House File 2377 - Introduced

HOUSE FILE 2377
BY COMMITTEE ON HUMAN RESOURCES

(SUCCESSOR TO HF 2299)

A BILL FOR

An Act relating to the regulation of the practice of pharmacy, providing penalties, and including effective date provisions.

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

TLSB 6028HV (3) 87
ss/rh

DIVISION I

REGULATION OF THE PRESCRIPTION MONITORING PROGRAM

Section 1. Section 124.550, Code 2018, is amended by adding the following new subsection:

NEW SUBSECTION. 3. *"Program"* means the information program for drug prescribing and dispensing.

Sec. 2. Section 124.551, subsection 2, Code 2018, is amended to read as follows:

2. The program shall collect from pharmacies dispensing information for controlled substances identified pursuant to section 124.554, subsection 1, paragraph *"g"*, and from first responders as defined in section 147A.1 administration information for opioid antagonists. 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.

Sec. 3. NEW SECTION. **124.551A Prescribing practitioner program registration.**

A prescribing practitioner shall register for the program at the same time the practitioner applies to the board to register or renews registration to prescribe controlled substances as required by the board. Once the prescribing practitioner registers for the program, the practitioner shall utilize the program database as prescribed by rule to assist the prescribing practitioner in determining appropriate treatment options and to improve the quality of patient care. A prescribing practitioner shall not be required to utilize the program database to assist in the treatment of a patient receiving inpatient hospice care or long-term residential facility patient care.

Sec. 4. Section 124.552, Code 2018, is amended to read as follows:

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 controlled substances 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.

l. 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~~ within twenty-four

hours of the dispensing of the controlled substance, 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.

Sec. 5. Section 124.553, subsection 4, Code 2018, is amended by striking the subsection.

Sec. 6. Section 124.554, subsection 1, paragraphs b, c, d, and g, Code 2018, are amended to read as follows:

b. An electronic format for the submission of information from pharmacies and prescribing practitioners.

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.

g. Including all schedule II 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, and opioid antagonists.

Sec. 7. Section 124.557, Code 2018, is amended to read as follows:

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 subchapter. The board may add a surcharge of not more than twenty-five percent to the applicable fee for a registration issued pursuant to section 124.302 and the surcharge shall be deposited into the fund. Moneys received by the board to establish and maintain the program must be used for the expenses of administering this subchapter. 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.

Sec. 8. Section 124.558, subsection 1, Code 2018, is amended to read as follows:

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 subchapter 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 pharmacist, ~~or~~ pharmacy, or prescribing practitioner that knowingly fails to comply with other requirements of this subchapter 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.

Sec. 9. Section 147A.4, Code 2018, is amended by adding the following new subsection:

NEW SUBSECTION. 5. The department shall adopt rules requiring first responders to report to the program the following information regarding the administration of opioid antagonists by first responders:

a. Patient identification.

b. Identification of the person administering opioid antagonists.

c. The date of administration.

d. The quantity of opioid antagonists administered.

DIVISION II

ELECTRONIC PRESCRIPTIONS

Sec. 10. Section 124.308, Code 2018, is amended by striking the section and inserting in lieu thereof the following:

124.308 Prescriptions.

1. Except when dispensed directly by a practitioner to an ultimate user, a prescription drug as defined in section 155A.3 that is a controlled substance shall not be dispensed without a prescription, unless such prescription is authorized by a practitioner and complies with this section, section 155A.27, applicable federal law and regulation, and rules of the board.

2. *a.* Beginning January 1, 2020, every prescription issued for a controlled substance shall be transmitted electronically as an electronic prescription pursuant to the requirements in subsection 2, paragraph *"b"*, unless exempt under subsection 2, paragraph *"c"*.

b. Except for prescriptions identified in paragraph *"c"*, a prescription that is transmitted pursuant to paragraph *"a"* shall be transmitted to a pharmacy by a practitioner or the practitioner's authorized agent in compliance with federal law and regulation for electronic prescriptions of controlled substances. The practitioner's electronic prescription system and the receiving pharmacy's dispensing system shall comply with federal law and regulation for electronic prescriptions of controlled substances.

c. Paragraph *"b"* shall not apply to any of the following:

(1) A prescription for a patient residing in a nursing home, long-term care facility, correctional facility, or jail.

(2) A prescription authorized by a licensed veterinarian.

(3) A prescription dispensed by a department of veterans affairs pharmacy.

(4) A prescription requiring information that makes electronic submission impractical, such as complicated or lengthy directions for use or attachments.

(5) A prescription for a compounded preparation containing two or more components.

(6) A prescription issued in response to a public health emergency in a situation where a non-patient specific prescription would be permitted.

(7) A prescription issued pursuant to an established and valid collaborative practice agreement, standing order, or drug research protocol, except for a standing order for an opioid antagonist.

