~(q) A person authorized to have prescription monitoring information pursuant to this section who intentionally uses this information in the furtherance of other crimes is guilty of a class E felony and, upon conviction, shall be fined not more than $10,000 nor imprisoned more than 5 years, or both.

~~(p)~~(r) A person or persons not authorized to have prescription monitoring information pursuant to this section who obtain such information fraudulently is guilty of a class E felony and, upon conviction, shall be fined not more than $10,000 nor imprisoned more than 5 years, or both.

SYNOPSIS

Section 1 creates the Controlled Substance Advisory Committee, a designee/recommending body that previously existed only in regulation; makes numerous grammatical corrections; makes uniform the language pertaining to the Secretary's duty to the public interest; codifies requirements applicants must meet before they are issued a controlled substance registration; adds discipline of one's professional license as a basis to have a controlled substance registration denied or disciplined; limits the Secretary's power to issue a rule to show cause order to those instances in which a registrant no longer meets the requirements for registration or has failed to complete mandatory continued education; increases the Secretary's power to fine from $500 to $1,000 per offense; clarifies that all hearings contemplated by this Subchapter are governed by the APA; and revamps the Secretary's power to temporarily suspend a controlled substance registration to create a process akin to that used by the Board of Medical Licensure & Discipline.

Section 2 corrects § 4798 (b)(9)(c) by deleting the word "prescribes" and replacing it with "dispenses".

Section 2 of this bill also creates a new requirement that dispensers check the patient utilization report for the past 12 months of any patient that the dispenser has a reasonable belief may be seeking controlled substances for any non-medical reason. This provision was inadvertently omitted from the initial bill creating the Prescription Monitoring Program.

Section 2 of this bill authorizes licensed chemical dependency professionals and licensed professional counselors of mental health to access the Prescription Monitoring Program when a patient is enrolled in a substance abuse treatment program, and for the Chief Medical Examiner or a licensed physician designee for the purpose of investigating a person's death. Finally, the bill authorizes the exchange of prescription information submitted to the PMP through an interstate commission with an authorized member state.

Author: Sen. Bushweller