Proposed Amendments – Iowa Code Chapter 24 re PMP Program: DIVISION VI – DRUG PRESCRIBING AND DISPENSING — INFORMATION PROGRAM

124.550 Definitions.

For the purposes of this division, unless the context otherwise requires:

- 1. "Pharmacist" means a practicing pharmacist who is actively engaged in and responsible for the pharmaceutical care of the patient about whom information is requested.
- 2. "Prescribing practitioner" means a practitioner who has prescribed or is contemplating the authorization of a prescription for the patient about whom information is requested.

124.551 Information program for drug prescribing and dispensing.

- 1. Contingent upon the receipt of funds pursuant to section 124.557 sufficient to carry out the purposes of this division, the board, in conjunction with the advisory council created in section 124.555, shall establish and maintain an information program for drug prescribing and dispensing.
- 2. The program shall collect from pharmacies dispensing information for controlled substances identified pursuant to section 124.554, subsection 1, paragraph "g". The information collected shall be used by prescribing practitioners and pharmacists on a need-to-know basis for purposes of improving patient health care by facilitating early identification of patients who may be at risk for addiction, or who may be using, abusing, or diverting drugs for unlawful or otherwise unauthorized purposes at risk to themselves and others, or who may be appropriately using controlled substances lawfully prescribed for them but unknown to the practitioner.
- 3. The board shall implement technological improvements to facilitate secure access to the program through electronic health and pharmacy information systems. The board shall collect, store, and disseminate program information consistent with security criteria established by rule, including use of appropriate encryption or other industry-recognized security technology.
- 4. The board shall seek any federal waiver necessary to implement the provisions of the program.

124.552 Information reporting.

- 1. Each Unless otherwise prohibited by federal or state law, each licensed pharmacy that dispenses controlled substances identified pursuant to section 124.554, subsection 1, paragraph "g", to patients in the state, and each licensed pharmacy located in the state that dispenses such controlled substances identified pursuant to section 124.554, subsection 1, paragraph "g", to patients inside or outside the state, unless specifically excepted in this section or by rule, and each prescribing practitioner furnishing, dispensing, or supplying drugs to the prescribing practitioner's patient, shall submit the following prescription information to the program:
 - a. Pharmacy identification.
 - b. Patient identification.

- c. Prescribing practitioner identification.
- d. The date the prescription was issued by the prescribing practitioner.
- e. The date the prescription was dispensed.
- f. An indication of whether the prescription dispensed is new or a refill.
- g. Identification of the drug dispensed.
- h. Quantity of the drug dispensed.
- *i.* The number of days' supply of the drug dispensed.
- *j.* Serial or prescription number assigned by the pharmacy.
- *k.* Type of payment for the prescription.
- 1. Other information identified by the board and advisory council by rule.
- 2. Information shall be submitted electronically in a secure format specified by the board unless the board has granted a waiver and approved an alternate secure format.
- 3. Information shall be timely transmitted as designated by the board and advisory council by rule, unless the board grants an extension. The board may grant an extension if either of the following occurs:
- a. The pharmacy or prescribing practitioner suffers a mechanical or electronic failure, or cannot meet the deadline established by the board for other reasons beyond the pharmacy's or practitioner's control.
 - b. The board is unable to receive electronic submissions.
- 4. This section shall not apply to a prescribing practitioner furnishing, dispensing, supplying, or administering drugs to the prescribing practitioner's patient, or to dispensing by a licensed pharmacy for the purposes of inpatient hospital care, inpatient hospice care, or long-term residential facility patient care.

124.553 Information access.

- 1. The board may provide information from the program to the following:
- a. (1) A pharmacist or prescribing practitioner who requests the information and certifies in a form specified by the board that it is for the purpose of providing medical or pharmaceutical care to a patient of the pharmacist or prescribing practitioner. A pharmacist or a prescribing practitioner may delegate program information access to another authorized individual or agent only if that individual or agent registers for program information access, pursuant to board rules, as an agent of the pharmacist or prescribing practitioner. Board rules shall identify the qualifications for a pharmacist's or prescribing practitioner's agent and shall limit the number of agents to whom each pharmacist or prescribing practitioner may delegate program information access.
- (2) Notwithstanding subparagraph (1), a prescribing practitioner may delegate program information access to another licensed health care professional in emergency situations where the patient would be placed in greater jeopardy if the prescribing practitioner was required to access the information personally.
- b. An individual who requests the individual's own program information in accordance with the procedure established in rules of the board and advisory council adopted under section 124.554.