(8) A prescription issued during a temporary technical or electronic failure at the prescriber's or pharmacy's location.

(9) A prescription issued in an emergency situation pursuant to federal law and regulation rules of the board.

d. A practitioner, as defined in section 124.101, subsection 27, paragraph *"a"*, who violates paragraph *"a"* is subject to an administrative penalty of two hundred fifty dollars per violation, up to a maximum of five thousand dollars per calendar year. The assessment of an administrative penalty pursuant to this paragraph by the appropriate licensing board of the practitioner alleged to have violated paragraph *"a"* shall not be considered a disciplinary action and shall not be released or reported as discipline. A practitioner may appeal the assessment of an administrative penalty pursuant to this paragraph, which shall initiate a contested case proceeding under chapter 17A. A penalty collected pursuant to this paragraph shall be deposited into the drug information program fund established pursuant to section 124.557. The board shall be notified of any administrative penalties assessed by the appropriate professional licensing board and deposited into the drug information program fund under this paragraph.

3. A prescription issued prior to January 1, 2020, or a prescription that is exempt from the electronic prescription

requirement in subsection 2, paragraph "*c*", may be transmitted by a practitioner or the practitioner's authorized agent to a pharmacy in any of the following ways:

a. Electronically, if transmitted in accordance with the requirements for electronic prescriptions pursuant to subsection 2.

b. By facsimile for a schedule III, IV, or V controlled substance, or for a schedule II controlled substance only pursuant to federal law and regulation and rules of the board.

c. Orally for a schedule III, IV, or V controlled substance, or for a schedule II controlled substance only in an emergency situation pursuant to federal regulation and rules of the board.

d. By providing an original signed prescription to a patient or a patient's authorized representative.

4. If permitted by federal law and in accordance with federal requirements, an electronic or facsimile prescription shall serve as the original signed prescription and the practitioner shall not provide a patient, a patient's authorized representative, or the dispensing pharmacy with a signed, written prescription. An original signed prescription shall be retained for a minimum of two years from the date of the latest dispensing or refill of the prescription.

5. A prescription for a schedule II controlled substance shall not be filled more than six months after the date of issuance. A prescription for a schedule II controlled substance shall not be refilled.

6. A prescription for a schedule III, IV, or V controlled substance shall not be filled or refilled more than six months after the date on which the prescription was issued or be refilled more than five times.

7. A controlled substance shall not be distributed or dispensed other than for a medical purpose.

8. A practitioner, medical group, or pharmacy that is unable to timely comply with the electronic prescribing requirements

in subsection 2, paragraph *"b"*, may petition the board for an exemption from the requirements based upon economic hardship, technical limitations that the practitioner, medical group, or pharmacy cannot control, or other exceptional circumstances. The board shall adopt rules establishing the form and specific information to be included in a request for an exemption and the specific criteria to be considered by the board in determining whether to approve a request for an exemption. The board may approve an exemption for a period of time determined by the board not to exceed one year from the date of approval, and may be renewed annually upon request subject to board approval.

Sec. 11. Section 155A.27, Code 2018, is amended by striking the section and inserting in lieu thereof the following:

155A.27 Requirements for prescription.

1. Except when dispensed directly by a prescriber to an ultimate user, a prescription drug shall not be dispensed without a prescription, authorized by a prescriber, and based on a valid patient-prescriber relationship.

2. *a.* Beginning January 1, 2020, every prescription issued for a prescription drug shall be transmitted electronically as an electronic prescription to a pharmacy by a prescriber or the prescriber's authorized agent unless exempt under paragraph *"b"*.

b. Paragraph *"a"* shall not apply to any of the following:

(1) A prescription for a patient residing in a nursing home, long-term care facility, correctional facility, or jail.

(2) A prescription authorized by a licensed veterinarian.

(3) A prescription for a device.

(4) A prescription dispensed by a department of veterans affairs pharmacy.

(5) A prescription requiring information that makes electronic transmission impractical, such as complicated or lengthy directions for use or attachments.

(6) A prescription for a compounded preparation containing

two or more components.

(7) A prescription issued in response to a public health emergency in a situation where a non-patient specific prescription would be permitted.

(8) A prescription issued for epinephrine pursuant to section 135.185.

(9) A prescription issued pursuant to an established and valid collaborative practice agreement, standing order, or drug research protocol except for a standing order for an opioid antagonist.

(10) A prescription issued during a temporary technical or electronic failure at the location of the prescriber or pharmacy.

