MINNESOTA BOARD OF PHARMACY

2023 Legislative Session

Executive Comment

Governor Tim Walz signed bills that were passed by the Minnesota Legislature during the 2023 Regular Session which have several provisions that will affect licensees and registrants of the Board of Pharmacy. Appendix A includes relevant language particularly from Chapter 151. Additional revisions to Chapter 152 and 62J impacting licensees are included; however, Appendix A is not inclusive of all revisions to those chapters, and the reader is encouraged to further review 2023 Regular Session law.

Per Minnesota Statute §645.02, *"**Each act, except one making appropriations**, enacted finally at any session of the legislature **takes effect on August 1** next following its final enactment, unless a different date is specified in the act."* The statute further states, *"**An appropriation act** or an act having appropriation items enacted finally at any session of the legislature **takes effect at the beginning of the first day of July** next following its final enactment, unless a different date is specified in the act.*

Each act takes effect at 12:01 a.m. on the day it becomes effective, unless a different time is specified in the act."

Highlights:

- Section 151.01, DEFINITIONS, was amended to add the definition of "syringe services provider." This is a community-based public health program that offers harm reduction services including but not limited to providing sterile needles, syringes, and other injection equipment; education for participants about overdose prevention; providing safe disposal containers for needles and syringes, etc. See Appendix A for the complete definition.
- Section 151.065, FEE AMOUNTS, amended the licensing and registration fees for the Board of Pharmacy's licensees and registrants. See Appendix A for the complete list of revised fees.
- Section 151.071, DISCIPLINARY ACTION, expanded the Board's disciplinary authority to include a civil penalty, not exceeding $25,000, which may be imposed for each separate violation of section 62J.842. Furthermore, it is prohibited and grounds for disciplinary action for a manufacturer to violate section 62J.842 or 62J.845.
- Section 151.071 was also amended by adding a subdivision regarding reproductive health care services, which, according to section 147.091, subd 1c. are defined as, *"For purposes of this subdivision, "reproductive health care services" means medical, surgical, counseling, or referral services relating to the human reproductive system, including but not limited to services related to pregnancy, contraception, or the termination of a pregnancy."* The Board shall not refuse to grant a license or impose disciplinary action based solely on the grounds that the applicant provided or assisted in the provision of reproductive health care services in a manner that is lawful in this state and that is within the applicable scope or practice. See Appendix A for the complete amendment.
- Section 151.37, LEGEND DRUGS; WHO MAY PRESCRIBE, POSSESS, was amended to include, *"transit rider investment program personnel authorized under section 473.4075*" as individuals permitted to administer opiate antagonists, as defined in section 604A.04, subd. 1, if authorized

by a licensed physician, a licensed advanced practice registered nurse authorized to prescribe drugs pursuant to section 148.235, or a licensed physician assistant. Chapter 151.37 was further revised such that, *"a nurse or any other personnel employed by, or under contract, a charter, public, or private school"* is permitted to administer opiate antagonists if authorized by the aforementioned prescribers.

- Section 151.40 was revised regarding the possession and sale of hypodermic syringes and needles. The chapter now includes syringe service providers, as well as participants receiving services from a syringe services provider. It also eliminates the quantity limits that a registered pharmacy or licensed pharmacist may sell, without the prescription or direction of a practitioner, provided the pharmacy or pharmacist complies with all of the requirements of the subdivision. See Appendix A for the complete revisions.
- Section 151.555, PRESCRIPTION DRUG REPOSITORY PROGRAM, was amended such that the Prescription Drug Repository Program is now termed the "medication repository program." It further directs the Board to pay the central repository any amount appropriated by the legislature for the operation and administration of the medication repository program. Defined performance measures are required of the central repository to the Board as well as auditing requirements of the central repository's expenditures. The amount appropriated from the general fund is $450,000 for FY24 and $450,000 for FY25.
- Section 151.72 includes several amendments regarding the sale of certain cannabinoid products. See Appendix A for the law enacted during the 2023 Regular Session. Effective March 1, 2025, Chapter 151.72 is repealed.
- Section 151.74 was amended such that the identification options for individuals with an urgent insulin need, or those participating in a manufacturer's patient assistance program, include an individual taxpayer identification number. See Appendix A for additional information.
- Section 152.02, SCHEDULES OF CONTROLLED SUBSTANCES, was amended by Chapter 52 and Chapter 63. Chapter 52 amendments further align the state's controlled substance law with federal regulations. Chapter 63 amendments address the scheduling of marijuana.
- Section 152.126, PRESCRIPTION MONITORING PROGRAM, was amended to include dispenser reporting requirements to the Minnesota Prescription Monitoring Program (PMP) database. This includes but is not limited to zero reports, a seven-calendar day requirement to correct erroneous prescription information, and clarification on PMP reporting requirements when prescriptions are mailed, shipped, or delivered from MN to another state. Additional amendments to §152.126 include but are not limited to, a health licensing board's ability to obtain utilization data in the event of a bona fide investigation of a specific licensee or registrant. See Appendix A for complete revisions.
- Section 62J.84, PRESCRIPTION DRUG PRICE TRANSPARENCY, includes several amendments. Highlights include but are not limited to:
    - The addition of numerous definitions (not inclusive):
        - *"Pharmacy" or "pharmacy provider" means a community/outpatient pharmacy as defined in Minnesota Rules, part 6800.0100, subpart 2, that is also licensed as a pharmacy by the Board of Pharmacy under section 151.19."*
        - *"Pharmacy benefit manager" or "PBM" means an entity licensed to act as a pharmacy benefit manager under section 62W.03.*

        - *"Reporting entity" means any manufacturer, pharmacy, pharmacy benefit manager, wholesale drug distributor, or any other entity required to submit data under this section.*
        - *"Wholesale drug distributor" or "wholesaler" means an entity that:*
          (1) is licensed to act as a wholesale drug distributor under section 151.47; and
          (2) distributes prescription drugs, for which it is not the manufacturer, to persons or entities, or both, other than a consumer or patient in the state.
    - Registration requirements: *"Beginning January 1, 2024, a reporting entity subject to this chapter shall register with the department in a form and manner prescribed by the commissioner."*
    - Manufacturers are required to report to the Commissioner of Health price information for prescription drugs when established criteria are met. The reporting requirements that went into effect January 1, 2022, have been expanded. See 62J.84 for complete revisions.
    - By January 31, 2024, the Commissioner shall post on its website a list of prescription drugs deemed to represent a substantial public interest and for which the Commissioner intends to request data from reporting entities (manufacturers, pharmacies, PBMs, wholesale drug distributors, or any other entity required to submit data under this section.) The reporting entities must submit to the Commissioner the requested and prescribed items as defined in 62J.84.
    - A reporting entity may be subject to a civil penalty for failing to register, failing to submit timely reports, failing to provide required information, or providing inaccurate or incomplete information.
- 62J.842, EXCESSIVE PRICE INCREASES PROHIBITED, was added. Per subd 1., "*No manufacturer shall impose, or cause to be imposed, an excessive price increase, whether directly or through a wholesale distributor, pharmacy, or similar intermediary, on the sale of any generic or off-patent drug sold, dispensed, or delivered to any consumer in the state."* "Excessive price increase" is further defined along with an exemption of the section for a wholesale distributor or pharmacy to increase the price of a generic or off-patent drug, if the price increase is directly attributable to additional costs for the drug imposed on the wholesale distributor or pharmacy, by the manufacturer of the drug. **For additional context, see 62J.841 to 62J.846.**
- 62J.845, PROHIBITION ON WITHDRAWAL OF GENERIC OR OFF-PATENT DRUGS FOR SALE, was added. Per subd 1., "*A manufacturer of a generic or off-patent drug is prohibited from withdrawing that drug from sale or distribution within this state for the purpose of avoiding the prohibition on excessive price increases under section 62J.842."* The attorney general shall assess a $500,000 penalty on any manufacturer that it determines has failed to comply with the requirements of the section. **For additional context, see 62J.841 to 62J.846.**
- Section 62W.15 was added to Chapter 62W, MINNESOTA PHARMACY BENEFIT MANAGER. 62W.15 provides a definition for a "clinician-administered drug" for the purposes of the section. Safety and care requirements were established for clinician-administered drugs as well as a requirement for a pharmacy benefit manager or health carrier who further requires the dispensing of a clinician-administered drug through a specialty pharmacy, a process which allows the health care provider or pharmacy to appeal and have exceptions to use the specialty pharmacy, when certain criteria are met. See Appendix A for more information.

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151.01 subd. 43 DEFINITIONS *(added)*

Chapter 52, Article 15, Sec. 2. Minnesota Statutes 2022, section 151.01, is amended by adding a subdivision to read:

Subd. 43. **Syringe services provider.** "Syringe services provider" means a community-based public health program that offers cost-free comprehensive harm reduction services, which may include: providing sterile needles, syringes, and other injection equipment; making safe disposal containers for needles and syringes available; educating participants and others about overdose prevention, safer injection practices, and infectious disease prevention; providing blood-borne pathogen testing or referrals to blood-borne pathogen testing; offering referrals to substance use disorder treatment, including substance use disorder treatment with medications for opioid use disorder; and providing referrals to medical treatment and services, mental health programs and services, and other social services.

EFFECTIVE DATE. This section is effective August 1, 2023.

151.065 FEE AMOUNTS *(amended)*

Chapter 70, Article 6, Sec. 22. Minnesota Statutes 2022, section 151.065, subdivision 1, is amended to read:

Subdivision 1. **Application fees.** Application fees for licensure and registration are as follows:

(1) pharmacist licensed by examination, ~~$175~~ $225;

(2) pharmacist licensed by reciprocity, ~~$275~~ $300;

(3) pharmacy intern, ~~$50~~ $75;

(4) pharmacy technician, ~~$50~~ $60;

(5) pharmacy, ~~$260~~ $450;

(6) drug wholesaler, legend drugs only, ~~$5,260~~ $5,500;

(7) drug wholesaler, legend and nonlegend drugs, ~~$5,260~~ $5,500;

(8) drug wholesaler, nonlegend drugs, veterinary legend drugs, or both, ~~$5,260~~ $5,500;

(9) drug wholesaler, medical gases, ~~$5,260~~ $5,500 for the first facility and ~~$260~~ $500 for each additional facility;

(10) third-party logistics provider, ~~$260~~ $300;

(11) drug manufacturer, nonopiate legend drugs only, ~~$5,260~~ $5,500;

(12) drug manufacturer, nonopiate legend and nonlegend drugs, ~~$5,260~~ $5,500;

(13) drug manufacturer, nonlegend or veterinary legend drugs, ~~$5,260~~ $5,500;

(14) drug manufacturer, medical gases, ~~$5,260~~ $5,500 for the first facility and ~~$260~~ $500 for each additional facility;

(15) drug manufacturer, also licensed as a pharmacy in Minnesota, ~~$5,260~~ $5,500;

(16) drug manufacturer of opiate-containing controlled substances listed in section 152.02, subdivisions 3 to 5, ~~$55,260~~ $55,500;

(17) medical gas dispenser, ~~$260~~ $400;

(18) controlled substance researcher, ~~$75~~ $150; and

(19) pharmacy professional corporation, $150.

Chapter 70, Article 6, Sec. 23. Minnesota Statutes 2022, section 151.065, subdivision 2, is amended to read:

Subd. 2.**Original license fee.** The pharmacist original licensure fee, ~~$175~~ $225.

Chapter 70, Article 6, Sec. 24. Minnesota Statutes 2022, section 151.065, subdivision 3, is amended to read:

Subd. 3. **Annual renewal fees.** Annual licensure and registration renewal fees are as follows:

(1) pharmacist, ~~$175~~ $225;

(2) pharmacy technician, ~~$50~~ $60;

(3) pharmacy, ~~$260~~ $450;

(4) drug wholesaler, legend drugs only, ~~$5,260~~ $5,500;

(5) drug wholesaler, legend and nonlegend drugs, ~~$5,260~~ $5,500;

(6) drug wholesaler, nonlegend drugs, veterinary legend drugs, or both, ~~$5,260~~ $5,500;

(7) drug wholesaler, medical gases, ~~$5,260~~ $5,500 for the first facility and ~~$260~~ $500 for each additional facility;

(8) third-party logistics provider, ~~$260~~ $300;

(9) drug manufacturer, nonopiate legend drugs only, ~~$5,260~~ $5,500;

(10) drug manufacturer, nonopiate legend and nonlegend drugs, ~~$5,260~~ $5,500;

(11) drug manufacturer, nonlegend, veterinary legend drugs, or both, ~~$5,260~~ $5,500;

(12) drug manufacturer, medical gases, ~~$5,260~~ $5,500 for the first facility and ~~$260~~ $500 for each additional facility;

(13) drug manufacturer, also licensed as a pharmacy in Minnesota, ~~$5,260~~ $5,500;

(14) drug manufacturer of opiate-containing controlled substances listed in section 152.02, subdivisions 3 to 5, ~~$55,260~~ $55,500;

(15) medical gas dispenser, ~~$260~~ $400;

(16) controlled substance researcher, ~~$75~~ $150; and

(17) pharmacy professional corporation, ~~$100~~ $150.

Chapter 70, Article 6, Sec. 25. Minnesota Statutes 2022, section 151.065, subdivision 4, is amended to read:

Subd. 4. **Miscellaneous fees.** Fees for issuance of affidavits and duplicate licenses and certificates are as follows:

(1) intern affidavit, ~~$20~~ $30;

(2) duplicate small license, ~~$20~~ $30; and

(3) duplicate large certificate, $30.

Chapter 70, Article 6, Sec. 26. Minnesota Statutes 2022, section 151.065, subdivision 6, is amended to read:

Subd. 6.**Reinstatement fees.** (a) A pharmacist who has allowed the pharmacist's license to lapse may reinstate the license with board approval and upon payment of any fees and late fees in arrears, up to a maximum of $1,000.

(b) A pharmacy technician who has allowed the technician's registration to lapse may reinstate the registration with board approval and upon payment of any fees and late fees in arrears, up to a maximum of ~~$90~~ $250.

(c) An owner of a pharmacy, a drug wholesaler, a drug manufacturer, third-party logistics provider, or a medical gas dispenser who has allowed the license of the establishment to lapse may reinstate the license with board approval and upon payment of any fees and late fees in arrears.

(d) A controlled substance researcher who has allowed the researcher's registration to lapse may reinstate the registration with board approval and upon payment of any fees and late fees in arrears.

(e) A pharmacist owner of a professional corporation who has allowed the corporation's registration to lapse may reinstate the registration with board approval and upon payment of any fees and late fees in arrears.

151.071 DISCIPLINARY ACTION *(amended and added)*

Chapter 57, Article 2, Sec. 59. Minnesota Statutes 2022, section 151.071, is amended to read:

Subdivision 1. **Forms of disciplinary action.** When the board finds that a licensee, registrant, or applicant has engaged in conduct prohibited under subdivision 2, it may do one or more of the following:

(1) deny the issuance of a license or registration;

(2) refuse to renew a license or registration;

(3) revoke the license or registration;

(4) suspend the license or registration;

(5) impose limitations, conditions, or both on the license or registration, including but not limited to: the limitation of practice to designated settings; the limitation of the scope of practice within designated settings; the imposition of retraining or rehabilitation requirements; the requirement of practice under supervision; the requirement of participation in a diversion program such as that established pursuant to section 214.31 or the conditioning of continued practice on demonstration of knowledge or skills by appropriate examination or other review of skill and competence;

(6) impose a civil penalty not exceeding $10,000 for each separate violation, except that a civil penalty not exceeding $25,000 may be imposed for each separate violation of section 62J.842, the amount of the civil penalty to be fixed so as to deprive a licensee or registrant of any economic advantage gained by reason of the violation, to discourage similar violations by the licensee or registrant or any other licensee or registrant, or to reimburse the board for the cost of the investigation and proceeding, including but not limited to, fees paid for services provided by the Office of Administrative Hearings, legal and investigative services provided by the Office of the Attorney General, court reporters, witnesses, reproduction of records, board members' per diem compensation, board staff time, and travel costs and expenses incurred by board staff and board members; and

(7) reprimand the licensee or registrant.