- c. Pursuant to an order, subpoena, or other means of legal compulsion for access to or release of program information that is issued based upon a determination of probable cause in the course of a specific investigation of a specific individual.
- d. A prescription database or monitoring program in another jurisdiction pursuant to subsection 8.
- e. An institutional user established by the board to facilitate the secure access of a prescribing practitioner or pharmacist to the program through electronic health and pharmacy information systems.
- f. By targeted distribution of unsolicited reports, a prescribing practitioner or a pharmacist who has been involved in authorizing or dispensing controlled substances to a patient who has been identified, based on thresholds or criteria designed to identify doctor or pharmacy shopping or the patient's excessive use of a controlled substance, as an at-risk patient who may be abusing or misusing controlled substances or who may be in jeopardy of overdose or addiction to controlled substances.
- 2. The board shall maintain a record of each person that requests information from the program and of all unsolicited reports distributed as provided in 124.553, subsection 1, paragraph "f". Pursuant to rules adopted by the board and advisory council under section 124.554, the board may use the records to document and report statistical information, and may provide program information for statistical, public research, public policy, or educational purposes, after removing personal identifying information of a patient, prescribing practitioner, dispenser, or other person who is identified in the information.
- 3. Information contained in the program and any information obtained from it, and information contained in the records of requests for information from the program and of unsolicited reports distributed to prescribing practitioners and dispensing pharmacists, is privileged and strictly confidential information. Such information is a confidential public record pursuant to section 22.7, and is not subject to discovery, subpoena, or other means of legal compulsion for release except as provided in this division. Information from the program shall not be released, shared with an agency or institution, or made public except as provided in this division.
- 4. Information collected for the program shall be retained in the program for four years from the date of dispensing. The information shall then be destroyed.
- 5. A pharmacist or other dispenser making a report to the program reasonably and in good faith pursuant to this division is immune from any liability, civil, criminal, or administrative, which might otherwise be incurred or imposed as a result of the report.
- 6. Nothing in this section shall require a pharmacist or prescribing practitioner to obtain information about a patient from the program. A pharmacist or prescribing practitioner does not have a duty and shall not be held liable in damages to any person in any civil or derivative criminal or administrative action for injury, death, or loss to person or property on the basis that the pharmacist or prescribing practitioner did or did not seek or obtain or use information from the program. A pharmacist or prescribing practitioner acting reasonably and in good faith is immune from any civil, criminal, or administrative liability that might otherwise be incurred or imposed for requesting or receiving or using information from the program.

- 7. The board shall not charge a fee to a pharmacy, pharmacist, or prescribing practitioner for the establishment, maintenance, or administration of the program, including costs for forms required to submit information to or access information from the program, except that the board may charge a fee to an individual who requests the individual's own program information. A fee charged pursuant to this subsection shall not exceed the actual cost of providing the requested information and shall be considered a repayment receipt as defined in section 8.2.
- 8. The board may enter into an agreement with a prescription database or monitoring program operated in a state bordering this state or in the state of Kansas any state for the mutual exchange of information. Any agreement entered into pursuant to this subsection shall specify that all the information exchanged pursuant to the agreement shall be used and disseminated in accordance with the laws of this state. *Referred to in* §22.7, §124.554, §124.558

124.554 Rules and reporting.

- 1. The board and advisory council shall jointly adopt rules in accordance with chapter 17A to carry out the purposes of, and to enforce the provisions of, this division. The rules shall include but not be limited to the development of procedures relating to:
 - a. Identifying each patient about whom information is entered into the program.
- *b.* An electronic format for the submission of information from pharmacies <u>and prescribing practitioners</u>.
- c. A waiver to submit information in another format for a pharmacy or prescribing practitioner unable to submit information electronically.
- d. An application by a pharmacy or prescribing practitioner for an extension of time for transmitting information to the program.
- e. The submission by an authorized requestor of a request for information and a procedure for the verification of the identity of the requestor.
- *f.* Use by the board or advisory council of the program request records required by section 124.553, subsection 2, to document and report statistical information.
- g. Including all schedule II through IV controlled substances and those substances in schedules III and IV that the advisory council and board determine can be addictive or fatal if not taken under the proper care and direction of a prescribing practitioner schedule V controlled substances except when dispensed by a pharmacist without a prescription.
- *h.* Access by a pharmacist or prescribing practitioner to information in the program pursuant to a written agreement with the board and advisory council.
 - *i.* The correction or deletion of erroneous information in the program.
- *j.* The establishment of thresholds or other criteria or measures to be used in identifying an at-risk patient as provided in section 124.553, subsection 1, paragraph "f," and the targeted distribution of unsolicited reports suggesting review of the patient's prescription history.
- 2. Beginning January 1, 2007 15, 2018, and annually by January 1 15 thereafter, the board and advisory council shall present to the general assembly and the governor

a report prepared consistent with section 124.555, subsection 3, paragraph "d", which shall include but not be limited to the following:

- a. The cost to the state of implementing and maintaining the program.
- b. Information from pharmacies, prescribing practitioners, the board, the advisory council, and others regarding the benefits or detriments of the program.
- c. Information from pharmacies, prescribing practitioners, the board, the advisory council, and others regarding the board's effectiveness in providing information from the program.