(11) A prescription issued in an emergency situation pursuant to federal law and regulation and rules of the board.

c. A practitioner, as defined in section 124.101, subsection 27, paragraph *"a"*, who violates paragraph *"a"* is subject to an administrative penalty of two hundred fifty dollars per violation, up to a maximum of five thousand dollars per calendar year. The assessment of an administrative penalty pursuant to this paragraph by the appropriate licensing board of the practitioner alleged to have violated paragraph *"a"* shall not be considered a disciplinary action and shall not be released or reported as discipline. A practitioner may appeal the assessment of an administrative penalty pursuant to this paragraph, which shall initiate a contested case proceeding under chapter 17A. A penalty collected pursuant to this paragraph shall be deposited into the drug information program fund established pursuant to section 124.557. The board shall be notified of any administrative penalties assessed by the appropriate professional licensing board and deposited into the drug information program fund under this paragraph.

3. For prescriptions issued prior to January 1, 2020, or for prescriptions exempt from the electronic prescription requirement in subsection 2, paragraph *"b"*, a prescriber or the

prescriber's authorized agent may transmit a prescription for a prescription drug to a pharmacy by any of the following means:

a. Electronically.

b. By facsimile.

c. Orally.

d. By providing an original signed prescription to a patient or a patient's authorized representative.

4. A prescription shall be issued in compliance with this subsection. Regardless of the means of transmission, a prescriber shall provide verbal verification of a prescription upon request of the pharmacy.

a. If written, electronic, or facsimile, each prescription shall contain all of the following:

(1) The date of issue.

(2) The name and address of the patient for whom, or the owner of the animal for which, the drug is dispensed.

(3) The name, strength, and quantity of the drug prescribed.

(4) The directions for use of the drug, medicine, or device prescribed.

(5) The name, address, and written or electronic signature of the prescriber issuing the prescription.

(6) The federal drug enforcement administration number, if required under chapter 124.

b. If electronic, each prescription shall comply with all of the following:

(1) The prescriber shall ensure that the electronic system used to transmit the electronic prescription has adequate security and safeguards designed to prevent and detect unauthorized access, modification, or manipulation of the prescription.

(2) Notwithstanding paragraph "*a*", subparagraph (5), for prescriptions that are not controlled substances, if transmitted by an authorized agent, the electronic prescription shall not require the written or electronic signature of the prescriber issuing the prescription.

c. If facsimile, in addition to the requirements of paragraph *"a"*, each prescription shall contain all of the following:

(1) The identification number of the facsimile machine which is used to transmit the prescription.

(2) The date and time of transmission of the prescription.

(3) The name, address, telephone number, and facsimile number of the pharmacy to which the prescription is being transmitted.

d. If oral, the prescriber issuing the prescription shall furnish the same information required for a written prescription, except for the written signature and address of the prescriber. Upon receipt of an oral prescription, the recipient shall promptly reduce the oral prescription to a written format by recording the information required in a written prescription.

e. A prescription transmitted by electronic, facsimile, or oral means by a prescriber's agent shall also include the name and title of the prescriber's agent completing the transmission.

5. An electronic, facsimile, or oral prescription shall serve as the original signed prescription and the prescriber shall not provide a patient, a patient's authorized representative, or the dispensing pharmacist with a signed written prescription. Prescription records shall be retained pursuant to rules of the board.

6. This section shall not prohibit a pharmacist, in exercising the pharmacist's professional judgment, from dispensing, at one time, additional quantities of a prescription drug, with the exception of a prescription drug that is a controlled substance as defined in section 124.101, up to the total number of dosage units authorized by the prescriber on the original prescription and any refills of the prescription, not to exceed a ninety-day supply of the prescription drug as specified on the prescription.

7. A prescriber, medical group, institution, or pharmacy that is unable to timely comply with the electronic prescribing requirements in subsection 2, paragraph *"a"*, may petition the board for an exemption from the requirements based upon economic hardship, technical limitations that the prescriber, medical group, institution, or pharmacy cannot control, or other exceptional circumstances. The board shall adopt rules establishing the form and specific information to be included in a request for an exemption and the specific criteria to be considered by the board in determining whether to approve a request for an exemption. The board may approve an exemption for a period of time determined by the board, not to exceed one year from the date of approval, and may be annually renewed subject to board approval upon request.

Sec. 12. Section 155A.29, subsection 4, Code 2018, is amended to read as follows:

4. An authorization to refill a prescription drug order ~~may~~ shall be transmitted to a ~~pharmacist~~ pharmacy by a prescriber or the prescriber's authorized agent ~~through word of mouth, note, telephone, facsimile, or other means of communication initiated by or directed by the practitioner. The transmission shall include the information required~~ pursuant to section 155A.27, except that prescription drug orders for controlled substances shall be transmitted pursuant to section 124.308, and, if not transmitted directly by the practitioner, shall ~~identify by~~ also include the name and title of the practitioner's agent completing the transmission.