Chapter 57, Article 2, Sec. 60. Minnesota Statutes 2022, section 151.071, subdivision 2, is amended to read:

Subd. 2. **Grounds for disciplinary action.** The following conduct is prohibited and is grounds for disciplinary action:

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(1) failure to demonstrate the qualifications or satisfy the requirements for a license or registration contained in this chapter or the rules of the board. The burden of proof is on the applicant to demonstrate such qualifications or satisfaction of such requirements;

(2) obtaining a license by fraud or by misleading the board in any way during the application process or obtaining a license by cheating, or attempting to subvert the licensing examination process. Conduct that subverts or attempts to subvert the licensing examination process includes, but is not limited to: (i) conduct that violates the security of the examination materials, such as removing examination materials from the examination room or having unauthorized possession of any portion of a future, current, or previously administered licensing examination; (ii) conduct that violates the standard of test administration, such as communicating with another examinee during administration of the examination, copying another examinee's answers, permitting another examinee to copy one's answers, or possessing unauthorized materials; or (iii) impersonating an examinee or permitting an impersonator to take the examination on one's own behalf;

(3) for a pharmacist, pharmacy technician, pharmacist intern, applicant for a pharmacist or pharmacy license, or applicant for a pharmacy technician or pharmacist intern registration, conviction of a felony reasonably related to the practice of pharmacy. Conviction as used in this subdivision includes a conviction of an offense that if committed in this state would be deemed a felony without regard to its designation elsewhere, or a criminal proceeding where a finding or verdict of guilt is made or returned but the adjudication of guilt is either withheld or not entered thereon. The board may delay the issuance of a new license or registration if the applicant has been charged with a felony until the matter has been adjudicated;

(4) for a facility, other than a pharmacy, licensed or registered by the board, if an owner or applicant is convicted of a felony reasonably related to the operation of the facility. The board may delay the issuance of a new license or registration if the owner or applicant has been charged with a felony until the matter has been adjudicated;

(5) for a controlled substance researcher, conviction of a felony reasonably related to controlled substances or to the practice of the researcher's profession. The board may delay the issuance of a registration if the applicant has been charged with a felony until the matter has been adjudicated;

(6) disciplinary action taken by another state or by one of this state's health licensing agencies:

(i) revocation, suspension, restriction, limitation, or other disciplinary action against a license or registration in another state or jurisdiction, failure to report to the board that charges or allegations regarding the person's license or registration have been brought in another state or jurisdiction, or having been refused a license or registration by any other state or jurisdiction. The board may delay the issuance of a new license or registration if an investigation or disciplinary action is pending in another state or jurisdiction until the investigation or action has been dismissed or otherwise resolved; and

(ii) revocation, suspension, restriction, limitation, or other disciplinary action against a license or registration issued by another of this state's health licensing agencies, failure to

report to the board that charges regarding the person's license or registration have been brought by another of this state's health licensing agencies, or having been refused a license or registration by another of this state's health licensing agencies. The board may delay the issuance of a new license or registration if a disciplinary action is pending before another of this state's health licensing agencies until the action has been dismissed or otherwise resolved;

(7) for a pharmacist, pharmacy, pharmacy technician, or pharmacist intern, violation of any order of the board, of any of the provisions of this chapter or any rules of the board or violation of any federal, state, or local law or rule reasonably pertaining to the practice of pharmacy;

(8) for a facility, other than a pharmacy, licensed by the board, violations of any order of the board, of any of the provisions of this chapter or the rules of the board or violation of any federal, state, or local law relating to the operation of the facility;

(9) engaging in any unethical conduct; conduct likely to deceive, defraud, or harm the public, or demonstrating a willful or careless disregard for the health, welfare, or safety of a patient; or pharmacy practice that is professionally incompetent, in that it may create unnecessary danger to any patient's life, health, or safety, in any of which cases, proof of actual injury need not be established;

(10) aiding or abetting an unlicensed person in the practice of pharmacy, except that it is not a violation of this clause for a pharmacist to supervise a properly registered pharmacy technician or pharmacist intern if that person is performing duties allowed by this chapter or the rules of the board;

(11) for an individual licensed or registered by the board, adjudication as mentally ill or developmentally disabled, or as a chemically dependent person, a person dangerous to the public, a sexually dangerous person, or a person who has a sexual psychopathic personality, by a court of competent jurisdiction, within or without this state. Such adjudication shall automatically suspend a license for the duration thereof unless the board orders otherwise;

(12) for a pharmacist or pharmacy intern, engaging in unprofessional conduct as specified in the board's rules. In the case of a pharmacy technician, engaging in conduct specified in board rules that would be unprofessional if it were engaged in by a pharmacist or pharmacist intern or performing duties specifically reserved for pharmacists under this chapter or the rules of the board;

(13) for a pharmacy, operation of the pharmacy without a pharmacist present and on duty except as allowed by a variance approved by the board;

(14) for a pharmacist, the inability to practice pharmacy with reasonable skill and safety to patients by reason of illness, use of alcohol, drugs, narcotics, chemicals, or any other type of material or as a result of any mental or physical condition, including deterioration through the aging process or loss of motor skills. In the case of registered pharmacy technicians, pharmacist interns, or controlled substance researchers, the inability to carry out duties allowed under this chapter or the rules of the board with reasonable skill and safety to patients by reason of illness, use of alcohol, drugs, narcotics, chemicals, or any other type of material or as a result of

any mental or physical condition, including deterioration through the aging process or loss of motor skills;

(15) for a pharmacist, pharmacy, pharmacist intern, pharmacy technician, medical gas dispenser, or controlled substance researcher, revealing a privileged communication from or relating to a patient except when otherwise required or permitted by law;

(16) for a pharmacist or pharmacy, improper management of patient records, including failure to maintain adequate patient records, to comply with a patient's request made pursuant to sections 144.291 to 144.298, or to furnish a patient record or report required by law;

(17) fee splitting, including without limitation:

(i) paying, offering to pay, receiving, or agreeing to receive, a commission, rebate, kickback, or other form of remuneration, directly or indirectly, for the referral of patients;

(ii) referring a patient to any health care provider as defined in sections 144.291 to 144.298 in which the licensee or registrant has a financial or economic interest as defined in section 144.6521, subdivision 3, unless the licensee or registrant has disclosed the licensee's or registrant's financial or economic interest in accordance with section 144.6521; and

(iii) any arrangement through which a pharmacy, in which the prescribing practitioner does not have a significant ownership interest, fills a prescription drug order and the prescribing practitioner is involved in any manner, directly or indirectly, in setting the price for the filled prescription that is charged to the patient, the patient's insurer or pharmacy benefit manager, or other person paying for the prescription or, in the case of veterinary patients, the price for the filled prescription that is charged to the client or other person paying for the prescription, except that a veterinarian and a pharmacy may enter into such an arrangement provided that the client or other person paying for the prescription is notified, in writing and with each prescription dispensed, about the arrangement, unless such arrangement involves pharmacy services provided for livestock, poultry, and agricultural production systems, in which case client notification would not be required;

(18) engaging in abusive or fraudulent billing practices, including violations of the federal Medicare and Medicaid laws or state medical assistance laws or rules;

(19) engaging in conduct with a patient that is sexual or may reasonably be interpreted by the patient as sexual, or in any verbal behavior that is seductive or sexually demeaning to a patient;

(20) failure to make reports as required by section 151.072 or to cooperate with an investigation of the board as required by section 151.074;

(21) knowingly providing false or misleading information that is directly related to the care of a patient unless done for an accepted therapeutic purpose such as the dispensing and administration of a placebo;

(22) aiding suicide or aiding attempted suicide in violation of section 609.215 as established by any of the following:

(i) a copy of the record of criminal conviction or plea of guilty for a felony in violation of section 609.215, subdivision 1 or 2;

(ii) a copy of the record of a judgment of contempt of court for violating an injunction issued under section 609.215, subdivision 4;

(iii) a copy of the record of a judgment assessing damages under section 609.215, subdivision 5; or

(iv) a finding by the board that the person violated section 609.215, subdivision 1 or 2. The board must investigate any complaint of a violation of section 609.215, subdivision 1 or 2;

(23) for a pharmacist, practice of pharmacy under a lapsed or nonrenewed license. For a pharmacist intern, pharmacy technician, or controlled substance researcher, performing duties permitted to such individuals by this chapter or the rules of the board under a lapsed or nonrenewed registration. For a facility required to be licensed under this chapter, operation of the facility under a lapsed or nonrenewed license or registration; ~~and~~

(24) for a pharmacist, pharmacist intern, or pharmacy technician, termination or discharge from the health professionals services program for reasons other than the satisfactory completion of the program~~.~~; and

(25) for a manufacturer, a violation of section 62J.842 or 62J.845.

Chapter 31, Sec. 5. Minnesota Statutes 2022, section 151.071, is amended by adding a subdivision to read:

Subd. 2b. **Reproductive health care services.** (a) For purposes of this subdivision, "reproductive health care services" has the meaning given in section 147.091, subdivision 1c.

(b) Notwithstanding subdivision 1 and subdivision 2, clause (3), (6), or (7), the board shall not refuse to grant a license to an applicant for licensure or impose disciplinary action against a pharmacist, pharmacy technician, or pharmacist intern solely on one or more of the following grounds:

(1) the applicant or a pharmacist, pharmacy technician, or pharmacist intern provided or assisted in the provision of reproductive health care services in a manner that is lawful in this state and that is within the applicable scope of practice;

(2) the applicant or a pharmacist, pharmacy technician, or pharmacist intern was convicted in another jurisdiction of a felony resulting from conduct specified in clause (1); or

(3) the applicant or a pharmacist, pharmacy technician, or pharmacist intern was subject to disciplinary action in another jurisdiction or was refused a license to practice pharmacy in another jurisdiction resulting from conduct specified in clause (1).

EFFECTIVE DATE. **This section is effective the day following final enactment.**

Appendix A

151.37 subd. 12 LEGEND DRUGS; WHO MAY PRESCRIBE, POSSESS *(amended)*

Chapter 68, Article 4, Sec. 13. Minnesota Statutes 2022, section 151.37, subdivision 12, is amended to read:

Subd. 12. **Administration of opiate antagonists for drug overdose.** (a) A licensed physician, a licensed advanced practice registered nurse authorized to prescribe drugs pursuant to section 148.235, or a licensed physician assistant may authorize the following individuals to administer opiate antagonists, as defined in section 604A.04, subdivision 1:

(1) an emergency medical responder registered pursuant to section 144E.27;

(2) a peace officer as defined in section 626.84, subdivision 1, paragraphs (c) and (d);

(3) correctional employees of a state or local political subdivision;

(4) staff of community-based health disease prevention or social service programs;

(5) a volunteer firefighter; ~~and~~

(6) a licensed school nurse or certified public health nurse employed by, or under contract with, a school board under section 121A.21; and

(7) transit rider investment program personnel authorized under section 473.4075.

(b) For the purposes of this subdivision, opiate antagonists may be administered by one of these individuals only if:

(1) the licensed physician, licensed physician assistant, or licensed advanced practice registered nurse has issued a standing order to, or entered into a protocol with, the individual; and

(2) the individual has training in the recognition of signs of opiate overdose and the use of opiate antagonists as part of the emergency response to opiate overdose.

(c) Nothing in this section prohibits the possession and administration of naloxone pursuant to section 604A.04.

Chapter 70, Article 3, Sec. 47. Minnesota Statutes 2022, section 151.37, subdivision 12, is amended to read:

Subd. 12. **Administration of opiate antagonists for drug overdose.** (a) A licensed physician, a licensed advanced practice registered nurse authorized to prescribe drugs pursuant to section 148.235, or a licensed physician assistant may authorize the following individuals to administer opiate antagonists, as defined in section 604A.04, subdivision 1:

(1) an emergency medical responder registered pursuant to section 144E.27;

(2) a peace officer as defined in section 626.84, subdivision 1, paragraphs (c) and (d);

(3) correctional employees of a state or local political subdivision;

(4) staff of community-based health disease prevention or social service programs;

(5) a volunteer firefighter; and

(6) a ~~licensed school~~ nurse or ~~certified public health nurse~~ any other personnel employed by, or under contract with, a ~~school board under section~~ 121A.21 charter, public, or private school.

(b) For the purposes of this subdivision, opiate antagonists may be administered by one of these individuals only if:

(1) the licensed physician, licensed physician assistant, or licensed advanced practice registered nurse has issued a standing order to, or entered into a protocol with, the individual; and

(2) the individual has training in the recognition of signs of opiate overdose and the use of opiate antagonists as part of the emergency response to opiate overdose.

(c) Nothing in this section prohibits the possession and administration of naloxone pursuant to section 604A.04.

(d) Notwithstanding section 148.235, subdivisions 8 and 9, a licensed practical nurse is authorized to possess and administer according to this subdivision an opiate antagonist in a school setting.

151.40 POSSESSION AND SALE OF HYPODERMIC SYRINGES AND NEEDLES *(amended)*

Chapter 52, Article 15, Sec. 3. Minnesota Statutes 2022, section 151.40, subdivision 1, is amended to read:

Subdivision 1. **Generally.** It is unlawful for any person to ~~possess, control,~~ manufacture~~,~~ or sell~~, furnish, dispense, or otherwise dispose of~~ hypodermic syringes or needles or any instrument or implement which can be adapted for subcutaneous injections, except for:

(1) the following persons when acting in the course of their practice or employment:

(i) licensed practitioners and their employees, agents, or delegates;

(ii) licensed pharmacies and their employees or agents;

(iii) licensed pharmacists;

(iv) registered nurses and licensed practical nurses;

(v) registered medical technologists;

(vi) medical interns and residents;

(vii) licensed drug wholesalers and their employees or agents;

(viii) licensed hospitals;

(ix) bona fide hospitals in which animals are treated;

(x) licensed nursing homes;

(xi) licensed morticians;

(xii) syringe and needle manufacturers and their dealers and agents;

(xiii) persons engaged in animal husbandry;

(xiv) clinical laboratories and their employees;

(xv) persons engaged in bona fide research or education or industrial use of hypodermic syringes and needles provided such persons cannot use hypodermic syringes and needles for the administration of drugs to human beings unless such drugs are prescribed, dispensed, and administered by a person lawfully authorized to do so; ~~and~~

(xvi) persons who administer drugs pursuant to an order or direction of a licensed practitioner; and

(xvii) syringe services providers and their employees and agents;

(2) a person who self-administers drugs pursuant to either the prescription or the direction of a practitioner, or a family member, caregiver, or other individual who is designated by such person to assist the person in obtaining and using needles and syringes for the administration of such drugs;

(3) a person who is disposing of hypodermic syringes and needles through an activity or program developed under section 325F.785; ~~or~~

(4) a person who sells~~, possesses,~~ or handles hypodermic syringes and needles pursuant to subdivision 2~~.~~; or

(5) a participant receiving services from a syringe services provider, who accesses or receives new syringes or needles from a syringe services provider or returns used syringes or needles to a syringe services provider.

EFFECTIVE DATE. This section is effective August 1, 2023.

Appendix A

Chapter 52, Article 15, Sec. 4. Minnesota Statutes 2022, section 151.40, subdivision 2, is amended to read:

Subd. 2. **Sales ~~of limited quantities~~ of clean needles and syringes.** (a) A registered pharmacy or a licensed pharmacist may sell, without the prescription or direction of a practitioner, unused hypodermic needles and syringes ~~in quantities of ten or fewer,~~ provided the pharmacy or pharmacist complies with all of the requirements of this subdivision.

(b) At any location where hypodermic needles and syringes are kept for retail sale under this subdivision, the needles and syringes shall be stored in a manner that makes them available only to authorized personnel and not openly available to customers.

(c) A registered pharmacy or licensed pharmacist that sells hypodermic needles or syringes under this subdivision may give the purchaser the materials developed by the commissioner of health under section 325F.785.

(d) A registered pharmacy or licensed pharmacist that sells hypodermic needles or syringes under this subdivision must certify to the commissioner of health participation in an activity, including but not limited to those developed under section 325F.785, that supports proper disposal of used hypodermic needles or syringes.

151.555 MEDICATION REPOSITORY PROGRAM *(amended)*

Chapter 70, Article 6, Sec. 27. Minnesota Statutes 2022, section 151.555, is amended to read:

151.555 ~~PRESCRIPTION DRUG~~ MEDICATION REPOSITORY PROGRAM.

Subdivision 1. **Definitions.**

(a) For the purposes of this section, the terms defined in this subdivision have the meanings given.

(b) "Central repository" means a wholesale distributor that meets the requirements under subdivision 3 and enters into a contract with the Board of Pharmacy in accordance with this section.

(c) "Distribute" means to deliver, other than by administering or dispensing.

(d) "Donor" means:

(1) a health care facility as defined in this subdivision;

(2) a skilled nursing facility licensed under chapter 144A;

(3) an assisted living facility licensed under chapter 144G;

(4) a pharmacy licensed under section 151.19, and located either in the state or outside the state;

(5) a drug wholesaler licensed under section 151.47;

(6) a drug manufacturer licensed under section 151.252; or

(7) an individual at least 18 years of age, provided that the drug or medical supply that is donated was obtained legally and meets the requirements of this section for donation.

(e) "Drug" means any prescription drug that has been approved for medical use in the United States, is listed in the United States Pharmacopoeia or National Formulary, and meets the criteria established under this section for donation; or any over-the-counter medication that meets the criteria established under this section for donation. This definition includes cancer drugs and antirejection drugs, but does not include controlled substances, as defined in section 152.01, subdivision 4, or a prescription drug that can only be dispensed to a patient registered with the drug's manufacturer in accordance with federal Food and Drug Administration requirements.

(f) "Health care facility" means:

(1) a physician's office or health care clinic where licensed practitioners provide health care to patients;

(2) a hospital licensed under section 144.50;

(3) a pharmacy licensed under section 151.19 and located in Minnesota; or

(4) a nonprofit community clinic, including a federally qualified health center; a rural health clinic; public health clinic; or other community clinic that provides health care utilizing a sliding fee scale to patients who are low-income, uninsured, or underinsured.

(g) "Local repository" means a health care facility that elects to accept donated drugs and medical supplies and meets the requirements of subdivision 4.

(h) "Medical supplies" or "supplies" means any prescription ~~and~~ or nonprescription medical supplies needed to administer a ~~prescription~~ drug.

(i) "Original, sealed, unopened, tamper-evident packaging" means packaging that is sealed, unopened, and tamper-evident, including a manufacturer's original unit dose or unit-of-use container, a repackager's original unit dose or unit-of-use container, or unit-dose packaging prepared by a licensed pharmacy according to the standards of Minnesota Rules, part 6800.3750.

(j) "Practitioner" has the meaning given in section 151.01, subdivision 23, except that it does not include a veterinarian.

Subd. 2. **Establishment; contract and oversight.**

Appendix A

~~By January 1, 2020,~~ (a) The Board of Pharmacy shall establish a ~~drug~~ medication repository program, through which donors may donate a drug or medical supply for use by an individual who meets the eligibility criteria specified under subdivision 5.

(b) The board shall contract with a central repository that meets the requirements of subdivision 3 to implement and administer the ~~prescription drug~~ medication repository program. The contract must:

(1) require payment by the board to the central repository any amount appropriated by the legislature for the operation and administration of the medication repository program;

(2) require the central repository to report the following performance measures to the board:

(i) the number of individuals served and the types of medications these individuals received;

(ii) the number of clinics, pharmacies, and long-term care facilities with which the central repository partnered;

(iii) the number and cost of medications accepted for inventory, disposed of, and dispensed to individuals in need; and

(iv) locations within the state to which medications were shipped or delivered; and

(3) require the board to annually audit the expenditure by the central repository of any money appropriated by the legislature and paid under a contract by the board to ensure that the amount appropriated is used only for purposes specified in the contract.