Referred to in §124.551, §124.552, §124.553, §124.555, §124.556

124.555 Advisory council established.

An advisory council shall be established to provide oversight to the board and the program and to comanage program activities. The board and advisory council shall jointly adopt rules specifying the duties and activities of the advisory council and related matters.

- 1. The council shall consist of eight members appointed by the governor. The members shall include three licensed pharmacists, four physicians licensed under chapter 148, and one licensed prescribing practitioner who is not a physician. The governor shall solicit recommendations for council members from Iowa health professional licensing boards, associations, and societies. The license of each member appointed to and serving on the advisory council shall be current and in good standing with the professional's licensing board.
- 2. The council shall advance the goals of the program, which include identification of misuse and diversion of controlled substances identified pursuant to section 124.554, subsection 1, paragraph "g", reduction of drug overdose and death attributable to prescription drug use and abuse, and enhancement of the quality of health care delivery in this state.
 - 3. Duties of the council shall include but not be limited to the following:
- a. Ensuring the confidentiality of the patient, prescribing practitioner, and dispensing pharmacist and pharmacy.
- *b.* Respecting and preserving the integrity of the patient's treatment relationship with the patient's health care providers.
- c. Encouraging and facilitating cooperative efforts among health care practitioners and other interested and knowledgeable persons in developing best practices for prescribing and dispensing controlled substances and in educating health care practitioners and patients regarding controlled substance use and abuse.
- d. Making recommendations regarding the continued benefits of maintaining the program in relationship to cost and other burdens to the patient, prescribing practitioner, pharmacist, and the board. The council's recommendations shall be included in reports required by section 124.554, subsection 2.
- e. One physician and one pharmacist member of the council shall include in their duties the responsibility for monitoring and ensuring that patient confidentiality, best interests, and civil liberties are at all times protected and preserved during the existence of the program.

4. Members of the advisory council shall be eligible to request and receive actual expenses for their duties as members of the advisory council, subject to reimbursement limits imposed by the department of administrative services, and shall also be eligible to receive a per diem compensation as provided in section 7E.6, subsection 1. Referred to in §124.551, §124.554

124.556 Education and treatment.

The program for drug prescribing and dispensing shall include education initiatives and outreach to consumers, prescribing practitioners, and pharmacists, and shall also include assistance for identifying substance abuse treatment programs and providers. The board and advisory council shall adopt rules, as provided under section 124.554, to implement this section.

124.557 Drug information program fund.

The drug information program fund is established to be used by the board to fund or assist in funding the program. The board may make deposits into the fund from any source, public or private, including grants or contributions of money or other items of value, which it determines necessary to carry out the purposes of this division. Moneys received by the board to establish and maintain the program must be used for the expenses of administering this division. Notwithstanding section 8.33, amounts contained in the fund that remain unencumbered or unobligated at the close of the fiscal year shall not revert but shall remain available for expenditure for the purposes designated in future years.

Referred to in §124.551

124.558 Prohibited acts — penalties.

- 1. Failure to comply with requirements. A pharmacist, pharmacy, prescribing practitioner, or agent of a pharmacist or prescribing practitioner who knowingly fails to comply with the confidentiality requirements of this division or who delegates program information access to another individual except as provided in section 124.553, is subject to disciplinary action by the appropriate professional licensing board. A prescribing practitioner, pharmacist, or pharmacy that knowingly fails to comply with other requirements of this division is subject to disciplinary action by the board. Each licensing board may adopt rules in accordance with chapter 17A to implement the provisions of this section.
- 2. Unlawful access, disclosure, or use of information. A person who intentionally or knowingly accesses, uses, or discloses program information in violation of this division, unless otherwise authorized by law, is guilty of a class "D" felony. This section shall not preclude a pharmacist or prescribing practitioner who requests and receives information from the program consistent with the requirements of this chapter from otherwise lawfully providing that information to any other person for medical or pharmaceutical care purposes.