DIVISION III

PRESCRIBER ACTIVITY REPORTS

Sec. 13. Section 124.553, subsection 1, Code 2018, is amended by adding the following new paragraph:

NEW PARAGRAPH. *g.* A prescribing practitioner for the issuance of a required report pursuant to section 124.554, subsection 3.

Sec. 14. Section 124.554, subsection 1, Code 2018, is

amended by adding the following new paragraph:

NEW PARAGRAPH. *j.* The issuance annually of a prescribing practitioner activity report compiled from information from the program pursuant to subsection 3.

Sec. 15. Section 124.554, Code 2018, is amended by adding the following new subsection:

NEW SUBSECTION. 3. *a.* Beginning February 1, 2019, and annually by February 1 thereafter, the board shall electronically, and at as low a cost as possible, issue each prescribing practitioner who prescribed a controlled substance reported to the program as dispensed in the preceding calendar year in this state a prescribing practitioner activity report which shall include but not be limited to the following:

(1) A cover letter.

(2) A summary of the prescribing practitioner's history of prescribing controlled substances.

(3) A comparison of the prescribing practitioner's history of prescribing controlled substances with the history of other prescribing practitioners of the same profession or specialty.

(4) The prescribing practitioner's history of program use.

(5) General patient risk factors.

(6) Educational updates.

(7) Other pertinent information identified by the board and advisory council by rule.

b. Information provided to a prescribing practitioner in a report required under this subsection is privileged and shall be kept confidential pursuant to section 124.553, subsection 3.

Sec. 16. Section 124.556, Code 2018, is amended to read as follows:

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 program shall also include

educational updates and information on general patient risk factors for prescribing practitioners. The board and advisory council shall adopt rules, as provided under section 124.554, to implement this section.

DIVISION IV

SUBSTANCE ABUSE PREVENTION

Sec. 17. Section 124.550, Code 2018, is amended by adding the following new subsection:

NEW SUBSECTION. 3. *"Proactive notification"* means a notification by the board, generated based on factors determined by the board and issued to a specific prescribing practitioner or pharmacist, indicating that a patient may be practitioner shopping or pharmacy shopping or at risk of abusing or misusing a controlled substance.

Sec. 18. Section 124.553, subsection 1, Code 2018, is amended by adding the following new paragraph:

NEW PARAGRAPH. *g.* A prescribing practitioner or pharmacist through the use of a targeted distribution of proactive notifications.

Sec. 19. Section 124.553, subsections 2 and 3, Code 2018, are amended to read as follows:

2. The board shall maintain a record of each person that requests information from the program and of all proactive notifications distributed to prescribing practitioners and dispensing pharmacists as provided in subsection 1, paragraph *"g"*. 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 information distributed to prescribing practitioners and dispensing pharmacists as provided in subsection 1, paragraph *"g"*, 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 subchapter. Information from the program shall not be released, shared with an agency or institution, or made public except as provided in this subchapter.

Sec. 20. Section 124.554, subsection 1, Code 2018, is amended by adding the following new paragraph:

NEW PARAGRAPH. *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 *"g"*, and the targeted distribution of proactive notifications suggesting review of the patient's prescription history.

Sec. 21. NEW SECTION. **147.162 Rules and directives relating to controlled substances.**

1. Any board created under this chapter that licenses a prescribing practitioner shall adopt rules under chapter 17A establishing penalties for prescribing practitioners that prescribe controlled substances in dosage amounts exceeding what would be prescribed by a reasonably prudent prescribing practitioner engaged in the same practice.

2. For the purposes of this section, *"prescribing practitioner"* means a licensed health care professional with the authority to prescribe prescription drugs including controlled substances.

DIVISION V

REGISTRATION

Sec. 22. Section 124.302, subsections 1 and 4, Code 2018, are amended to read as follows:

1. Every person who manufactures, distributes, or dispenses any controlled substance ~~within~~ in this state or who proposes

to engage in the manufacture, distribution, or dispensing of any controlled substance within this state, shall obtain and maintain a ~~biennial~~ registration issued by the board in accordance with its rules.

4. A separate registration is required for each principal place of business or professional practice where the applicant manufactures, distributes, ~~or~~ dispenses, or conducts research with controlled substances.

Sec. 23. Section 124.304, subsection 1, Code 2018, is amended to read as follows:

1. The board may suspend, revoke, or restrict a registration under section 124.303 ~~to manufacture, distribute, or dispense a controlled substance~~, or otherwise discipline a registrant, upon a finding that any of the following apply to the registrant:

a. The registrant has furnished false or fraudulent material information in any application filed under this chapter or any other chapter which applies to the registrant or the registrant's practice.

b. The registrant has had the registrant's federal registration to manufacture, distribute, ~~or~~ dispense, or conduct research with controlled substances suspended, revoked, or restricted.

c. The registrant has been convicted of a public offense under any state or federal law relating to any controlled substance. For the purpose of this section only, a conviction shall include a plea of guilty, a forfeiture of bail or collateral deposited to secure a defendant's appearance in court which forfeiture has not been vacated, or a finding of guilt in a criminal action even though the entry of the judgment or sentence has been withheld and the individual placed on probation.

d. The registrant has committed such acts as would render the registrant's registration under section 124.303 inconsistent with the public interest as determined under that

section.

e. If the registrant is a licensed health care professional, the registrant has had the registrant's professional license revoked or suspended or has been otherwise disciplined in a way that restricts the registrant's authority to handle or prescribe controlled substances.