Subd. 3. **Central repository requirements.**

(a) The board may publish a request for proposal for participants who meet the requirements of this subdivision and are interested in acting as the central repository for the ~~drug~~ medication repository program. If the board publishes a request for proposal, it shall follow all applicable state procurement procedures in the selection process. The board may also work directly with the University of Minnesota to establish a central repository.

(b) To be eligible to act as the central repository, the participant must be a wholesale drug distributor located in Minnesota, licensed pursuant to section 151.47, and in compliance with all applicable federal and state statutes, rules, and regulations.

(c) The central repository shall be subject to inspection by the board pursuant to section 151.06, subdivision 1.

(d) The central repository shall comply with all applicable federal and state laws, rules, and regulations pertaining to the ~~drug~~ medication repository program, drug storage, and

dispensing. The facility must maintain in good standing any state license or registration that applies to the facility.

Subd. 4. **Local repository requirements.**

(a) To be eligible for participation in the ~~drug~~ medication repository program, a health care facility must agree to comply with all applicable federal and state laws, rules, and regulations pertaining to the ~~drug~~ medication repository program, drug storage, and dispensing. The facility must also agree to maintain in good standing any required state license or registration that may apply to the facility.

(b) A local repository may elect to participate in the program by submitting the following information to the central repository on a form developed by the board and made available on the board's website:

(1) the name, street address, and telephone number of the health care facility and any state-issued license or registration number issued to the facility, including the issuing state agency;

(2) the name and telephone number of a responsible pharmacist or practitioner who is employed by or under contract with the health care facility; and

(3) a statement signed and dated by the responsible pharmacist or practitioner indicating that the health care facility meets the eligibility requirements under this section and agrees to comply with this section.

(c) Participation in the ~~drug~~ medication repository program is voluntary. A local repository may withdraw from participation in the ~~drug~~ medication repository program at any time by providing written notice to the central repository on a form developed by the board and made available on the board's website. The central repository shall provide the board with a copy of the withdrawal notice within ten business days from the date of receipt of the withdrawal notice.

Subd. 5. **Individual eligibility and application requirements.**

(a) To be eligible for the ~~drug~~ medication repository program, an individual must submit to a local repository an intake application form that is signed by the individual and attests that the individual:

(1) is a resident of Minnesota;

(2) is uninsured and is not enrolled in the medical assistance program under chapter 256B or the MinnesotaCare program under chapter 256L, has no prescription drug coverage, or is underinsured;

(3) acknowledges that the drugs or medical supplies to be received through the program may have been donated; and

(4) consents to a waiver of the child-resistant packaging requirements of the federal Poison Prevention Packaging Act.

(b) Upon determining that an individual is eligible for the program, the local repository shall furnish the individual with an identification card. The card shall be valid for one year from the date of issuance and may be used at any local repository. A new identification card may be issued upon expiration once the individual submits a new application form.

(c) The local repository shall send a copy of the intake application form to the central repository by regular mail, facsimile, or secured email within ten days from the date the application is approved by the local repository.

(d) The board shall develop and make available on the board's website an application form and the format for the identification card.

Subd. 6. **Standards and procedures for accepting donations of drugs and supplies.**

(a) A donor may donate ~~prescription~~ drugs or medical supplies to the central repository or a local repository if the drug or supply meets the requirements of this section as determined by a pharmacist or practitioner who is employed by or under contract with the central repository or a local repository.

(b) A ~~prescription~~ drug is eligible for donation under the ~~drug~~ medication repository program if the following requirements are met:

(1) the donation is accompanied by a ~~drug~~ medication repository donor form described under paragraph (d) that is signed by an individual who is authorized by the donor to attest to the donor's knowledge in accordance with paragraph (d);

(2) the drug's expiration date is at least six months after the date the drug was donated. If a donated drug bears an expiration date that is less than six months from the donation date, the drug may be accepted and distributed if the drug is in high demand and can be dispensed for use by a patient before the drug's expiration date;

(3) the drug is in its original, sealed, unopened, tamper-evident packaging that includes the expiration date. Single-unit-dose drugs may be accepted if the single-unit-dose packaging is unopened;

(4) the drug or the packaging does not have any physical signs of tampering, misbranding, deterioration, compromised integrity, or adulteration;

(5) the drug does not require storage temperatures other than normal room temperature as specified by the manufacturer or United States Pharmacopoeia, unless the drug

is being donated directly by its manufacturer, a wholesale drug distributor, or a pharmacy located in Minnesota; and

(6) the ~~prescription~~ drug is not a controlled substance.

(c) A medical supply is eligible for donation under the ~~drug~~ medication repository program if the following requirements are met:

(1) the supply has no physical signs of tampering, misbranding, or alteration and there is no reason to believe it has been adulterated, tampered with, or misbranded;

(2) the supply is in its original, unopened, sealed packaging;

(3) the donation is accompanied by a ~~drug~~ medication repository donor form described under paragraph (d) that is signed by an individual who is authorized by the donor to attest to the donor's knowledge in accordance with paragraph (d); and

(4) if the supply bears an expiration date, the date is at least six months later than the date the supply was donated. If the donated supply bears an expiration date that is less than six months from the date the supply was donated, the supply may be accepted and distributed if the supply is in high demand and can be dispensed for use by a patient before the supply's expiration date.

(d) The board shall develop the ~~drug~~ medication repository donor form and make it available on the board's website. The form must state that to the best of the donor's knowledge the donated drug or supply has been properly stored under appropriate temperature and humidity conditions and that the drug or supply has never been opened, used, tampered with, adulterated, or misbranded.

(e) Donated drugs and supplies may be shipped or delivered to the premises of the central repository or a local repository, and shall be inspected by a pharmacist or an authorized practitioner who is employed by or under contract with the repository and who has been designated by the repository to accept donations. A drop box must not be used to deliver or accept donations.

(f) The central repository and local repository shall inventory all drugs and supplies donated to the repository. For each drug, the inventory must include the drug's name, strength, quantity, manufacturer, expiration date, and the date the drug was donated. For each medical supply, the inventory must include a description of the supply, its manufacturer, the date the supply was donated, and, if applicable, the supply's brand name and expiration date.

Subd. 7. **Standards and procedures for inspecting and storing donated ~~prescription~~ drugs and supplies.**

(a) A pharmacist or authorized practitioner who is employed by or under contract with the central repository or a local repository shall inspect all donated ~~prescription~~ drugs and

supplies before the drug or supply is dispensed to determine, to the extent reasonably possible in the professional judgment of the pharmacist or practitioner, that the drug or supply is not adulterated or misbranded, has not been tampered with, is safe and suitable for dispensing, has not been subject to a recall, and meets the requirements for donation. The pharmacist or practitioner who inspects the drugs or supplies shall sign an inspection record stating that the requirements for donation have been met. If a local repository receives drugs and supplies from the central repository, the local repository does not need to reinspect the drugs and supplies.

(b) The central repository and local repositories shall store donated drugs and supplies in a secure storage area under environmental conditions appropriate for the drug or supply being stored. Donated drugs and supplies may not be stored with nondonated inventory.

(c) The central repository and local repositories shall dispose of all ~~prescription~~ drugs and medical supplies that are not suitable for donation in compliance with applicable federal and state statutes, regulations, and rules concerning hazardous waste.

(d) In the event that controlled substances or ~~prescription~~ drugs that can only be dispensed to a patient registered with the drug's manufacturer are shipped or delivered to a central or local repository for donation, the shipment delivery must be documented by the repository and returned immediately to the donor or the donor's representative that provided the drugs.

(e) Each repository must develop drug and medical supply recall policies and procedures. If a repository receives a recall notification, the repository shall destroy all of the drug or medical supply in its inventory that is the subject of the recall and complete a record of destruction form in accordance with paragraph (f). If a drug or medical supply that is the subject of a Class I or Class II recall has been dispensed, the repository shall immediately notify the recipient of the recalled drug or medical supply. A drug that potentially is subject to a recall need not be destroyed if its packaging bears a lot number and that lot of the drug is not subject to the recall. If no lot number is on the drug's packaging, it must be destroyed.

(f) A record of destruction of donated drugs and supplies that are not dispensed under subdivision 8, are subject to a recall under paragraph (e), or are not suitable for donation shall be maintained by the repository for at least two years. For each drug or supply destroyed, the record shall include the following information:

(1) the date of destruction;

(2) the name, strength, and quantity of the drug destroyed; and

(3) the name of the person or firm that destroyed the drug.

Subd. 8. **Dispensing requirements.**

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(a) Donated drugs and supplies may be dispensed if the drugs or supplies are prescribed by a practitioner for use by an eligible individual and are dispensed by a pharmacist or practitioner. A repository shall dispense drugs and supplies to eligible individuals in the following priority order: (1) individuals who are uninsured; (2) individuals with no prescription drug coverage; and (3) individuals who are underinsured. A repository shall dispense donated ~~prescription~~ drugs in compliance with applicable federal and state laws and regulations for dispensing ~~prescription~~ drugs, including all requirements relating to packaging, labeling, record keeping, drug utilization review, and patient counseling.

(b) Before dispensing or administering a drug or supply, the pharmacist or practitioner shall visually inspect the drug or supply for adulteration, misbranding, tampering, and date of expiration. Drugs or supplies that have expired or appear upon visual inspection to be adulterated, misbranded, or tampered with in any way must not be dispensed or administered.

(c) Before a drug or supply is dispensed or administered to an individual, the individual must sign a drug repository recipient form acknowledging that the individual understands the information stated on the form. The board shall develop the form and make it available on the board's website. The form must include the following information:

(1) that the drug or supply being dispensed or administered has been donated and may have been previously dispensed;

(2) that a visual inspection has been conducted by the pharmacist or practitioner to ensure that the drug or supply has not expired, has not been adulterated or misbranded, and is in its original, unopened packaging; and

(3) that the dispensing pharmacist, the dispensing or administering practitioner, the central repository or local repository, the Board of Pharmacy, and any other participant of the ~~drug~~ medication repository program cannot guarantee the safety of the drug or medical supply being dispensed or administered and that the pharmacist or practitioner has determined that the drug or supply is safe to dispense or administer based on the accuracy of the donor's form submitted with the donated drug or medical supply and the visual inspection required to be performed by the pharmacist or practitioner before dispensing or administering.

Subd. 9. **Handling fees.**

(a) The central or local repository may charge the individual receiving a drug or supply a handling fee of no more than 250 percent of the medical assistance program dispensing fee for each drug or medical supply dispensed or administered by that repository.

(b) A repository that dispenses or administers a drug or medical supply through the ~~drug~~ medication repository program shall not receive reimbursement under the medical assistance program or the MinnesotaCare program for that dispensed or administered drug or supply.

Subd. 10. **Distribution of donated drugs and supplies.**

(a) The central repository and local repositories may distribute drugs and supplies donated under the ~~drug~~ medication repository program to other participating repositories for use pursuant to this program.

(b) A local repository that elects not to dispense donated drugs or supplies must transfer all donated drugs and supplies to the central repository. A copy of the donor form that was completed by the original donor under subdivision 6 must be provided to the central repository at the time of transfer.

Subd. 11. **Forms and record-keeping requirements.**

(a) The following forms developed for the administration of this program shall be utilized by the participants of the program and shall be available on the board's website:

(1) intake application form described under subdivision 5;

(2) local repository participation form described under subdivision 4;

(3) local repository withdrawal form described under subdivision 4;

(4) ~~drug~~ medication repository donor form described under subdivision 6;

(5) record of destruction form described under subdivision 7; and

(6) ~~drug~~ medication repository recipient form described under subdivision 8.

(b) All records, including drug inventory, inspection, and disposal of donated ~~prescription~~ drugs and medical supplies, must be maintained by a repository for a minimum of two years. Records required as part of this program must be maintained pursuant to all applicable practice acts.

(c) Data collected by the ~~drug~~ medication repository program from all local repositories shall be submitted quarterly or upon request to the central repository. Data collected may consist of the information, records, and forms required to be collected under this section.

(d) The central repository shall submit reports to the board as required by the contract or upon request of the board.

Subd. 12. **Liability.**

(a) The manufacturer of a drug or supply is not subject to criminal or civil liability for injury, death, or loss to a person or to property for causes of action described in clauses (1) and (2). A manufacturer is not liable for:

(1) the intentional or unintentional alteration of the drug or supply by a party not under the control of the manufacturer; or

(2) the failure of a party not under the control of the manufacturer to transfer or communicate product or consumer information or the expiration date of the donated drug or supply.

(b) A health care facility participating in the program, a pharmacist dispensing a drug or supply pursuant to the program, a practitioner dispensing or administering a drug or supply pursuant to the program, or a donor of a drug or medical supply is immune from civil liability for an act or omission that causes injury to or the death of an individual to whom the drug or supply is dispensed and no disciplinary action by a health-related licensing board shall be taken against a pharmacist or practitioner so long as the drug or supply is donated, accepted, distributed, and dispensed according to the requirements of this section. This immunity does not apply if the act or omission involves reckless, wanton, or intentional misconduct, or malpractice unrelated to the quality of the drug or medical supply.

Subd. 13. **Drug returned for credit.**

Nothing in this section allows a long-term care facility to donate a drug to a central or local repository when federal or state law requires the drug to be returned to the pharmacy that initially dispensed it, so that the pharmacy can credit the payer for the amount of the drug returned.

Subd. 14. **Cooperation.**

The central repository, as approved by the Board of Pharmacy, may enter into an agreement with another state that has an established drug repository or drug donation program if the other state's program includes regulations to ensure the purity, integrity, and safety of the drugs and supplies donated, to permit the central repository to offer to another state program inventory that is not needed by a Minnesota resident and to accept inventory from another state program to be distributed to local repositories and dispensed to Minnesota residents in accordance with this program.

Subd. 15. **Funding.**

The central repository may seek grants and other money from nonprofit charitable organizations, the federal government, and other sources to fund the ongoing operations of the medication repository program.

151.72 SALE OF CERTAIN CANNABINOID PRODUCTS *(amended and repealed)*

Chapter 63, Article 7, Sec. 2. Minnesota Statutes 2022, section 151.72, is amended to read:

151.72 SALE OF CERTAIN CANNABINOID PRODUCTS.

Subdivision 1. **Definitions**.

Appendix A

(a) For the purposes of this section, the following terms have the meanings given.

(a) "Artificially derived cannabinoid" means a cannabinoid extracted from a hemp plant or hemp plant parts with a chemical makeup that is changed after extraction to create a different cannabinoid or other chemical compound by applying a catalyst other than heat or light. Artificially derived cannabinoid includes but is not limited to any tetrahydrocannabinol created from cannabidiol.

(b) "Batch" means a specific quantity of a specific product containing cannabinoids derived from hemp, including an edible cannabinoid product, that is manufactured at the same time and using the same methods, equipment, and ingredients that is uniform and intended to meet specifications for identity, strength, purity, and composition, and that is manufactured, packaged, and labeled according to a single batch production record executed and documented.

~~(b)~~ (c) "Certified hemp" means hemp plants that have been tested and found to meet the requirements of chapter 18K and the rules adopted thereunder.

(d) "Commissioner" means the commissioner of health.

(e) "Distributor" means a person who sells, arranges a sale, or delivers a product containing cannabinoids derived from hemp, including an edible cannabinoid product, that the person did not manufacture to a retail establishment for sale to consumers. Distributor does not include a common carrier used only to complete delivery to a retailer.

~~(c)~~ (f) "Edible cannabinoid product" means any product that is intended to be eaten or consumed as a beverage by humans, contains a cannabinoid in combination with food ingredients, and is not a drug.

~~(d)~~ (g) "Hemp" has the meaning given to "industrial hemp" in section 18K.02, subdivision 3.

~~(e)~~ (h) "Label" has the meaning given in section 151.01, subdivision 18.

~~(f)~~ (i) "Labeling" means all labels and other written, printed, or graphic matter that are:

(1) affixed to the immediate container in which a product regulated under this section is sold;

(2) provided, in any manner, with the immediate container, including but not limited to outer containers, wrappers, package inserts, brochures, or pamphlets; or

(3) provided on that portion of a manufacturer's website that is linked by a scannable barcode or matrix barcode.

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~~(g)~~ (j) "Matrix barcode" means a code that stores data in a two-dimensional array of geometrically shaped dark and light cells capable of being read by the camera on a smartphone or other mobile device.

~~(h)~~ (k) "Nonintoxicating cannabinoid" means substances extracted from certified hemp plants that do not produce intoxicating effects when consumed by any route of administration.

(l) "Synthetic cannabinoid" means a substance with a similar chemical structure and pharmacological activity to a cannabinoid, but which is not extracted or derived from hemp plants, or hemp plant parts and is instead created or produced by chemical or biochemical synthesis.

Subd. 2. **Scope.**

(a) This section applies to the sale of any product that contains cannabinoids extracted from hemp and that is an edible cannabinoid product or is intended for human or animal consumption by any route of administration.

(b) This section does not apply to any product dispensed by a registered medical cannabis manufacturer pursuant to sections 152.22 to 152.37.

(c) The ~~board~~ commissioner must have no authority over food products, as defined in section 34A.01, subdivision 4, that do not contain cannabinoids extracted or derived from hemp.

Subd. 3. **Sale of cannabinoids derived from hemp.**

(a) Notwithstanding any other section of this chapter, a product containing nonintoxicating cannabinoids, including an edible cannabinoid product, may be sold for human or animal consumption only if all of the requirements of this section are met, provided that a product sold for human or animal consumption does not contain more than 0.3 percent of any tetrahydrocannabinol and an edible cannabinoid product does not contain an amount of any tetrahydrocannabinol that exceeds the limits established in subdivision 5a, paragraph (f).