Sec. 24. Section 124.304, subsections 2, 3, and 4, Code 2018, are amended to read as follows:

2. The board may limit revocation, ~~or~~ suspension, or restriction of a registration or discipline of a registrant to the particular controlled substance with respect to which grounds for revocation, ~~or~~ suspension, restriction, or discipline exist.

3. If the board suspends, ~~or~~ revokes, or restricts a registration, or otherwise disciplines a registrant, all controlled substances owned or possessed by the registrant at the time of the suspension, revocation, restriction, or discipline, or at the time of 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, orders the sale of perishable substances and the deposit of the proceeds of the sale with the court. Upon ~~a revocation~~ an order becoming final, all such controlled substances may be forfeited to the state.

4. The board shall promptly notify the bureau and the department of all orders suspending, ~~or~~ revoking, or restricting a registration ~~and all forfeitures of controlled substances~~, or otherwise disciplining a registrant.

Sec. 25. Section 124.305, Code 2018, is amended to read as follows:

124.305 ~~Order to show cause~~ Contested case proceedings.

1. ~~Before denying,~~ Prior to suspending, restricting, or revoking a registration, ~~or~~ refusing a renewal of registration, or otherwise disciplining a registrant, the board shall serve

upon the ~~applicant or~~ registrant ~~an order to show cause why registration should not be denied, revoked, or suspended, or why the renewal should not be refused. The order to show cause shall contain a statement of the basis therefor and shall call upon the applicant or registrant to appear before the board at a time and place not less than thirty 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 thirty days before the expiration of the registration~~ a notice in accordance with section 17A.12, subsection 1. The proceedings shall comply with the contested case procedures in accordance with chapter 17A. ~~These~~ The proceedings shall also be conducted 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.

2. The board~~, without an order to show cause,~~ may suspend any registration while simultaneously ~~with the institution of proceedings under section 124.304, or where renewal of registration is refused,~~ pursuing emergency adjudicative proceedings in accordance with section 17A.18A, if it 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, under the provisions of the Iowa administrative procedure Act, chapter 17A, unless sooner withdrawn by the board or dissolved by the order of the district court or an appellate court.

DIVISION VI

CONTROLLED SUBSTANCES —— PRECURSOR SUBSTANCES

Sec. 26. Section 124.204, subsection 9, Code 2018, is amended by adding the following new paragraphs:

NEW PARAGRAPH. *t.* Methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate, its optical,

positional, and geometric isomers, salts, and salts of isomers. Other names: 5F-ADB; 5F-MDMB-PINACA.

NEW PARAGRAPH. *u.* Methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3-methylbutanoate, its optical, positional, and geometric isomers, salts, and salts of isomers. Other name: 5F-AMB.

NEW PARAGRAPH. *v.* N-(adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide, its optical, positional, and geometric isomers, salts, and salts of isomers. Other names: 5F-APINACA, 5F-AKB48.

NEW PARAGRAPH. *w.* N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide, its optical, positional, and geometric isomers, salts, and salts of isomers. Other name: ADB-FUBINACA.

NEW PARAGRAPH. *x.* Methyl 2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate, its optical, positional, and geometric isomers, salts, and salts of isomers. Other names: MDMB-CHMICA, MMB-CHMINACA.

NEW PARAGRAPH. *y.* Methyl 2-(1-(4-fluorobenzyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate, its optical, positional, and geometric isomers, salts, and salts of isomers. Other name: MDMB-FUBINACA.

NEW PARAGRAPH. *z.* N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)isobutyramide, its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers. Other names: 4-fluoroisobutyryl fentanyl, para-fluoroisobutyryl fentanyl.

NEW PARAGRAPH. *aa.* N-(2-fluorophenyl)-N-(1-phenethylpiperidin-4-yl) propionamide. Other names: ortho-fluorofentanyl or 2-fluorofentanyl.

NEW PARAGRAPH. *ab.* N-(1-phenethylpiperidin-4-yl)-N-phenyltetrahydrofuran-2-carboxamide. Other name: tetrahydrofuranyl fentanyl.

NEW PARAGRAPH. *ac.* 2-methoxy-N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide. Other name: methoxyacetyl fentanyl.

NEW PARAGRAPH. *ad.* N-(1-phenethylpiperidin-4-yl)-N-phenylacrylamide. Other names: acryl fentanyl or acryloylfentanyl.

NEW PARAGRAPH. *ae.* Methyl 2-(1-(4-fluorobenzyl)-1H-indazole-3-carboxamido)-3-methylbutanoate, its optical, positional, and geometric isomers, salts, and salts of isomers. Other names: FUB-AMB, MMB-FUBINACA, AMB-FUBINACA.

Sec. 27. Section 124.206, subsection 7, Code 2018, is amended by adding the following new paragraph:

NEW PARAGRAPH. *c.* Dronabinol [(-)-delta-9-trans-tetrahydrocannabinol] in an oral solution in a drug product approved for marketing by the United States food and drug administration.

Sec. 28. Section 124B.2, subsection 1, Code 2018, is amended by adding the following new paragraph:

NEW PARAGRAPH. *ab.* Alpha-phenylacetoacetonitrile and its salts, optical isomers, and salts of optical isomers. Other name: APAAN.

Sec. 29. EFFECTIVE DATE. This division of this Act, being deemed of immediate importance, takes effect upon enactment.

DIVISION VII

GOOD SAMARITAN IMMUNITY

Sec. 30. NEW SECTION. **124.418 Persons seeking medical assistance for drug-related overdose.**

1. As used in this section, unless the context otherwise requires:

a. "Drug-related overdose" means a condition of a person for which each of the following is true:

(1) The person is in need of medical assistance.

(2) The person displays symptoms including but not limited to extreme physical illness, pinpoint pupils, decreased level of consciousness including coma, or respiratory depression.

(3) The person's condition is the result of, or a prudent layperson would reasonably believe such condition to be the result of, the consumption or use of a controlled substance.

b. "Overdose patient" means a person who is, or would reasonably be perceived to be, suffering a drug-related overdose and who has not previously received immunity under this section.

c. "Overdose reporter" means a person who seeks medical assistance for an overdose patient and who has not previously received immunity under this section.

d. "Protected information" means information or evidence collected or derived as a result of any of the following:

(1) An overdose patient's good-faith actions to seek medical assistance while experiencing a drug-related overdose.

(2) An overdose reporter's good-faith actions to seek medical assistance for an overdose patient experiencing a drug-related overdose if all of the following are true:

(a) The overdose patient is in need of medical assistance for an immediate health or safety concern.

(b) The overdose reporter is the first person to seek medical assistance for the overdose patient.

(c) The overdose reporter provides the overdose reporter's name and contact information to medical or law enforcement personnel.

(d) The overdose reporter remains on the scene until assistance arrives or is provided.

(e) The overdose reporter cooperates with medical and law enforcement personnel.

2. Protected information shall not be considered to support probable cause and shall not be admissible as evidence against an overdose patient or overdose reporter for any of the following offenses:

a. Delivery of a controlled substance under section 124.401, subsection 1, if such delivery involved the sharing of the controlled substance without profit.

b. Possession of a controlled substance under section 124.401, subsection 5.

c. Violation of section 124.407.

d. Violation of section 124.414.

3. A person's pretrial release, probation, supervised release, or parole shall not be revoked based on protected information.

4. Notwithstanding any other provision of law to the contrary, a court may consider the act of providing first aid or other medical assistance to someone who is experiencing a drug-related overdose as a mitigating factor in a criminal prosecution.

5. This section shall not be construed to limit the use or admissibility of any evidence in a criminal case other than as provided in subsection 2.

EXPLANATION

The inclusion of this explanation does not constitute agreement with the explanation's substance by the members of the general assembly.

This bill relates to the regulation of the practice of pharmacy. This bill is organized into divisions.

DIVISION I —— REGULATION OF THE PRESCRIPTION MONITORING PROGRAM. This division relates to regulation of the Iowa information program for drug prescribing and dispensing, also known as the prescription monitoring program (PMP). The bill requires first responders to report information regarding the administration of opioid antagonists to the PMP. The bill also requires prescribing practitioners to register for the PMP at the same time the practitioner applies to the board of pharmacy to register or renews registration to prescribe controlled substances as required by the board. Code section 124.550 defines "prescribing practitioner" as a practitioner who has prescribed or is contemplating the authorization of a prescription for the patient about whom information is requested. Once a prescribing practitioner registers for the PMP, the bill requires the prescribing practitioner to use the PMP database to determine treatment options and improve the quality of patient care, except that a prescribing practitioner shall not be required to use the PMP database to assist in

the treatment of a patient receiving inpatient hospice care or long-term residential facility patient care. The bill also requires a licensed pharmacy that dispenses a controlled substance, or a prescribing practitioner that dispenses a controlled substance to the prescribing practitioner's own patient, to report the dispensing of the controlled substance within 24 hours of the dispensing. A pharmacist or prescribing practitioner that does not comply with reporting, usage, or other requirements is subject to discipline by the relevant professional board. The bill requires first responders who administer opioid antagonists to report to the PMP certain information relating to the administration of the opioid antagonists. The bill authorizes the board of pharmacy to impose a surcharge, to be deposited into the drug information program fund, on controlled substance registrations under Code chapter 124, which a person who manufactures, distributes, or dispenses a controlled substance must obtain and maintain, to be used for the expenses of administering the PMP.