(b) A product containing nonintoxicating cannabinoids, other than an edible cannabinoid product, may be sold for human or animal consumption only if it is intended for application externally to a part of the body of a human or animal. Such a product must not be manufactured, marketed, distributed, or intended to be consumed:

(1) by combustion or vaporization of the product and inhalation of smoke, aerosol, or vapor from the product;

(2) through chewing, drinking, or swallowing; or

(3) through injection or application to a mucous membrane or nonintact skin.

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~~(b)~~ (c) No other substance extracted or otherwise derived from hemp may be sold for human consumption if the substance is intended:

(1) for external or internal use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals; or

(2) to affect the structure or any function of the bodies of humans or other animals.

~~(c)~~ (d) No product containing any cannabinoid or tetrahydrocannabinol extracted or otherwise derived from hemp may be sold to any individual who is under the age of 21.

~~(d)~~ (e) Products that meet the requirements of this section are not controlled substances under section 152.02.

(f) Products may be sold for on-site consumption provided that all of the following conditions are met:

(1) the retailer must also hold an on-sale license issued under chapter 340A;

(2) products must be served in original packaging, but may be removed from the products' packaging by customers and consumed on site;

(3) products must not be sold to a customer who the retailer knows or reasonably should know is intoxicated;

(4) products must not be permitted to be mixed with an alcoholic beverage; and

(5) products that have been removed from packaging must not be removed from the premises.

Subd. 4. **Testing requirements.**

(a) A manufacturer of a product regulated under this section must submit representative samples of each batch of the product to an independent, accredited laboratory in order to certify that the product complies with the standards adopted by the board on or before July 1, 2023, or the standards adopted by the commissioner. Testing must be consistent with generally accepted industry standards for herbal and botanical substances, and, at a minimum, the testing must confirm that the product:

(1) contains the amount or percentage of cannabinoids that is stated on the label of the product;

(2) does not contain more than trace amounts of any mold, residual solvents or other catalysts, pesticides, fertilizers, or heavy metals; and

(3) does not contain more than 0.3 percent of any tetrahydrocannabinol.

(b) A manufacturer of a product regulated under this section must disclose all known information regarding pesticides, fertilizers, solvents, or other foreign materials applied to industrial hemp or added to industrial hemp during any production or processing stages of any batch from which a representative sample has been sent for testing, including any catalysts used to create artificially derived cannabinoids. The disclosure must be made to the laboratory performing testing or sampling and, upon request, to the commissioner. The disclosure must include all information known to the licensee regardless of whether the application or addition was made intentionally or accidentally, or by the manufacturer or any other person.

~~(b)~~ (c) Upon the request of the ~~board~~ commissioner, the manufacturer of the product must provide the ~~board~~ commissioner with the results of the testing required in this section.

(d) The commissioner may determine that any testing laboratory that does not operate formal management systems under the International Organization for Standardization is not an accredited laboratory and require that a representative sample of a batch of the product be retested by a testing laboratory that meets this requirement.

~~(c)~~ (e) Testing of the hemp from which the nonintoxicating cannabinoid was derived, or possession of a certificate of analysis for such hemp, does not meet the testing requirements of this section.

Subd. 5. **Labeling requirements.**

(a) A product regulated under this section must bear a label that contains, at a minimum:

(1) the name, location, contact phone number, and website of the manufacturer of the product;

(2) the name and address of the independent, accredited laboratory used by the manufacturer to test the product; ~~and~~

(3) the batch number; and

~~(3)~~ (4) an accurate statement of the amount or percentage of cannabinoids found in each unit of the product meant to be consumed.

(b) The information in paragraph (a) may be provided on an outer package if the immediate container that holds the product is too small to contain all of the information.

(c) The information required in paragraph (a) may be provided through the use of a scannable barcode or matrix barcode that links to a page on the manufacturer's website if that page contains all of the information required by this subdivision.

(d) The label must also include a statement stating that the product does not claim to diagnose, treat, cure, or prevent any disease and has not been evaluated or approved by the United States Food and Drug Administration (FDA) unless the product has been so approved.

(e) The information required by this subdivision must be prominently and conspicuously placed on the label or displayed on the website in terms that can be easily read and understood by the consumer.

(f) The labeling must not contain any claim that the product may be used or is effective for the prevention, treatment, or cure of a disease or that it may be used to alter the structure or function of human or animal bodies, unless the claim has been approved by the FDA.

Subd. 5a. **Additional requirements for edible cannabinoid products.**

(a) In addition to the testing and labeling requirements under subdivisions 4 and 5, an edible cannabinoid must meet the requirements of this subdivision.

(b) An edible cannabinoid product must not:

(1) bear the likeness or contain cartoon-like characteristics of a real or fictional person, animal, or fruit that appeals to children;

(2) be modeled after a brand of products primarily consumed by or marketed to children;

(3) be made by applying an extracted or concentrated hemp-derived cannabinoid to a commercially available candy or snack food item;

(4) be substantively similar to a meat food product; poultry food product as defined in section 31A.02, subdivision 10; or a dairy product as defined in section 32D.01, subdivision 7;

~~(4)~~ (5) contain an ingredient, other than a hemp-derived cannabinoid, that is not approved by the United States Food and Drug Administration for use in food;

~~(5)~~ (6) be packaged in a way that resembles the trademarked, characteristic, or product-specialized packaging of any commercially available food product; or

~~(6)~~ (7) be packaged in a container that includes a statement, artwork, or design that could reasonably mislead any person to believe that the package contains anything other than an edible cannabinoid product.

(c) An edible cannabinoid product must be prepackaged in packaging or a container that is child-resistant, tamper-evident, and opaque or placed in packaging or a container that is child-resistant, tamper-evident, and opaque at the final point of sale to a customer. The requirement that packaging be child-resistant does not apply to an edible cannabinoid product that is intended to be consumed as a beverage ~~and which contains no more than a trace amount of any tetrahydrocannabinol~~.

(d) If an edible cannabinoid product, other than a product that is intended to be consumed as a beverage, is intended for more than a single use or contains multiple servings, each serving must be indicated by scoring, wrapping, or other indicators designating the individual serving size that appear on the edible cannabinoid product.

(e) A label containing at least the following information must be affixed to the packaging or container of all edible cannabinoid products sold to consumers:

(1) the serving size;

(2) the cannabinoid profile per serving and in total;

(3) a list of ingredients, including identification of any major food allergens declared by name; and

(4) the following statement: "Keep this product out of reach of children."

(f) An edible cannabinoid product must not contain more than five milligrams of any tetrahydrocannabinol in a single serving~~, or~~. An edible cannabinoid product, other than a product that is intended to be consumed as a beverage, may not contain more than a total of 50 milligrams of any tetrahydrocannabinol per package. An edible cannabinoid product that is intended to be consumed as a beverage may not contain more than two servings per container.

(g) An edible cannabinoid product may contain delta-8 tetrahydrocannabinol or delta-9 tetrahydrocannabinol that is extracted from hemp plants or hemp plant parts or is an artificially derived cannabinoid. Edible cannabinoid products are prohibited from containing any other artificially derived cannabinoid, including but not limited to THC-P, THC-O, and HHC, unless the commissioner authorizes use of the artificially derived cannabinoid in edible cannabinoid products. Edible cannabinoid products are prohibited from containing synthetic cannabinoids.

(h) Every person selling edible cannabinoid products to consumers, other than products that are intended to be consumed as a beverage, must ensure that all edible cannabinoid products are displayed behind a checkout counter where the public is not permitted or in a locked case.

Subd. 5b. **Registration; prohibitions.**

(a) On or before October 1, 2023, every person selling edible cannabinoid products to consumers must register with the commissioner in a form and manner established by the commissioner. After October 1, 2023, the sale of edible cannabinoid products by a person that is not registered is prohibited.

(b) The registration form must contain an attestation of compliance and each registrant must affirm that it is operating and will continue to operate in compliance with the requirements of this section and all other applicable state and local laws and ordinances.

(c) The commissioner shall not charge a fee for registration under this subdivision.

Subd. 5c. **Age verification.**

(a) Prior to initiating a sale or otherwise providing an edible cannabinoid product to an individual, an employee of a retailer must verify that the individual is at least 21 years of age.

(b) Proof of age may be established only by one of the following:

(1) a valid driver's license or identification card issued by Minnesota, another state, or a province of Canada and including the photograph and date of birth of the licensed person;

(2) a valid Tribal identification card as defined in section 171.072, paragraph (b);

(3) a valid passport issued by the United States;

(4) a valid instructional permit issued under section 171.05 to a person of legal age to purchase edible cannabinoid products, which includes a photograph and the date of birth of the person issued the permit; or

(5) in the case of a foreign national, by a valid passport.

(c) A registered retailer may seize a form of identification listed under paragraph (b) if the registered retailer has reasonable grounds to believe that the form of identification has been altered or falsified or is being used to violate any law. A registered retailer that seizes a form of identification as authorized under this paragraph must deliver it to a law enforcement agency within 24 hours of seizing it.

Subd. 6. **Noncompliant products; enforcement.**

(a) A product regulated under this section, including an edible cannabinoid product, shall be considered ~~an adulterated drug~~ a noncompliant product if the product is offered for sale in this state or if the product is manufactured, imported, distributed, or stored with the intent to be offered for sale in this state in violation of any provision of this section, including but not limited to if:

(1) it consists, in whole or in part, of any filthy, putrid, or decomposed substance;

(2) it has been produced, prepared, packed, or held under unsanitary conditions where it may have been rendered injurious to health, or where it may have been contaminated with filth;

(3) its container is composed, in whole or in part, of any poisonous or deleterious substance that may render the contents injurious to health;

(4) it contains any food additives, color additives, or excipients that have been found by the FDA to be unsafe for human or animal consumption;

(5) it contains an amount or percentage of nonintoxicating cannabinoids that is different than the amount or percentage stated on the label;

(6) it contains more than 0.3 percent of any tetrahydrocannabinol or, if the product is an edible cannabinoid product, an amount of tetrahydrocannabinol that exceeds the limits established in subdivision 5a, paragraph (f); or

(7) it contains more than trace amounts of mold, residual solvents, pesticides, fertilizers, or heavy metals.

(b) A product regulated under this section shall be considered a ~~misbranded drug~~ noncompliant product if the product's labeling is false or misleading in any manner or in violation of the requirements of this section.

(c) The ~~board's authority to issue cease and desist orders under section 151.06; to embargo adulterated and misbranded drugs under section 151.38; and to seek injunctive relief under section 214.11, extends to any~~ commissioner may assume that any product regulated under this section that is present in the state, other than a product lawfully possessed for personal use, has been manufactured, imported, distributed, or stored with the intent to be offered for sale in this state if a product of the same type and brand was sold in the state on or after July 1, 2023, or if the product is in the possession of a person who has sold any product in violation of this section.

(d) The commissioner may enforce this section, including enforcement against a manufacturer or distributor of a product regulated under this section, under sections 144.989 to 144.993.

(e) The commissioner may enter into an interagency agreement with the Office of Cannabis Management and the commissioner of agriculture to perform inspections and take other enforcement actions on behalf of the commissioner.

Subd. 7. **Violations; criminal penalties.**

(a) Notwithstanding section 144.99, subdivision 11, a person who does any of the following regarding a product regulated under this section is guilty of a gross misdemeanor and may be sentenced to imprisonment for not more than one year or to payment of a fine of not more than $3,000, or both:

(1) knowingly alters or otherwise falsifies testing results;

(2) intentionally alters or falsifies any information required to be included on the label of an edible cannabinoid product; or

(3) intentionally makes a false material statement to the commissioner.

(b) Notwithstanding section 144.99, subdivision 11, a person who does any of the following on the premises of a registered retailer or another business that sells retail goods to customers is guilty of a gross misdemeanor and may be sentenced to imprisonment for not more than one year or to payment of a fine of not more than $3,000, or both:

(1) sells an edible cannabinoid product knowing that the product does not comply with the limits on the amount or types of cannabinoids that a product may contain;

(2) sells an edible cannabinoid product knowing that the product does not comply with the applicable testing, packaging, or labeling requirements; or

(3) sells an edible cannabinoid product to a person under the age of 21, except that it is an affirmative defense to a charge under this clause if the defendant proves by a preponderance of the evidence that the defendant reasonably and in good faith relied on proof of age as described in subdivision 5c.

EFFECTIVE DATE.

This section is effective the day following final enactment.

Chapter 63, Article 7, Sec. 6. **REPEALER.**

Minnesota Statutes 2022, section 151.72, is repealed.

EFFECTIVE DATE. This section is effective March 1, 2025.

151.74 INSULIN SAFETY NET PROGRAM *(amended)*

Chapter 70, Article 6, Sec. 28. Minnesota Statutes 2022, section 151.74, subdivision 3, is amended to read:

Subd. 3. **Access to urgent-need insulin.** (a) MNsure shall develop an application form to be used by an individual who is in urgent need of insulin. The application must ask the individual to attest to the eligibility requirements described in subdivision 2. The form shall be accessible through MNsure's website. MNsure shall also make the form available to pharmacies and health care providers who prescribe or dispense insulin, hospital emergency departments, urgent care clinics, and community health clinics. By submitting a completed, signed, and dated application to a pharmacy, the individual attests that the information contained in the application is correct.

(b) If the individual is in urgent need of insulin, the individual may present a completed, signed, and dated application form to a pharmacy. The individual must also:

(1) have a valid insulin prescription; and

(2) present the pharmacist with identification indicating Minnesota residency in the form of a valid Minnesota identification card, driver's license or permit, individual taxpayer

identification number, or Tribal identification card as defined in section 171.072, paragraph (b). If the individual in urgent need of insulin is under the age of 18, the individual's parent or legal guardian must provide the pharmacist with proof of residency.

(c) Upon receipt of a completed and signed application, the pharmacist shall dispense the prescribed insulin in an amount that will provide the individual with a 30-day supply. The pharmacy must notify the health care practitioner who issued the prescription order no later than 72 hours after the insulin is dispensed.

(d) The pharmacy may submit to the manufacturer of the dispensed insulin product or to the manufacturer's vendor a claim for payment that is in accordance with the National Council for Prescription Drug Program standards for electronic claims processing, unless the manufacturer agrees to send to the pharmacy a replacement supply of the same insulin as dispensed in the amount dispensed. If the pharmacy submits an electronic claim to the manufacturer or the manufacturer's vendor, the manufacturer or vendor shall reimburse the pharmacy in an amount that covers the pharmacy's acquisition cost.

(e) The pharmacy may collect an insulin co-payment from the individual to cover the pharmacy's costs of processing and dispensing in an amount not to exceed $35 for the 30-day supply of insulin dispensed.

(f) The pharmacy shall also provide each eligible individual with the information sheet described in subdivision 7 and a list of trained navigators provided by the Board of Pharmacy for the individual to contact if the individual is in need of accessing ongoing insulin coverage options, including assistance in:

(1) applying for medical assistance or MinnesotaCare;

(2) applying for a qualified health plan offered through MNsure, subject to open and special enrollment periods;

(3) accessing information on providers who participate in prescription drug discount programs, including providers who are authorized to participate in the 340B program under section 340b of the federal Public Health Services Act, United States Code, title 42, section 256b; and

(4) accessing insulin manufacturers' patient assistance programs, co-payment assistance programs, and other foundation-based programs.

(g) The pharmacist shall retain a copy of the application form submitted by the individual to the pharmacy for reporting and auditing purposes.

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Chapter 70, Article 6, Sec. 29. Minnesota Statutes 2022, section 151.74, subdivision 4, is amended to read:

Subd. 4.**Continuing safety net program; general.**

(a) Each manufacturer shall make a patient assistance program available to any individual who meets the requirements of this subdivision. Each manufacturer's patient assistance programs must meet the requirements of this section. Each manufacturer shall provide the Board of Pharmacy with information regarding the manufacturer's patient assistance program, including contact information for individuals to call for assistance in accessing their patient assistance program.

(b) To be eligible to participate in a manufacturer's patient assistance program, the individual must:

(1) be a Minnesota resident with a valid Minnesota identification card that indicates Minnesota residency in the form of a Minnesota identification card, driver's license or permit, individual taxpayer identification number, or Tribal identification card as defined in section 171.072, paragraph (b). If the individual is under the age of 18, the individual's parent or legal guardian must provide proof of residency;

(2) have a family income that is equal to or less than 400 percent of the federal poverty guidelines;

(3) not be enrolled in medical assistance or MinnesotaCare;

(4) not be eligible to receive health care through a federally funded program or receive prescription drug benefits through the Department of Veterans Affairs; and

(5) not be enrolled in prescription drug coverage through an individual or group health plan that limits the total amount of cost-sharing that an enrollee is required to pay for a 30-day supply of insulin, including co-payments, deductibles, or coinsurance to $75 or less, regardless of the type or amount of insulin needed.

(c) Notwithstanding the requirement in paragraph (b), clause (4), an individual who is enrolled in Medicare Part D is eligible for a manufacturer's patient assistance program if the individual has spent $1,000 on prescription drugs in the current calendar year and meets the eligibility requirements in paragraph (b), clauses (1) to (3).

(d) An individual who is interested in participating in a manufacturer's patient assistance program may apply directly to the manufacturer; apply through the individual's health care practitioner, if the practitioner participates; or contact a trained navigator for assistance in finding a long-term insulin supply solution, including assistance in applying to a manufacturer's patient assistance program.

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152.02, SCHEDULES OF CONTROLLED SUBSTANCES; *(Chapter 52 amendments)*

Chapter 52, Article 16, Section 1. Minnesota Statutes 2022, section 152.02, subdivision 2, is amended to read:

Subd. 2. **Schedule I.** (a) Schedule I consists of the substances listed in this subdivision.

(b) Opiates. Unless specifically excepted or unless listed in another schedule, any of the following substances, including their analogs, isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of the analogs, isomers, esters, ethers, and salts is possible:

(1) acetylmethadol;

(2) allylprodine;

(3) alphacetylmethadol (except levo-alphacetylmethadol, also known as levomethadyl acetate);

(4) alphameprodine;

(5) alphamethadol;

(6) alpha-methylfentanyl benzethidine;

(7) betacetylmethadol;

(8) betameprodine;

(9) betamethadol;

(10) betaprodine;

(11) clonitazene;

(12) dextromoramide;

(13) diampromide;

(14) diethyliambutene;

(15) difenoxin;

(16) dimenoxadol;

(17) dimepheptanol;

(18) dimethyliambutene;

(19) dioxaphetyl butyrate;

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(20) dipipanone;

(21) ethylmethylthiambutene;

(22) etonitazene;

(23) etoxeridine;

(24) furethidine;

(25) hydroxypethidine;

(26) ketobemidone;

(27) levomoramide;

(28) levophenacylmorphan;

(29) 3-methylfentanyl;

(30) acetyl-alpha-methylfentanyl;

(31) alpha-methylthiofentanyl;

(32) benzylfentanyl beta-hydroxyfentanyl;

(33) beta-hydroxy-3-methylfentanyl;

(34) 3-methylthiofentanyl;

(35) thenylfentanyl;

(36) thiofentanyl;

(37) para-fluorofentanyl;

(38) morpheridine;

(39) 1-methyl-4-phenyl-4-propionoxypiperidine;

(40) noracymethadol;

(41) norlevorphanol;

(42) normethadone;

(43) norpipanone;

(44) 1-(2-phenylethyl)-4-phenyl-4-acetoxypiperidine (PEPAP);

(45) phenadoxone;

(46) phenampromide;

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(47) phenomorphan;

(48) phenoperidine;

(49) piritramide;

(50) proheptazine;

(51) properidine;

(52) propiram;

(53) racemoramide;

(54) tilidine;

(55) trimeperidine;

(56) N-(1-Phenethylpiperidin-4-yl)-N-phenylacetamide (acetyl fentanyl);

(57) 3,4-dichloro-N-[(1R,2R)-2-(dimethylamino)cyclohexyl]-N-methylbenzamide(U47700);

(58) N-phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]furan-2-carboxamide(furanylfentanyl);

(59) 4-(4-bromophenyl)-4-dimethylamino-1-phenethylcyclohexanol (bromadol);

(60) N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopropanecarboxamide (Cyclopropryl fentanyl);

(61) N-(1-phenethylpiperidin-4-yl)-N-phenylbutanamide) (butyryl fentanyl);

(62) 1-cyclohexyl-4-(1,2-diphenylethyl)piperazine) (MT-45);

(63) N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopentanecarboxamide (cyclopentyl fentanyl);

(64) N-(1-phenethylpiperidin-4-yl)-N-phenylisobutyramide (isobutyryl fentanyl);

(65) N-(1-phenethylpiperidin-4-yl)-N-phenylpentanamide (valeryl fentanyl);

(66) N-(4-chlorophenyl)-N-(1-phenethylpiperidin-4-yl)isobutyramide (para-chloroisobutyryl fentanyl);

(67) N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)butyramide (para-fluorobutyryl fentanyl);

(68) N-(4-methoxyphenyl)-N-(1-phenethylpiperidin-4-yl)butyramide (para-methoxybutyryl fentanyl);

(69) N-(2-fluorophenyl)-2-methoxy-N-(1-phenethylpiperidin-4-yl)acetamide (ocfentanil);

(70) N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)isobutyramide (4-fluoroisobutyryl fentanyl or para-fluoroisobutyryl fentanyl);

(71) N-(1-phenethylpiperidin-4-yl)-N-phenylacrylamide (acryl fentanyl or acryloylfentanyl);

(72) 2-methoxy-N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide (methoxyacetyl fentanyl);

(73) N-(2-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)propionamide (ortho-fluorofentanyl or 2-fluorofentanyl);

(74) N-(1-phenethylpiperidin-4-yl)-N-phenyltetrahydrofuran-2-carboxamide (tetrahydrofuranyl fentanyl); ~~and~~

(75) Fentanyl-related substances, their isomers, esters, ethers, salts and salts of isomers, esters and ethers, meaning any substance not otherwise listed under another federal Administration Controlled Substance Code Number or not otherwise listed in this section, and for which no exemption or approval is in effect under section 505 of the Federal Food, Drug, and Cosmetic Act, United States Code , title 21, section 355, that is structurally related to fentanyl by one or more of the following modifications:

(i) replacement of the phenyl portion of the phenethyl group by any monocycle, whether or not further substituted in or on the monocycle;

(ii) substitution in or on the phenethyl group with alkyl, alkenyl, alkoxyl, hydroxyl, halo, haloalkyl, amino, or nitro groups;

(iii) substitution in or on the piperidine ring with alkyl, alkenyl, alkoxyl, ester, ether, hydroxyl, halo, haloalkyl, amino, or nitro groups;

(iv) replacement of the aniline ring with any aromatic monocycle whether or not further substituted in or on the aromatic monocycle; or

(v) replacement of the N-propionyl group by another acyl group~~.~~;

(76) 1-(1-(1-(4-bromophenyl)ethyl)piperidin-4-yl)-1,3- dihydro-2H-benzo[d]imidazol-2-one (brorphine);

(77) 4'-methyl acetyl fentanyl;

(78) beta-hydroxythiofentanyl;

(79) beta-methyl fentanyl;

(80) beta'-phenyl fentanyl;

(81) crotonyl fentanyl ((E)-N-(1-phenethylpiperidin-4-yl)-N-phenylbut-2-enamide);

(82) cyclopropyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopropanecarboxamide);

(83) fentanyl carbamate;

(84) isotonitazene (N,N-diethyl-2-(2-(4 isopropoxybenzyl)-5-nitro-1H-benzimidazol-1-yl)ethan-1-amine);

(85) para-fluoro furanyl fentanyl;

(86) para-methylfentanyl;

(87) phenyl fentanyl;

(88) ortho-fluoroacryl fentanyl;

(89) ortho-fluorobutyryl fentanyl;

(90) ortho-fluoroisobutyryl fentanyl;

(91) ortho-methyl acetylfentanyl;

(92) thiofuranyl fentanyl;

(93) metonitazene (N,N-diethyl-2-(2-(4-methoxybenzyl)-5-nitro-1H-benzimidazol-1-yl)ethan-1-amine);

(94) metodesnitazene (N,N-diethyl-2-(2-(4-methoxybenzyl)-1H-benzimidazol-1-yl)ethan-1-amine);

(95) etodesnitazene; etazene (2-(2-(4-ethoxybenzyl)-1H-benzimidazol-1-yl)-N,N-diethylethan-1-amine);

(96) protonitazene (N,N-diethyl-2-(5-nitro-2-(4-propoxybenzyl)-1H-benzimidazol-1-yl)ethan-1-amine);

(97) butonitazene (2-(2-(4-butoxybenzyl)-5-nitro-1H-benzimidazol-1-yl)-N,N-diethylethan-1-amine);

(98) flunitazene (N,N-diethyl-2-(2-(4-fluorobenzyl)-5-nitro-1H-benzimidazol-1-yl)ethan-1-amine); and

(99) N-pyrrolidino etonitazene; etonitazepyne (2-(4-ethoxybenzyl)-5-nitro-1-(2-(pyrrolidin-1-yl)ethyl)-1H-benzimidazole).

(c) Opium derivatives. Any of the following substances, their analogs, salts, isomers, and salts of isomers, unless specifically excepted or unless listed in another schedule, whenever the existence of the analogs, salts, isomers, and salts of isomers is possible:

(1) acetorphine;

(2) acetyldihydrocodeine;

(3) benzylmorphine;

(4) codeine methylbromide;

(5) codeine-n-oxide;

(6) cyprenorphine;

(7) desomorphine;

(8) dihydromorphine;

(9) drotebanol;

(10) etorphine;

(11) heroin;

(12) hydromorphinol;

(13) methyldesorphine;

(14) methyldihydromorphine;

(15) morphine methylbromide;

(16) morphine methylsulfonate;

(17) morphine-n-oxide;

(18) myrophine;

(19) nicocodeine;

(20) nicomorphine;

(21) normorphine;

(22) pholcodine; and

(23) thebacon.

(d) Hallucinogens. Any material, compound, mixture or preparation which contains any quantity of the following substances, their analogs, salts, isomers (whether optical, positional, or geometric), and salts of isomers, unless specifically excepted or unless listed in another schedule, whenever the existence of the analogs, salts, isomers, and salts of isomers is possible:

(1) methylenedioxy amphetamine;

(2) methylenedioxymethamphetamine;

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(3) methylenedioxy-N-ethylamphetamine (MDEA);

(4) n-hydroxy-methylenedioxyamphetamine;

(5) 4-bromo-2,5-dimethoxyamphetamine (DOB);

(6) 2,5-dimethoxyamphetamine (2,5-DMA);

(7) 4-methoxyamphetamine;

(8) 5-methoxy-3, 4-methylenedioxyamphetamine;

(9) alpha-ethyltryptamine;

(10) bufotenine;

(11) diethyltryptamine;

(12) dimethyltryptamine;

(13) 3,4,5-trimethoxyamphetamine;

(14) 4-methyl-2, 5-dimethoxyamphetamine (DOM);

(15) ibogaine;

(16) lysergic acid diethylamide (LSD);

(17) mescaline;

(18) parahexyl;

(19) N-ethyl-3-piperidyl benzilate;

(20) N-methyl-3-piperidyl benzilate;

(21) psilocybin;

(22) psilocyn;

(23) tenocyclidine (TPCP or TCP);

(24) N-ethyl-1-phenyl-cyclohexylamine (PCE);

(25) 1-(1-phenylcyclohexyl) pyrrolidine (PCPy);

(26) 1-[1-(2-thienyl)cyclohexyl]-pyrrolidine (TCPy);

(27) 4-chloro-2,5-dimethoxyamphetamine (DOC);

(28) 4-ethyl-2,5-dimethoxyamphetamine (DOET);

(29) 4-iodo-2,5-dimethoxyamphetamine (DOI);

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(30) 4-bromo-2,5-dimethoxyphenethylamine (2C-B);

(31) 4-chloro-2,5-dimethoxyphenethylamine (2C-C);

(32) 4-methyl-2,5-dimethoxyphenethylamine (2C-D);

(33) 4-ethyl-2,5-dimethoxyphenethylamine (2C-E);

(34) 4-iodo-2,5-dimethoxyphenethylamine (2C-I);

(35) 4-propyl-2,5-dimethoxyphenethylamine (2C-P);

(36) 4-isopropylthio-2,5-dimethoxyphenethylamine (2C-T-4);

(37) 4-propylthio-2,5-dimethoxyphenethylamine (2C-T-7);

(38) 2-(8-bromo-2,3,6,7-tetrahydrofuro [2,3-f][1]benzofuran-4-yl)ethanamine (2-CB-FLY);

(39) bromo-benzodifuranyl-isopropylamine (Bromo-DragonFLY);

(40) alpha-methyltryptamine (AMT);

(41) N,N-diisopropyltryptamine (DiPT);

(42) 4-acetoxy-N,N-dimethyltryptamine (4-AcO-DMT);

(43) 4-acetoxy-N,N-diethyltryptamine (4-AcO-DET);

(44) 4-hydroxy-N-methyl-N-propyltryptamine (4-HO-MPT);

(45) 4-hydroxy-N,N-dipropyltryptamine (4-HO-DPT);

(46) 4-hydroxy-N,N-diallyltryptamine (4-HO-DALT);

(47) 4-hydroxy-N,N-diisopropyltryptamine (4-HO-DiPT);

(48) 5-methoxy-N,N-diisopropyltryptamine (5-MeO-DiPT);

(49) 5-methoxy-α-methyltryptamine (5-MeO-AMT);

(50) 5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT);

(51) 5-methylthio-N,N-dimethyltryptamine (5-MeS-DMT);

(52) 5-methoxy-N-methyl-N-isopropyltryptamine (5-MeO-MiPT);

(53) 5-methoxy-α-ethyltryptamine (5-MeO-AET);

(54) 5-methoxy-N,N-dipropyltryptamine (5-MeO-DPT);

(55) 5-methoxy-N,N-diethyltryptamine (5-MeO-DET);

(56) 5-methoxy-N,N-diallyltryptamine (5-MeO-DALT);

(57) methoxetamine (MXE);

(58) 5-iodo-2-aminoindane (5-IAI);

(59) 5,6-methylenedioxy-2-aminoindane (MDAI);

(60) 2-(4-bromo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25B-NBOMe);

(61) 2-(4-chloro-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25C-NBOMe);

(62) 2-(4-iodo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25I-NBOMe);

(63) 2-(2,5-Dimethoxyphenyl)ethanamine (2C-H);

(64) 2-(4-Ethylthio-2,5-dimethoxyphenyl)ethanamine (2C-T-2);

(65) N,N-Dipropyltryptamine (DPT);

(66) 3-[1-(Piperidin-1-yl)cyclohexyl]phenol (3-HO-PCP);

(67) N-ethyl-1-(3-methoxyphenyl)cyclohexanamine (3-MeO-PCE);

(68) 4-[1-(3-methoxyphenyl)cyclohexyl]morpholine (3-MeO-PCMo);

(69) 1-[1-(4-methoxyphenyl)cyclohexyl]-piperidine (methoxydine, 4-MeO-PCP);

(70) 2-(2-Chlorophenyl)-2-(ethylamino)cyclohexan-1-one (N-Ethylnorketamine, ethketamine, NENK);

(71) methylenedioxy-N,N-dimethylamphetamine (MDDMA);

(72) 3-(2-Ethyl(methyl)aminoethyl)-1H-indol-4-yl (4-AcO-MET); and

(73) 2-Phenyl-2-(methylamino)cyclohexanone (deschloroketamine).

(e) Peyote. All parts of the plant presently classified botanically as Lophophora williamsii Lemaire, whether growing or not, the seeds thereof, any extract from any part of the plant, and every compound, manufacture, salts, derivative, mixture, or preparation of the plant, its seeds or extracts. The listing of peyote as a controlled substance in Schedule I does not apply to the nondrug use of peyote in bona fide religious ceremonies of the American Indian Church, and members of the American Indian Church are exempt from registration. Any person who manufactures peyote for or distributes peyote to the American Indian Church, however, is required to obtain federal registration annually and to comply with all other requirements of law.

(f) Central nervous system depressants. Unless specifically excepted or unless listed in another schedule, any material compound, mixture, or preparation which contains any quantity

of the following substances, their analogs, salts, isomers, and salts of isomers whenever the existence of the analogs, salts, isomers, and salts of isomers is possible:

(1) mecloqualone;

(2) methaqualone;

(3) gamma-hydroxybutyric acid (GHB), including its esters and ethers;

(4) flunitrazepam;

(5) 2-(2-Methoxyphenyl)-2-(methylamino)cyclohexanone (2-MeO-2-deschloroketamine, methoxyketamine);

(6) tianeptine;

(7) clonazolam;

(8) etizolam;

(9) flubromazolam; and

(10) flubromazepam.

(g) Stimulants. Unless specifically excepted or unless listed in another schedule, any material compound, mixture, or preparation which contains any quantity of the following substances, their analogs, salts, isomers, and salts of isomers whenever the existence of the analogs, salts, isomers, and salts of isomers is possible:

(1) aminorex;

(2) cathinone;

(3) fenethylline;

(4) methcathinone;

(5) methylaminorex;

(6) N,N-dimethylamphetamine;

(7) N-benzylpiperazine (BZP);

(8) methylmethcathinone (mephedrone);

(9) 3,4-methylenedioxy-N-methylcathinone (methylone);

(10) methoxymethcathinone (methedrone);

(11) methylenedioxypyrovalerone (MDPV);

(12) 3-fluoro-N-methylcathinone (3-FMC);

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(13) methylethcathinone (MEC);

(14) 1-benzofuran-6-ylpropan-2-amine (6-APB);

(15) dimethylmethcathinone (DMMC);

(16) fluoroamphetamine;

(17) fluoromethamphetamine;

(18) α-methylaminobutyrophenone (MABP or buphedrone);

(19) 1-(1,3-benzodioxol-5-yl)-2-(methylamino)butan-1-one (butylone);

(20) 2-(methylamino)-1-(4-methylphenyl)butan-1-one (4-MEMABP or BZ-6378);

(21) 1-(naphthalen-2-yl)-2-(pyrrolidin-1-yl) pentan-1-one (naphthylpyrovalerone or naphyrone);

(22) (alpha-pyrrolidinopentiophenone (alpha-PVP);

(23) (RS)-1-(4-methylphenyl)-2-(1-pyrrolidinyl)-1-hexanone (4-Me-PHP or MPHP);

(24) 2-(1-pyrrolidinyl)-hexanophenone (Alpha-PHP);

(25) 4-methyl-N-ethylcathinone (4-MEC);

(26) 4-methyl-alpha-pyrrolidinopropiophenone (4-MePPP);

(27) 2-(methylamino)-1-phenylpentan-1-one (pentedrone);

(28) 1-(1,3-benzodioxol-5-yl)-2-(methylamino)pentan-1-one (pentylone);

(29) 4-fluoro-N-methylcathinone (4-FMC);

(30) 3,4-methylenedioxy-N-ethylcathinone (ethylone);

(31) alpha-pyrrolidinobutiophenone (α-PBP);

(32) 5-(2-Aminopropyl)-2,3-dihydrobenzofuran (5-APDB);

(33) 1-phenyl-2-(1-pyrrolidinyl)-1-heptanone (PV8);

(34) 6-(2-Aminopropyl)-2,3-dihydrobenzofuran (6-APDB);

(35) 4-methyl-alpha-ethylaminopentiophenone (4-MEAPP);

(36) 4'-chloro-alpha-pyrrolidinopropiophenone (4'-chloro-PPP);

(37) 1-(1,3-Benzodioxol-5-yl)-2-(dimethylamino)butan-1-one (dibutylone, bk-DMBDB);

(38) 1-(3-chlorophenyl) piperazine (meta-chlorophenylpiperazine or mCPP);

(39) 1-(1,3-benzodioxol-5-yl)-2-(ethylamino)-pentan-1-one (N-ethylpentylone, ephylone); ~~and~~

(40) any other substance, except bupropion or compounds listed under a different schedule, that is structurally derived from 2-aminopropan-1-one by substitution at the 1-position with either phenyl, naphthyl, or thiophene ring systems, whether or not the compound is further modified in any of the following ways:

(i) by substitution in the ring system to any extent with alkyl, alkylenedioxy, alkoxy, haloalkyl, hydroxyl, or halide substituents, whether or not further substituted in the ring system by one or more other univalent substituents;

(ii) by substitution at the 3-position with an acyclic alkyl substituent;

(iii) by substitution at the 2-amino nitrogen atom with alkyl, dialkyl, benzyl, or methoxybenzyl groups; or

(iv) by inclusion of the 2-amino nitrogen atom in a cyclic structure~~.~~;

(41) 4,4'-dimethylaminorex (4,4'-DMAR; 4,5-dihydro-4-methyl-5-(4-methylphenyl)-2-oxazolamine);

(42) 4-chloro-alpha-pyrrolidinovalerophenone (4-chloro-A-PVP);

(43) para-methoxymethamphetamine (PMMA), 1-(4-methoxyphenyl)-N-methylpropan-2-amine; and

(44) N-ethylhexedrone.