DIVISION II —— ELECTRONIC PRESCRIPTIONS. This division relates to electronic prescriptions. The bill requires all prescriptions for prescription drugs to transmitted to a pharmacy electronically, effective January 1, 2020. The bill also requires prescriptions for controlled substances that are issued electronically to comply with federal law for the electronic transmittal of prescriptions for controlled substances. The bill provides exemptions from this requirement in certain circumstances and provides alternative methods for the transmittal of prescriptions in those circumstances and for prescriptions transmitted prior to January 1, 2020. The bill also allows a person subject to the requirements of the bill to petition the board of pharmacy for exemption from the requirements of the bill based on economic hardship, technical limitations, or other exceptional circumstances. The bill requires refills for prescription drugs and controlled substances to be transmitted in the same manner as required for

initial prescriptions.

A practitioner who does not transmit a prescription drug order electronically as required by the bill shall be subject to an administrative penalty of $250 per violation, up to a maximum of $5,000 per calendar year. Such a penalty shall be assessed by the professional licensing board of the practitioner alleged to have committed the violation. A practitioner may contest such penalty, which shall initiate a contested case proceeding under Code chapter 17A. Any such penalty collected by a professional licensing board shall be deposited into the drug information program fund and reported to the board.

A person who does not comply with Code section 124.308 is guilty of an aggravated misdemeanor pursuant to Code section 124.402. An aggravated misdemeanor is punishable by confinement for no more than two years and a fine of at least $625 but not more than $6,250.

DIVISION III —— PRESCRIBER ACTIVITY REPORTS. This division relates to the issuance of activity reports to prescribing practitioners. The bill requires the board of pharmacy and the advisory council to promulgate rules allowing the annual issuance of privileged and confidential activity reports to prescribing practitioners who prescribe any controlled substances in an electronic format and at as low a cost as possible. The reports would include information from the PMP, including a summary of the prescribing practitioner's history of prescribing controlled substances, comparisons to other prescribing practitioners of the same profession and specialty, the prescribing practitioner's history of program use, general patient risk factors, educational updates, and other pertinent information. The bill amends Code section 124.553 to allow the board to disclose such information when issuing annual activity reports. The bill also requires the board to include information on general patient risk factors and educational updates in the PMP.

DIVISION IV —— SUBSTANCE ABUSE PREVENTION. This division relates to mitigating the abuse of opioids. The bill allows the board and PMP advisory council to establish criteria for the identification of patients who are potentially misusing or abusing prescription controlled substances and authorizes the board to proactively notify the pharmacists and prescribing practitioner involved in the patient's care of its concerns. The bill also directs professional boards that license prescribing practitioners that prescribe controlled substances to establish penalties for prescribing practitioners who prescribe controlled substances in an amount exceeding what would be prescribed by a reasonably prudent prescribing practitioner engaged in the same practice.

DIVISION V —— REGISTRATION. This division relates to registration with the board of pharmacy by persons working with controlled substances. The bill provides that a person who manufactures, distributes, or dispenses any controlled substance in this state or who proposes to engage in such activities in this state (registrant), obtain and maintain a registration issued by the board of pharmacy. Currently, a registrant is required to obtain and maintain a biennial registration issued by the board of pharmacy.

The bill requires a separate registration for each principal place of business of a registrant, when the registrant is conducting research with controlled substances. Currently, a separate registration is required for each principal place of business where a registrant manufactures, distributes, or dispenses controlled substances.

The bill permits the board of pharmacy to take disciplinary action against a registrant who manufactures, distributes, or dispenses any controlled substance within this state, without restricting, suspending, or revoking the registration. Currently, the board of pharmacy does not have the option to take disciplinary action against a registrant.

The bill provides that the board of pharmacy may discipline

a registrant when the registrant has furnished false or fraudulent material information in any application under any Code chapter which applies to the registrant. Currently, the board of pharmacy may take action against a registrant when the registrant has furnished false or fraudulent material information in any application under only Code chapter 124 (controlled substances).

The bill provides that the board of pharmacy may limit the restriction of a registrant's registration or discipline of a registrant to a particular controlled substance when grounds exist for such restriction or discipline. Currently, the board of pharmacy may impose such limits only when revoking or suspending a registrant's registration.