(h) Marijuana, tetrahydrocannabinols, and synthetic cannabinoids. Unless specifically excepted or unless listed in another schedule, any natural or synthetic material, compound, mixture, or preparation that contains any quantity of the following substances, their analogs, isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of the isomers, esters, ethers, or salts is possible:

(1) marijuana;

(2) tetrahydrocannabinols naturally contained in a plant of the genus Cannabis, except that tetrahydrocannabinols do not include any material, compound, mixture, or preparation that qualifies as industrial hemp as defined in section 18K.02, subdivision 3; synthetic equivalents of the substances contained in the cannabis plant or in the resinous extractives of the plant; or synthetic substances with similar chemical structure and pharmacological activity to those substances contained in the plant or resinous extract, including, but not limited to, 1 cis or trans tetrahydrocannabinol, 6 cis or trans tetrahydrocannabinol, and 3,4 cis or trans tetrahydrocannabinol;

(3) synthetic cannabinoids, including the following substances:

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(i) Naphthoylindoles, which are any compounds containing a 3-(1-napthoyl)indole structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent. Examples of naphthoylindoles include, but are not limited to:

(A) 1-Pentyl-3-(1-naphthoyl)indole (JWH-018 and AM-678);

(B) 1-Butyl-3-(1-naphthoyl)indole (JWH-073);

(C) 1-Pentyl-3-(4-methoxy-1-naphthoyl)indole (JWH-081);

(D) 1-[2-(4-morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200);

(E) 1-Propyl-2-methyl-3-(1-naphthoyl)indole (JWH-015);

(F) 1-Hexyl-3-(1-naphthoyl)indole (JWH-019);

(G) 1-Pentyl-3-(4-methyl-1-naphthoyl)indole (JWH-122);

(H) 1-Pentyl-3-(4-ethyl-1-naphthoyl)indole (JWH-210);

(I) 1-Pentyl-3-(4-chloro-1-naphthoyl)indole (JWH-398);

(J) 1-(5-fluoropentyl)-3-(1-naphthoyl)indole (AM-2201).

(ii) Napthylmethylindoles, which are any compounds containing a 1H-indol-3-yl-(1-naphthyl)methane structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent. Examples of naphthylmethylindoles include, but are not limited to:

(A) 1-Pentyl-1H-indol-3-yl-(1-naphthyl)methane (JWH-175);

(B) 1-Pentyl-1H-indol-3-yl-(4-methyl-1-naphthyl)methane (JWH-184).

(iii) Naphthoylpyrroles, which are any compounds containing a 3-(1-naphthoyl)pyrrole structure with substitution at the nitrogen atom of the pyrrole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl or 2-(4-morpholinyl)ethyl group whether or not further substituted in the pyrrole ring to any extent, whether or not substituted in the naphthyl ring to any extent. Examples of naphthoylpyrroles include, but are not limited to, (5-(2-fluorophenyl)-1-pentylpyrrol-3-yl)-naphthalen-1-ylmethanone (JWH-307).

(iv) Naphthylmethylindenes, which are any compounds containing a naphthylideneindene structure with substitution at the 3-position of the indene ring by an alkyl,

haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl or 2-(4-morpholinyl)ethyl group whether or not further substituted in the indene ring to any extent, whether or not substituted in the naphthyl ring to any extent. Examples of naphthylemethylindenes include, but are not limited to, E-1-[1-(1-naphthalenylmethylene)-1H-inden-3-yl]pentane (JWH-176).

(v) Phenylacetylindoles, which are any compounds containing a 3-phenylacetylindole structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl or 2-(4-morpholinyl)ethyl group whether or not further substituted in the indole ring to any extent, whether or not substituted in the phenyl ring to any extent. Examples of phenylacetylindoles include, but are not limited to:

(A) 1-(2-cyclohexylethyl)-3-(2-methoxyphenylacetyl)indole (RCS-8);

(B) 1-pentyl-3-(2-methoxyphenylacetyl)indole (JWH-250);

(C) 1-pentyl-3-(2-methylphenylacetyl)indole (JWH-251);

(D) 1-pentyl-3-(2-chlorophenylacetyl)indole (JWH-203).

(vi) Cyclohexylphenols, which are compounds containing a 2-(3-hydroxycyclohexyl)phenol structure with substitution at the 5-position of the phenolic ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl or 2-(4-morpholinyl)ethyl group whether or not substituted in the cyclohexyl ring to any extent. Examples of cyclohexylphenols include, but are not limited to:

(A) 5-(1,1-dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (CP 47,497);

(B) 5-(1,1-dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (Cannabicyclohexanol or CP 47,497 C8 homologue);

(C) 5-(1,1-dimethylheptyl)-2-[(1R,2R)-5-hydroxy-2-(3-hydroxypropyl)cyclohexyl] -phenol (CP 55,940).

(vii) Benzoylindoles, which are any compounds containing a 3-(benzoyl)indole structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl or 2-(4-morpholinyl)ethyl group whether or not further substituted in the indole ring to any extent and whether or not substituted in the phenyl ring to any extent. Examples of benzoylindoles include, but are not limited to:

(A) 1-Pentyl-3-(4-methoxybenzoyl)indole (RCS-4);

(B) 1-(5-fluoropentyl)-3-(2-iodobenzoyl)indole (AM-694);

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(C) (4-methoxyphenyl-[2-methyl-1-(2-(4-morpholinyl)ethyl)indol-3-yl]methanone (WIN 48,098 or Pravadoline).

(viii) Others specifically named:

(A) (6aR,10aR)-9-(hydroxymethyl)-6,6-dimethyl-3-(2-methyloctan-2-yl) -6a,7,10,10a-tetrahydrobenzo[c]chromen-1-ol (HU-210);

(B) (6aS,10aS)-9-(hydroxymethyl)-6,6-dimethyl-3-(2-methyloctan-2-yl) -6a,7,10,10a-tetrahydrobenzo[c]chromen-1-ol (Dexanabinol or HU-211);

(C) 2,3-dihydro-5-methyl-3-(4-morpholinylmethyl)pyrrolo[1,2,3-de] -1,4-benzoxazin-6-yl-1-naphthalenylmethanone (WIN 55,212-2);

(D) (1-pentylindol-3-yl)-(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144);

(E) (1-(5-fluoropentyl)-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (XLR-11);

(F) 1-pentyl-N-tricyclo[3.3.1.13,7]dec-1-yl-1H-indazole-3-carboxamide (AKB-48(APINACA));

(G) N-((3s,5s,7s)-adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide (5-Fluoro-AKB-48);

(H) 1-pentyl-8-quinolinyl ester-1H-indole-3-carboxylic acid (PB-22);

(I) 8-quinolinyl ester-1-(5-fluoropentyl)-1H-indole-3-carboxylic acid (5-Fluoro PB-22);

(J) N-[(1S)-1-(aminocarbonyl)-2-methylpropyl]-1-pentyl-1H-indazole- 3-carboxamide (AB-PINACA);

(K) N-[(1S)-1-(aminocarbonyl)-2-methylpropyl]-1-[(4-fluorophenyl)methyl]- 1H-indazole-3-carboxamide (AB-FUBINACA);

(L) N-[(1S)-1-(aminocarbonyl)-2-methylpropyl]-1-(cyclohexylmethyl)-1H- indazole-3-carboxamide(AB-CHMINACA);

(M) (S)-methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3- methylbutanoate (5-fluoro-AMB);

(N) [1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl) methanone (THJ-2201);

(O) (1-(5-fluoropentyl)-1H-benzo[d]imidazol-2-yl)(naphthalen-1-yl)methanone) (FUBIMINA);

(P) (7-methoxy-1-(2-morpholinoethyl)-N-((1S,2S,4R)-1,3,3-trimethylbicyclo [2.2.1]heptan-2-yl)-1H-indole-3-carboxamide (MN-25 or UR-12);

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(Q) (S)-N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl) -1H-indole-3-carboxamide (5-fluoro-ABICA);

(R) N-(1-amino-3-phenyl-1-oxopropan-2-yl)-1-(5-fluoropentyl) -1H-indole-3-carboxamide;

(S) N-(1-amino-3-phenyl-1-oxopropan-2-yl)-1-(5-fluoropentyl) -1H-indazole-3-carboxamide;

(T) methyl 2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido) -3,3-dimethylbutanoate;

(U) N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1(cyclohexylmethyl)-1 H-indazole-3-carboxamide (MAB-CHMINACA);

(V) N-(1-Amino-3,3-dimethyl-1-oxo-2-butanyl)-1-pentyl-1H-indazole-3-carboxamide (ADB-PINACA);

(W) methyl (1-(4-fluorobenzyl)-1H-indazole-3-carbonyl)-L-valinate (FUB-AMB);

(X) N-[(1S)-2-amino-2-oxo-1-(phenylmethyl)ethyl]-1-(cyclohexylmethyl)-1H-Indazole-3-carboxamide. (APP-CHMINACA);

(Y) quinolin-8-yl 1-(4-fluorobenzyl)-1H-indole-3-carboxylate (FUB-PB-22); and

(Z) methyl N-[1-(cyclohexylmethyl)-1H-indole-3-carbonyl]valinate (MMB-CHMICA).

(ix) Additional substances specifically named:

(A) 1-(5-fluoropentyl)-N-(2-phenylpropan-2-yl)-1 H-pyrrolo[2,3-B]pyridine-3-carboxamide (5F-CUMYL-P7AICA);

(B) 1-(4-cyanobutyl)-N-(2- phenylpropan-2-yl)-1 H-indazole-3-carboxamide (4-CN-Cumyl-Butinaca);

(C) naphthalen-1-yl-1-(5-fluoropentyl)-1-H-indole-3-carboxylate (NM2201; CBL2201);

(D) N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-1 H-indazole-3-carboxamide (5F-ABPINACA);

(E) methyl-2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate (MDMB CHMICA);

(F) methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate (5F-ADB; 5F-MDMB-PINACA); ~~and~~

(G) N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl) 1H-indazole-3-carboxamide (ADB-FUBINACA)~~.~~;

(H) 1-(5-fluoropentyl)-N-(2-phenylpropan-2-yl)-1H-indazole-3-carboxamide;

(I) (1-(4-fluorobenzyl)-1H-indol-3-yl)(2,2,3,3- tetramethylcyclopropyl)methanone;

(J) methyl 2-(1-(4-fluorobenzyl)-1Hindazole-3-carboxamido)-3,3-dimethylbutanoate;

(K) methyl 2-(1-(5-fluoropentyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate;

(L) ethyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate;

(M) methyl 2-(1-(4-fluorobenzyl)-1Hindazole-3-carboxamido)-3- methylbutanoate;

(N) N-(adamantan-1-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide; and

(O) N-(adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide.

(i) A controlled substance analog, to the extent that it is implicitly or explicitly intended for human consumption.

EFFECTIVE DATE. This section is effective the day following final enactment.

Chapter 52, Article 16, Sec. 2. Minnesota Statutes 2022, section 152.02, subdivision 3, is amended to read:

Subd. 3. **Schedule II.** (a) Schedule II consists of the substances listed in this subdivision.

(b) Unless specifically excepted or unless listed in another schedule, any of the following substances whether produced directly or indirectly by extraction from substances of vegetable origin or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate.

(i) Excluding:

(A) apomorphine;

(B) thebaine-derived butorphanol;

(C) dextrophan;

(D) nalbuphine;

(E) nalmefene;

(F) naloxegol;

(G) naloxone;

(H) naltrexone; and

(I) their respective salts;

(ii) but including the following:

(A) opium, in all forms and extracts;

(B) codeine;

(C) dihydroetorphine;

(D) ethylmorphine;

(E) etorphine hydrochloride;

(F) hydrocodone;

(G) hydromorphone;

(H) metopon;

(I) morphine;

(J) oxycodone;

(K) oxymorphone;

(L) thebaine;

(M) oripavine;

(2) any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in clause (1), except that these substances shall not include the isoquinoline alkaloids of opium;

(3) opium poppy and poppy straw;

(4) coca leaves and any salt, cocaine compound, derivative, or preparation of coca leaves (including cocaine and ecgonine and their salts, isomers, derivatives, and salts of isomers and derivatives), and any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, except that the substances shall not include decocainized coca leaves or extraction of coca leaves, which extractions do not contain cocaine or ecgonine;

(5) concentrate of poppy straw (the crude extract of poppy straw in either liquid, solid, or powder form which contains the phenanthrene alkaloids of the opium poppy).

(c) Any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters and ethers, unless specifically excepted, or unless listed in another schedule, whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation:

(1) alfentanil;

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(2) alphaprodine;

(3) anileridine;

(4) bezitramide;

(5) bulk dextropropoxyphene (nondosage forms);

(6) carfentanil;

(7) dihydrocodeine;

(8) dihydromorphinone;

(9) diphenoxylate;

(10) fentanyl;

(11) isomethadone;

(12) levo-alpha-acetylmethadol (LAAM);

(13) levomethorphan;

(14) levorphanol;

(15) metazocine;

(16) methadone;

(17) methadone - intermediate, 4-cyano-2-dimethylamino-4, 4-diphenylbutane;

(18) moramide - intermediate, 2-methyl-3-morpholino-1, 1-diphenyl-propane-carboxylic acid;

(19) pethidine;

(20) pethidine - intermediate - a, 4-cyano-1-methyl-4-phenylpiperidine;

(21) pethidine - intermediate - b, ethyl-4-phenylpiperidine-4-carboxylate;

(22) pethidine - intermediate - c, 1-methyl-4-phenylpiperidine-4-carboxylic acid;

(23) phenazocine;

(24) piminodine;

(25) racemethorphan;

(26) racemorphan;

(27) remifentanil;

(28) sufentanil;

(29) tapentadol;

(30) 4-Anilino-N-phenethylpiperidine~~.~~;

(31) oliceridine;

(32) norfentanyl (N-phenyl-N-(piperidin-4-yl) propionamide).

(d) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system:

(1) amphetamine, its salts, optical isomers, and salts of its optical isomers;

(2) methamphetamine, its salts, isomers, and salts of its isomers;

(3) phenmetrazine and its salts;

(4) methylphenidate;

(5) lisdexamfetamine.

(e) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) amobarbital;

(2) glutethimide;

(3) secobarbital;

(4) pentobarbital;

(5) phencyclidine;

(6) phencyclidine immediate precursors:

(i) 1-phenylcyclohexylamine;

(ii) 1-piperidinocyclohexanecarbonitrile;

(7) phenylacetone.

(f) Cannabinoids:

(1) nabilone;

(2) dronabinol [(-)-delta-9-trans-tetrahydrocannabinol (delta-9-THC)] in an oral solution in a drug product approved for marketing by the United States Food and Drug Administration.

EFFECTIVE DATE. This section is effective the day following final enactment.

Chapter 52, Article 16, Sec. 3. Minnesota Statutes 2022, section 152.02, subdivision 5, is amended to read:

Subd. 5. **Schedule IV.** (a) Schedule IV consists of the substances listed in this subdivision.

(b) Narcotic drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as follows:

(1) not more than one milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit;

(2) dextropropoxyphene (Darvon and Darvocet);

(3) 2-[(dimethylamino)methyl]-1-(3-methoxyphenyl)cyclohexanol, its salts, optical and geometric isomers, and salts of these isomers (including tramadol);

(4) eluxadoline;

(5) pentazocine; and

(6) butorphanol (including its optical isomers).

(c) Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any quantity of the following substances, including its salts, isomers, and salts of isomers whenever the existence of the salts, isomers, and salts of isomers is possible:

(1) alfaxalone (5α-pregnan-3α-ol-11,20-dione);

(2) alprazolam;

(3) barbital;

(4) bromazepam;

(5) camazepam;

(6) carisoprodol;

(7) chloral betaine;

(8) chloral hydrate;

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(9) chlordiazepoxide;

(10) clobazam;

(11) clonazepam;

(12) clorazepate;

(13) clotiazepam;

(14) cloxazolam;

(15) delorazepam;

(16) diazepam;

(17) dichloralphenazone;

(18) estazolam;

(19) ethchlorvynol;

(20) ethinamate;

(21) ethyl loflazepate;

(22) fludiazepam;

(23) flurazepam;

(24) fospropofol;

(25) halazepam;

(26) haloxazolam;

(27) ketazolam;

(28) loprazolam;

(29) lorazepam;

(30) lormetazepam mebutamate;

(31) medazepam;

(32) meprobamate;

(33) methohexital;

(34) methylphenobarbital;

(35) midazolam;

(36) nimetazepam;

(37) nitrazepam;

(38) nordiazepam;

(39) oxazepam;

(40) oxazolam;

(41) paraldehyde;

(42) petrichloral;

(43) phenobarbital;

(44) pinazepam;

(45) prazepam;

(46) quazepam;

(47) suvorexant;

(48) temazepam;

(49) tetrazepam;

(50) triazolam;

(51) zaleplon;

(52) zolpidem;

(53) zopiclone~~.~~;

(54) brexanolone (3α-hydroxy-5α-pregnan-20-one);

(55) lemborexant;

(56) remimazolam (4H-imidazol[1,2-a][1,4]benzodiazepine4-propionic acid).

(d) Any material, compound, mixture, or preparation which contains any quantity of the following substance including its salts, isomers, and salts of such isomers, whenever the existence of such salts, isomers, and salts of isomers is possible: fenfluramine.

(e) Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers, and salts of isomers:

(1) cathine (norpseudoephedrine);

(2) diethylpropion;

(3) fencamfamine;

(4) fenproporex;

(5) mazindol;

(6) mefenorex;

(7) modafinil;

(8) pemoline (including organometallic complexes and chelates thereof);

(9) phentermine;

(10) pipradol;

(11) sibutramine;

(12) SPA (1-dimethylamino-1,2-diphenylethane)~~.~~;

(13) serdexmethylphenidate;

(14) solriamfetol (2-amino-3-phenylpropyl car-bamate; benzenepropanol, beta-amino-, carbamate (ester)).

(f) lorcaserin.

EFFECTIVE DATE. This section is effective the day following final enactment.

Chapter 52, Article 16, Sec. 4. Minnesota Statutes 2022, section 152.02, subdivision 6, is amended to read:

Subd. 6. **Schedule V; restrictions on methamphetamine precursor drugs.** (a) As used in this subdivision, the following terms have the meanings given:

(1) "methamphetamine precursor drug" means any compound, mixture, or preparation intended for human consumption containing ephedrine or pseudoephedrine as its sole active ingredient or as one of its active ingredients; and

(2) "over-the-counter sale" means a retail sale of a drug or product but does not include the sale of a drug or product pursuant to the terms of a valid prescription.

(b) The following items are listed in Schedule V:

(1) any compound, mixture, or preparation containing any of the following limited quantities of narcotic drugs, which shall include one or more nonnarcotic active medicinal

ingredients in sufficient proportion to confer upon the compound, mixture or preparation valuable medicinal qualities other than those possessed by the narcotic drug alone:

(i) not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams;

(ii) not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams;

(iii) not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit;

(iv) not more than 100 milligrams of opium per 100 milliliters or per 100 grams; or

(v) not more than 0.5 milligrams of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.

(2) Stimulants. Unless specifically exempted or excluded or unless listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of the following substance having a stimulant effect on the central nervous system, including its salts, isomers, and salts of isomers: pyrovalerone.

(3) Depressants. Unless specifically exempted or excluded or unless listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of the following substance having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers:

(i) ezogabine;

(ii) pregabalin;

(iii) lacosamide~~.~~;

(iv) cenobamate [(1R)-1-(2-chlorophenyl)-2-(tetrazol-2-yl)ethyl]carbamate.

(4) Any compound, mixture, or preparation containing ephedrine or pseudoephedrine as its sole active ingredient or as one of its active ingredients.

(c) No person may sell in a single over-the-counter sale more than two packages of a methamphetamine precursor drug or a combination of methamphetamine precursor drugs or any combination of packages exceeding a total weight of six grams, calculated as the base.

(d) Over-the-counter sales of methamphetamine precursor drugs are limited to:

(1) packages containing not more than a total of three grams of one or more methamphetamine precursor drugs, calculated in terms of ephedrine base or pseudoephedrine base; or

(2) for nonliquid products, sales in blister packs, where each blister contains not more than two dosage units, or, if the use of blister packs is not technically feasible, sales in unit dose packets or pouches.

(e) A business establishment that offers for sale methamphetamine precursor drugs in an over-the-counter sale shall ensure that all packages of the drugs are displayed behind a checkout counter where the public is not permitted and are offered for sale only by a licensed pharmacist, a registered pharmacy technician, or a pharmacy clerk. The establishment shall ensure that the person making the sale requires the buyer:

(1) to provide photographic identification showing the buyer's date of birth; and

(2) to sign a written or electronic document detailing the date of the sale, the name of the buyer, and the amount of the drug sold.

A document described under clause (2) must be retained by the establishment for at least three years and must at all reasonable times be open to the inspection of any law enforcement agency.

Nothing in this paragraph requires the buyer to obtain a prescription for the drug's purchase.

(f) No person may acquire through over-the-counter sales more than six grams of methamphetamine precursor drugs, calculated as the base, within a 30-day period.

(g) No person may sell in an over-the-counter sale a methamphetamine precursor drug to a person under the age of 18 years. It is an affirmative defense to a charge under this paragraph if the defendant proves by a preponderance of the evidence that the defendant reasonably and in good faith relied on proof of age as described in section 340A.503, subdivision 6.

(h) A person who knowingly violates paragraph (c), (d), (e), (f), or (g) is guilty of a misdemeanor and may be sentenced to imprisonment for not more than 90 days, or to payment of a fine of not more than $1,000, or both.

(i) An owner, operator, supervisor, or manager of a business establishment that offers for sale methamphetamine precursor drugs whose employee or agent is convicted of or charged with violating paragraph (c), (d), (e), (f), or (g) is not subject to the criminal penalties for violating any of those paragraphs if the person:

(1) did not have prior knowledge of, participate in, or direct the employee or agent to commit the violation; and

(2) documents that an employee training program was in place to provide the employee or agent with information on the state and federal laws and regulations regarding methamphetamine precursor drugs.

(j) Any person employed by a business establishment that offers for sale methamphetamine precursor drugs who sells such a drug to any person in a suspicious transaction shall report the transaction to the owner, supervisor, or manager of the establishment. The owner, supervisor, or manager may report the transaction to local law enforcement. A person who reports information under this subdivision in good faith is immune from civil liability relating to the report.

(k) Paragraphs (b) to (j) do not apply to:

(1) pediatric products labeled pursuant to federal regulation primarily intended for administration to children under 12 years of age according to label instructions;

(2) methamphetamine precursor drugs that are certified by the Board of Pharmacy as being manufactured in a manner that prevents the drug from being used to manufacture methamphetamine;

(3) methamphetamine precursor drugs in gel capsule or liquid form; or

(4) compounds, mixtures, or preparations in powder form where pseudoephedrine constitutes less than one percent of its total weight and is not its sole active ingredient.

(l) The Board of Pharmacy, in consultation with the Department of Public Safety, shall certify methamphetamine precursor drugs that meet the requirements of paragraph (k), clause (2), and publish an annual listing of these drugs.

(m) Wholesale drug distributors licensed and regulated by the Board of Pharmacy pursuant to sections ~~151.42~~ ~~to~~ ~~151.51~~ 151.43 to 151.471 and registered with and regulated by the United States Drug Enforcement Administration are exempt from the methamphetamine precursor drug storage requirements of this section.

(n) This section preempts all local ordinances or regulations governing the sale by a business establishment of over-the-counter products containing ephedrine or pseudoephedrine. All ordinances enacted prior to the effective date of this act are void.

EFFECTIVE DATE. This section is effective the day following final enactment.

152.02, SCHEDULES OF CONTROLLED SUBSTANCES *(Chapter 63 amendments)*

Chapter 63, Article 8, Section 1. Minnesota Statutes 2022, section 152.02, subdivision 2, is amended to read:

Subd. 2. **Schedule I.** (a) Schedule I consists of the substances listed in this subdivision.

(b) Opiates. Unless specifically excepted or unless listed in another schedule, any of the following substances, including their analogs, isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of the analogs, isomers, esters, ethers, and salts is possible:

(1) acetylmethadol;

(2) allylprodine;

(3) alphacetylmethadol (except levo-alphacetylmethadol, also known as levomethadyl acetate);

(4) alphameprodine;

(5) alphamethadol;

(6) alpha-methylfentanyl benzethidine;

(7) betacetylmethadol;

(8) betameprodine;

(9) betamethadol;

(10) betaprodine;

(11) clonitazene;

(12) dextromoramide;

(13) diampromide;

(14) diethyliambutene;

(15) difenoxin;

(16) dimenoxadol;

(17) dimepheptanol;

(18) dimethyliambutene;

(19) dioxaphetyl butyrate;

(20) dipipanone;

(21) ethylmethylthiambutene;

(22) etonitazene;

(23) etoxeridine;

(24) furethidine;

(25) hydroxypethidine;

(26) ketobemidone;

(27) levomoramide;

(28) levophenacylmorphan;

(29) 3-methylfentanyl;

(30) acetyl-alpha-methylfentanyl;

(31) alpha-methylthiofentanyl;

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(32) benzylfentanyl beta-hydroxyfentanyl;

(33) beta-hydroxy-3-methylfentanyl;

(34) 3-methylthiofentanyl;

(35) thenylfentanyl;

(36) thiofentanyl;

(37) para-fluorofentanyl;

(38) morpheridine;

(39) 1-methyl-4-phenyl-4-propionoxypiperidine;

(40) noracymethadol;

(41) norlevorphanol;

(42) normethadone;

(43) norpipanone;

(44) 1-(2-phenylethyl)-4-phenyl-4-acetoxypiperidine (PEPAP);

(45) phenadoxone;

(46) phenampromide;

(47) phenomorphan;

(48) phenoperidine;

(49) piritramide;

(50) proheptazine;

(51) properidine;

(52) propiram;

(53) racemoramide;

(54) tilidine;

(55) trimeperidine;

(56) N-(1-Phenethylpiperidin-4-yl)-N-phenylacetamide (acetyl fentanyl);

(57) 3,4-dichloro-N-[(1R,2R)-2-(dimethylamino)cyclohexyl]-N-methylbenzamide(U47700);

(58) N-phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]furan-2-carboxamide(furanylfentanyl);

(59) 4-(4-bromophenyl)-4-dimethylamino-1-phenethylcyclohexanol (bromadol);

(60) N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopropanecarboxamide (Cyclopropryl fentanyl);

(61) N-(1-phenethylpiperidin-4-yl)-N-phenylbutanamide) (butyryl fentanyl);

(62) 1-cyclohexyl-4-(1,2-diphenylethyl)piperazine) (MT-45);

(63) N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopentanecarboxamide (cyclopentyl fentanyl);

(64) N-(1-phenethylpiperidin-4-yl)-N-phenylisobutyramide (isobutyryl fentanyl);

(65) N-(1-phenethylpiperidin-4-yl)-N-phenylpentanamide (valeryl fentanyl);

(66) N-(4-chlorophenyl)-N-(1-phenethylpiperidin-4-yl)isobutyramide (para-chloroisobutyryl fentanyl);

(67) N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)butyramide (para-fluorobutyryl fentanyl);

(68) N-(4-methoxyphenyl)-N-(1-phenethylpiperidin-4-yl)butyramide (para-methoxybutyryl fentanyl);

(69) N-(2-fluorophenyl)-2-methoxy-N-(1-phenethylpiperidin-4-yl)acetamide (ocfentanil);

(70) N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)isobutyramide (4-fluoroisobutyryl fentanyl or para-fluoroisobutyryl fentanyl);

(71) N-(1-phenethylpiperidin-4-yl)-N-phenylacrylamide (acryl fentanyl or acryloylfentanyl);

(72) 2-methoxy-N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide (methoxyacetyl fentanyl);

(73) N-(2-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)propionamide (ortho-fluorofentanyl or 2-fluorofentanyl);

(74) N-(1-phenethylpiperidin-4-yl)-N-phenyltetrahydrofuran-2-carboxamide (tetrahydrofuranyl fentanyl); and

(75) Fentanyl-related substances, their isomers, esters, ethers, salts and salts of isomers, esters and ethers, meaning any substance not otherwise listed under another federal Administration Controlled Substance Code Number or not otherwise listed in this section, and for which no exemption or approval is in effect under section 505 of the Federal Food, Drug, and Cosmetic Act, United States Code , title 21, section 355, that is structurally related to fentanyl by one or more of the following modifications:

(i) replacement of the phenyl portion of the phenethyl group by any monocycle, whether or not further substituted in or on the monocycle;

(ii) substitution in or on the phenethyl group with alkyl, alkenyl, alkoxyl, hydroxyl, halo, haloalkyl, amino, or nitro groups;

(iii) substitution in or on the piperidine ring with alkyl, alkenyl, alkoxyl, ester, ether, hydroxyl, halo, haloalkyl, amino, or nitro groups;

(iv) replacement of the aniline ring with any aromatic monocycle whether or not further substituted in or on the aromatic monocycle; or

(v) replacement of the N-propionyl group by another acyl group.

(c) Opium derivatives. Any of the following substances, their analogs, salts, isomers, and salts of isomers, unless specifically excepted or unless listed in another schedule, whenever the existence of the analogs, salts, isomers, and salts of isomers is possible:

(1) acetorphine;

(2) acetyldihydrocodeine;

(3) benzylmorphine;

(4) codeine methylbromide;

(5) codeine-n-oxide;

(6) cyprenorphine;

(7) desomorphine;

(8) dihydromorphine;

(9) drotebanol;

(10) etorphine;

(11) heroin;

(12) hydromorphinol;

(13) methyldesorphine;

(14) methyldihydromorphine;

(15) morphine methylbromide;

(16) morphine methylsulfonate;

(17) morphine-n-oxide;

(18) myrophine;

(19) nicocodeine;

(20) nicomorphine;

(21) normorphine;

(22) pholcodine; and

(23) thebacon.

(d) Hallucinogens. Any material, compound, mixture or preparation which contains any quantity of the following substances, their analogs, salts, isomers (whether optical, positional, or geometric), and salts of isomers, unless specifically excepted or unless listed in another schedule, whenever the existence of the analogs, salts, isomers, and salts of isomers is possible:

(1) methylenedioxy amphetamine;

(2) methylenedioxymethamphetamine;

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(3) methylenedioxy-N-ethylamphetamine (MDEA);

(4) n-hydroxy-methylenedioxyamphetamine;

(5) 4-bromo-2,5-dimethoxyamphetamine (DOB);

(6) 2,5-dimethoxyamphetamine (2,5-DMA);

(7) 4-methoxyamphetamine;

(8) 5-methoxy-3, 4-methylenedioxyamphetamine;

(9) alpha-ethyltryptamine;

(10) bufotenine;

(11) diethyltryptamine;

(12) dimethyltryptamine;

(13) 3,4,5-trimethoxyamphetamine;

(14) 4-methyl-2, 5-dimethoxyamphetamine (DOM);

(15) ibogaine;

(16) lysergic acid diethylamide (LSD);

(17) mescaline;

(18) parahexyl;

(19) N-ethyl-3-piperidyl benzilate;

(20) N-methyl-3-piperidyl benzilate;

(21) psilocybin;

(22) psilocyn;

(23) tenocyclidine (TPCP or TCP);

(24) N-ethyl-1-phenyl-cyclohexylamine (PCE);

(25) 1-(1-phenylcyclohexyl) pyrrolidine (PCPy);

(26) 1-[1-(2-thienyl)cyclohexyl]-pyrrolidine (TCPy);

(27) 4-chloro-2,5-dimethoxyamphetamine (DOC);

(28) 4-ethyl-2,5-dimethoxyamphetamine (DOET);

(29) 4-iodo-2,5-dimethoxyamphetamine (DOI);

(30) 4-bromo-2,5-dimethoxyphenethylamine (2C-B);

(31) 4-chloro-2,5-dimethoxyphenethylamine (2C-C);

(32) 4-methyl-2,5-dimethoxyphenethylamine (2C-D);

(33) 4-ethyl-2,5-dimethoxyphenethylamine (2C-E);

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(34) 4-iodo-2,5-dimethoxyphenethylamine (2C-I);

(35) 4-propyl-2,5-dimethoxyphenethylamine (2C-P);

(36) 4-isopropylthio-2,5-dimethoxyphenethylamine (2C-T-4);

(37) 4-propylthio-2,5-dimethoxyphenethylamine (2C-T-7);

(38) 2-(8-bromo-2,3,6,7-tetrahydrofuro [2,3-f][1]benzofuran-4-yl)ethanamine (2-CB-FLY);

(39) bromo-benzodifuranyl-isopropylamine (Bromo-DragonFLY);

(40) alpha-methyltryptamine (AMT);

(41) N,N-diisopropyltryptamine (DiPT);

(42) 4-acetoxy-N,N-dimethyltryptamine (4-AcO-DMT);

(43) 4-acetoxy-N,N-diethyltryptamine (4-AcO-DET);

(44) 4-hydroxy-N-methyl-N-propyltryptamine (4-HO-MPT);

(45) 4-hydroxy-N,N-dipropyltryptamine (4-HO-DPT);

(46) 4-hydroxy-N,N-diallyltryptamine (4-HO-DALT);

(47) 4-hydroxy-N,N-diisopropyltryptamine (4-HO-DiPT);

(48) 5-methoxy-N,N-diisopropyltryptamine (5-MeO-DiPT);

(49) 5-methoxy-α-methyltryptamine (5-MeO-AMT);

(50) 5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT);

(51) 5-methylthio-N,N-dimethyltryptamine (5-MeS-DMT);

(52) 5-methoxy-N-methyl-N-isopropyltryptamine (5-MeO-MiPT);

(53) 5-methoxy-α-ethyltryptamine (5-MeO-AET);

(54) 5-methoxy-N,N-dipropyltryptamine (5-MeO-DPT);

(55) 5-methoxy-N,N-diethyltryptamine (5-MeO-DET);

(56) 5-methoxy-N,N-diallyltryptamine (5-MeO-DALT);

(57) methoxetamine (MXE);

(58) 5-iodo-2-aminoindane (5-IAI);

(59) 5,6-methylenedioxy-2-aminoindane (MDAI);

(60) 2-(4-bromo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25B-NBOMe);

(61) 2-(4-chloro-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25C-NBOMe);

(62) 2-(4-iodo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25I-NBOMe);

(63) 2-(2,5-Dimethoxyphenyl)ethanamine (2C-H);

(64) 2-(4-Ethylthio-2,5-dimethoxyphenyl)ethanamine (2C-T-2);

(65) N,N-Dipropyltryptamine (DPT);

(66) 3-[1-(Piperidin-1-yl)cyclohexyl]phenol (3-HO-PCP);

(67) N-ethyl-1-(3-methoxyphenyl)cyclohexanamine (3-MeO-PCE);

(68) 4-[1-(3-methoxyphenyl)cyclohexyl]morpholine (3-MeO-PCMo);

(69) 1-[1-(4-methoxyphenyl)cyclohexyl]-piperidine (methoxydine, 4-MeO-PCP);

(70) 2-(2-Chlorophenyl)-2-(ethylamino)cyclohexan-1-one (N-Ethylnorketamine, ethketamine, NENK);

(71) methylenedioxy-N,N-dimethylamphetamine (MDDMA);

(72) 3-(2-Ethyl(methyl)aminoethyl)-1H-indol-4-yl (4-AcO-MET); and

(73) 2-Phenyl-2-(methylamino)cyclohexanone (deschloroketamine).