Under the bill, if the board of pharmacy restricts a registrant's registration or disciplines a registrant, all controlled substances owned or possessed by the registrant at the time of the restriction or at the time of the effective date of the order may be place under seal. Currently, if the board of pharmacy suspends or revokes a registrant's registration, all controlled substances owned or possessed by the registrant at the time of the suspension or revocation or at the time of the effective date of the order may be placed under seal.

The bill requires the board of pharmacy to notify the federal bureau of narcotics and dangerous drugs, United States department of justice, or its successor agency, of all orders restricting a registrant's registration or disciplining a registrant. Under current law, the board shall notify the federal agency when suspending or revoking the registration of a registrant including all forfeitures of controlled substances.

If the board of pharmacy decides to suspend, restrict, or revoke a registrant's registration or discipline a registrant, the bill requires the board to serve upon the registrant a notice in accordance with Code section 17A.12. Currently, the

board of pharmacy institutes such proceedings by serving an order to show cause why the registrant should not be denied, revoked, or suspended, or why the registration should not be refused.

The bill permits the board of pharmacy to suspend a registrant's registration while simultaneously pursuing an emergency adjudicative proceeding in accordance with Code section 17A.18A, if the board finds there is an immediate danger to the public health, safety, or welfare. Currently, the board of pharmacy may suspend a registrant's registration without an order to show cause, if the board finds there is an imminent danger to the public health or safety.

DIVISION VI —— CONTROLLED SUBSTANCES —— PRECURSOR SUBSTANCES. This division relates to the classification of controlled substances. The bill classifies nine substances as schedule I controlled substances and one substance as a schedule II controlled substance in conformance with scheduling actions taken by the United States department of justice, drug enforcement administration.

For the nine schedule I controlled substances added in Code section 124.204(9) under the bill, the penalties under Code section 124.401(1)(a), (b), and (c) range, depending upon the amount of the controlled substance involved, from a class "B" felony punishable by confinement for not more than 50 years and a fine of not more than $1 million, to a class "C" felony punishable by confinement of not more than 10 years and a fine of at least $1,000 and not more than $50,000. If a person unlawfully possesses any such controlled substance in violation of Code section 124.401(5), the person commits a serious misdemeanor for a first offense. A serious misdemeanor is punishable by confinement for no more than one year and a fine of at least $315 but not more than $1,875.

For the schedule II controlled substance added under Code section 124.206, it is a class "C" felony pursuant to Code section 124.401(1)(c)(9) for any unauthorized person to violate

a provision of Code section 124.401(1) involving a schedule II controlled substance. A class "C" felony for this particular offense is punishable by confinement for no more than 10 years and a fine of at least $1,000 but not more than $50,000. If a person unlawfully possesses a schedule II controlled substance in violation of Code section 124.401(5), the person commits a serious misdemeanor for a first offense. A serious misdemeanor is punishable by confinement for no more than one year and a fine of at least $315 but not more than $1,875.

The bill also classifies a substance as a precursor substance for purposes of certain reporting requirements. A "precursor substance" is defined in Code section 124B.1 to mean a substance which may be used as a precursor in the illegal production of a controlled substance. A person who sells, transfers, or otherwise furnishes a precursor substance with knowledge or the intent that the recipient will use the precursor substance to unlawfully manufacture a controlled substance commits a class "C" felony under Code section 124B.9(1). A person who receives a precursor substance with the intent that the substance be used unlawfully to manufacture a controlled substance commits a class "C" felony under Code section 124B.9(2). A class "C" felony is punishable by confinement for no more than 10 years and a fine of at least $1,000 but not more than $10,000.

The division of the bill takes effect upon enactment.

DIVISION VII —— GOOD SAMARITAN IMMUNITY. This division relates to certain protections against arrest and prosecution for people seeking medical assistance for a drug-related overdose. The bill provides that a person seeking treatment for a drug-related overdose or a person seeking medical treatment for a person experiencing a drug-related overdose cannot be arrested or prosecuted for possession of a controlled substance, delivery of a controlled substance without profit, violations of Code section 124.407, or violations of Code section 124.414 on the basis of information collected or

derived from a person's actions in seeking medical assistance if the person has not previously received such immunity. Such information shall also be inadmissible at trial for any of the enumerated offenses and shall not be used to revoke a person's pretrial release, probation, supervised release, or parole. The bill only extends these protections to a person who acted in good faith seeking medical attention for an overdose patient in need of medical assistance for an immediate health or safety concern, who was the first person to seek medical assistance, who provides the person's name and contact information to medical or law enforcement personnel, who waits on the scene until assistance arrives or is provided, and who cooperates with law enforcement and medical personnel. The bill also provides that a person's attempts to provide medical assistance to a person experiencing a drug-related overdose may be considered by the court as a mitigating factor in a criminal prosecution.