(e) Peyote. All parts of the plant presently classified botanically as Lophophora williamsii Lemaire, whether growing or not, the seeds thereof, any extract from any part of the plant, and every compound, manufacture, salts, derivative, mixture, or preparation of the plant, its seeds or extracts. The listing of peyote as a controlled substance in Schedule I does not apply to the nondrug use of peyote in bona fide religious ceremonies of the American Indian Church, and members of the American Indian Church are exempt from registration. Any person who manufactures peyote for or distributes peyote to the American Indian Church, however, is required to obtain federal registration annually and to comply with all other requirements of law.

(f) Central nervous system depressants. Unless specifically excepted or unless listed in another schedule, any material compound, mixture, or preparation which contains any quantity of the following substances, their analogs, salts, isomers, and salts of isomers whenever the existence of the analogs, salts, isomers, and salts of isomers is possible:

(1) mecloqualone;

(2) methaqualone;

(3) gamma-hydroxybutyric acid (GHB), including its esters and ethers;

(4) flunitrazepam;

(5) 2-(2-Methoxyphenyl)-2-(methylamino)cyclohexanone (2-MeO-2-deschloroketamine, methoxyketamine);

(6) tianeptine;

(7) clonazolam;

(8) etizolam;

(9) flubromazolam; and

(10) flubromazepam.

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(g) Stimulants. Unless specifically excepted or unless listed in another schedule, any material compound, mixture, or preparation which contains any quantity of the following substances, their analogs, salts, isomers, and salts of isomers whenever the existence of the analogs, salts, isomers, and salts of isomers is possible:

(1) aminorex;

(2) cathinone;

(3) fenethylline;

(4) methcathinone;

(5) methylaminorex;

(6) N,N-dimethylamphetamine;

(7) N-benzylpiperazine (BZP);

(8) methylmethcathinone (mephedrone);

(9) 3,4-methylenedioxy-N-methylcathinone (methylone);

(10) methoxymethcathinone (methedrone);

(11) methylenedioxypyrovalerone (MDPV);

(12) 3-fluoro-N-methylcathinone (3-FMC);

(13) methylethcathinone (MEC);

(14) 1-benzofuran-6-ylpropan-2-amine (6-APB);

(15) dimethylmethcathinone (DMMC);

(16) fluoroamphetamine;

(17) fluoromethamphetamine;

(18) α-methylaminobutyrophenone (MABP or buphedrone);

(19) 1-(1,3-benzodioxol-5-yl)-2-(methylamino)butan-1-one (butylone);

(20) 2-(methylamino)-1-(4-methylphenyl)butan-1-one (4-MEMABP or BZ-6378);

(21) 1-(naphthalen-2-yl)-2-(pyrrolidin-1-yl) pentan-1-one (naphthylpyrovalerone or naphyrone);

(22) (alpha-pyrrolidinopentiophenone (alpha-PVP);

(23) (RS)-1-(4-methylphenyl)-2-(1-pyrrolidinyl)-1-hexanone (4-Me-PHP or MPHP);

(24) 2-(1-pyrrolidinyl)-hexanophenone (Alpha-PHP);

(25) 4-methyl-N-ethylcathinone (4-MEC);

(26) 4-methyl-alpha-pyrrolidinopropiophenone (4-MePPP);

(27) 2-(methylamino)-1-phenylpentan-1-one (pentedrone);

(28) 1-(1,3-benzodioxol-5-yl)-2-(methylamino)pentan-1-one (pentylone);

(29) 4-fluoro-N-methylcathinone (4-FMC);

(30) 3,4-methylenedioxy-N-ethylcathinone (ethylone);

(31) alpha-pyrrolidinobutiophenone (α-PBP);

(32) 5-(2-Aminopropyl)-2,3-dihydrobenzofuran (5-APDB);

(33) 1-phenyl-2-(1-pyrrolidinyl)-1-heptanone (PV8);

(34) 6-(2-Aminopropyl)-2,3-dihydrobenzofuran (6-APDB);

(35) 4-methyl-alpha-ethylaminopentiophenone (4-MEAPP);

(36) 4'-chloro-alpha-pyrrolidinopropiophenone (4'-chloro-PPP);

(37) 1-(1,3-Benzodioxol-5-yl)-2-(dimethylamino)butan-1-one (dibutylone, bk-DMBDB);

(38) 1-(3-chlorophenyl) piperazine (meta-chlorophenylpiperazine or mCPP);

(39) 1-(1,3-benzodioxol-5-yl)-2-(ethylamino)-pentan-1-one (N-ethylpentylone, ephylone); and

(40) any other substance, except bupropion or compounds listed under a different schedule, that is structurally derived from 2-aminopropan-1-one by substitution at the 1-position with either phenyl, naphthyl, or thiophene ring systems, whether or not the compound is further modified in any of the following ways:

(i) by substitution in the ring system to any extent with alkyl, alkylenedioxy, alkoxy, haloalkyl, hydroxyl, or halide substituents, whether or not further substituted in the ring system by one or more other univalent substituents;

(ii) by substitution at the 3-position with an acyclic alkyl substituent;

(iii) by substitution at the 2-amino nitrogen atom with alkyl, dialkyl, benzyl, or methoxybenzyl groups; or

(iv) by inclusion of the 2-amino nitrogen atom in a cyclic structure.

~~(h) Marijuana, tetrahydrocannabinols, and synthetic cannabinoids. Unless specifically excepted or unless listed in another schedule, any natural or synthetic material, compound, mixture, or preparation that contains any quantity of the following substances, their analogs, isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of the isomers, esters, ethers, or salts is possible:~~

~~(1) marijuana;~~

~~(2) tetrahydrocannabinols naturally contained in a plant of the genus Cannabis, except that tetrahydrocannabinols do not include any material, compound, mixture, or preparation that qualifies as industrial hemp as defined in section~~ 18K.02, subdivision 3~~; synthetic equivalents of the substances contained in the cannabis plant or in the resinous extractives of the plant; or synthetic substances with similar chemical structure and pharmacological activity to those substances contained in the plant or resinous extract, including, but not limited to, 1~~

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~~cis or trans tetrahydrocannabinol, 6 cis or trans tetrahydrocannabinol, and 3,4 cis or trans tetrahydrocannabinol;~~

~~(3)~~ (h) Synthetic cannabinoids, including the following substances:

~~(i)~~ (1) Naphthoylindoles, which are any compounds containing a 3-(1-napthoyl)indole structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent. Examples of naphthoylindoles include, but are not limited to:

~~(A)~~ (i) 1-Pentyl-3-(1-naphthoyl)indole (JWH-018 and AM-678);

~~(B)~~ (ii) 1-Butyl-3-(1-naphthoyl)indole (JWH-073);

~~(C)~~ (iii) 1-Pentyl-3-(4-methoxy-1-naphthoyl)indole (JWH-081);

~~(D)~~ (iv) 1-[2-(4-morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200);

~~(E)~~ (v) 1-Propyl-2-methyl-3-(1-naphthoyl)indole (JWH-015);

~~(F)~~ (vi) 1-Hexyl-3-(1-naphthoyl)indole (JWH-019);

~~(G)~~ (vii) 1-Pentyl-3-(4-methyl-1-naphthoyl)indole (JWH-122);

~~(H)~~ (viii) 1-Pentyl-3-(4-ethyl-1-naphthoyl)indole (JWH-210);

~~(I)~~ (ix) 1-Pentyl-3-(4-chloro-1-naphthoyl)indole (JWH-398);

~~(J)~~ (x) 1-(5-fluoropentyl)-3-(1-naphthoyl)indole (AM-2201).

~~(ii)~~ (2) Napthylmethylindoles, which are any compounds containing a 1H-indol-3-yl-(1-naphthyl)methane structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent. Examples of naphthylmethylindoles include, but are not limited to:

~~(A)~~ (i) 1-Pentyl-1H-indol-3-yl-(1-naphthyl)methane (JWH-175);

~~(B)~~ (ii) 1-Pentyl-1H-indol-3-yl-(4-methyl-1-naphthyl)methane (JWH-184).

~~(iii)~~ (3) Naphthoylpyrroles, which are any compounds containing a 3-(1-naphthoyl)pyrrole structure with substitution at the nitrogen atom of the pyrrole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl or 2-(4-morpholinyl)ethyl group whether or not further substituted in the pyrrole ring to any extent, whether or not substituted in the naphthyl ring to any extent. Examples of naphthoylpyrroles include, but are not limited to, (5-(2-fluorophenyl)-1-pentylpyrrol-3-yl)-naphthalen-1-ylmethanone (JWH-307).

~~(iv)~~ (4) Naphthylmethylindenes, which are any compounds containing a naphthylideneindene structure with substitution at the 3-position of the indene ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl or 2-(4-

morpholinyl)ethyl group whether or not further substituted in the indene ring to any extent, whether or not substituted in the naphthyl ring to any extent. Examples of naphthylemethylindenes include, but are not limited to, E-1-[1-(1-naphthalenylmethylene)-1H-inden-3-yl]pentane (JWH-176).

~~(v)~~ (5) Phenylacetylindoles, which are any compounds containing a 3-phenylacetylindole structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl or 2-(4-morpholinyl)ethyl group whether or not further substituted in the indole ring to any extent, whether or not substituted in the phenyl ring to any extent. Examples of phenylacetylindoles include, but are not limited to:

~~(A)~~ (i) 1-(2-cyclohexylethyl)-3-(2-methoxyphenylacetyl)indole (RCS-8);

~~(B)~~ (ii) 1-pentyl-3-(2-methoxyphenylacetyl)indole (JWH-250);

~~(C)~~ (iii) 1-pentyl-3-(2-methylphenylacetyl)indole (JWH-251);

~~(D)~~ (iv) 1-pentyl-3-(2-chlorophenylacetyl)indole (JWH-203).

~~(vi)~~ (6) Cyclohexylphenols, which are compounds containing a 2-(3-hydroxycyclohexyl)phenol structure with substitution at the 5-position of the phenolic ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl or 2-(4-morpholinyl)ethyl group whether or not substituted in the cyclohexyl ring to any extent. Examples of cyclohexylphenols include, but are not limited to:

~~(A)~~ (i) 5-(1,1-dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (CP 47,497);

~~(B)~~ (ii) 5-(1,1-dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (Cannabicyclohexanol or CP 47,497 C8 homologue);

~~(C)~~ (iii) 5-(1,1-dimethylheptyl)-2-[(1R,2R)-5-hydroxy-2-(3-hydroxypropyl)cyclohexyl] -phenol (CP 55,940).

~~(vii)~~ (7) Benzoylindoles, which are any compounds containing a 3-(benzoyl)indole structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl or 2-(4-morpholinyl)ethyl group whether or not further substituted in the indole ring to any extent and whether or not substituted in the phenyl ring to any extent. Examples of benzoylindoles include, but are not limited to:

~~(A)~~ (i) 1-Pentyl-3-(4-methoxybenzoyl)indole (RCS-4);

~~(B)~~ (ii) 1-(5-fluoropentyl)-3-(2-iodobenzoyl)indole (AM-694);

~~(C)~~ (iii) (4-methoxyphenyl-[2-methyl-1-(2-(4-morpholinyl)ethyl)indol-3-yl]methanone (WIN 48,098 or Pravadoline).

~~(viii)~~ (8) Others specifically named:

~~(A)~~ (i) (6aR,10aR)-9-(hydroxymethyl)-6,6-dimethyl-3-(2-methyloctan-2-yl) -6a,7,10,10a-tetrahydrobenzo[c]chromen-1-ol (HU-210);

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~~(B)~~ (ii) (6aS,10aS)-9-(hydroxymethyl)-6,6-dimethyl-3-(2-methyloctan-2-yl) -6a,7,10,10a-tetrahydrobenzo[c]chromen-1-ol (Dexanabinol or HU-211);

~~(C)~~ (iii) 2,3-dihydro-5-methyl-3-(4-morpholinylmethyl)pyrrolo[1,2,3-de] -1,4-benzoxazin-6-yl-1-naphthalenylmethanone (WIN 55,212-2);

~~(D)~~ (iv) (1-pentylindol-3-yl)-(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144);

~~(E)~~ (v) (1-(5-fluoropentyl)-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (XLR-11);

~~(F)~~ (vi) 1-pentyl-N-tricyclo[3.3.1.13,7]dec-1-yl-1H-indazole-3-carboxamide (AKB-48(APINACA));

~~(G)~~ (vii) N-((3s,5s,7s)-adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide (5-Fluoro-AKB-48);

~~(H)~~ (viii) 1-pentyl-8-quinolinyl ester-1H-indole-3-carboxylic acid (PB-22);

~~(I)~~ (ix) 8-quinolinyl ester-1-(5-fluoropentyl)-1H-indole-3-carboxylic acid (5-Fluoro PB-22);

~~(J)~~ (x) N-[(1S)-1-(aminocarbonyl)-2-methylpropyl]-1-pentyl-1H-indazole- 3-carboxamide (AB-PINACA);

~~(K)~~ (xi) N-[(1S)-1-(aminocarbonyl)-2-methylpropyl]-1-[(4-fluorophenyl)methyl]- 1H-indazole-3-carboxamide (AB-FUBINACA);

~~(L)~~ (xii) N-[(1S)-1-(aminocarbonyl)-2-methylpropyl]-1-(cyclohexylmethyl)-1H- indazole-3-carboxamide(AB-CHMINACA);

~~(M)~~ (xiii) (S)-methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3-methylbutanoate (5-fluoro-AMB);

~~(N)~~ (xiv) [1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl) methanone (THJ-2201);

~~(O)~~ (xv) (1-(5-fluoropentyl)-1H-benzo[d]imidazol-2-yl)(naphthalen-1-yl)methanone) (FUBIMINA);

~~(P)~~ (xvi) (7-methoxy-1-(2-morpholinoethyl)-N-((1S,2S,4R)-1,3,3-trimethylbicyclo [2.2.1]heptan-2-yl)-1H-indole-3-carboxamide (MN-25 or UR-12);

~~(Q)~~ (xvii) (S)-N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl) -1H-indole-3-carboxamide (5-fluoro-ABICA);

~~(R)~~ (xviii) N-(1-amino-3-phenyl-1-oxopropan-2-yl)-1-(5-fluoropentyl) -1H-indole-3-carboxamide;

~~(S)~~ (xix) N-(1-amino-3-phenyl-1-oxopropan-2-yl)-1-(5-fluoropentyl) -1H-indazole-3-carboxamide;

~~(T)~~ (xx) methyl 2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido) -3,3-dimethylbutanoate;

~~(U)~~ (xxi) N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1(cyclohexylmethyl)-1 H-indazole-3-carboxamide (MAB-CHMINACA);

~~(V)~~ (xxii) N-(1-Amino-3,3-dimethyl-1-oxo-2-butanyl)-1-pentyl-1H-indazole-3-carboxamide (ADB-PINACA);

~~(W)~~ (xxiii) methyl (1-(4-fluorobenzyl)-1H-indazole-3-carbonyl)-L-valinate (FUB-AMB);

~~(X)~~ (xxiv) N-[(1S)-2-amino-2-oxo-1-(phenylmethyl)ethyl]-1-(cyclohexylmethyl)-1H-Indazole-
3-carboxamide. (APP-CHMINACA);

~~(Y)~~ (xxv) quinolin-8-yl 1-(4-fluorobenzyl)-1H-indole-3-carboxylate (FUB-PB-22); and

~~(Z)~~ (xxvi) methyl N-[1-(cyclohexylmethyl)-1H-indole-3-carbonyl]valinate (MMB-CHMICA).

~~(ix)~~ (9) Additional substances specifically named:

~~(A)~~ (i) 1-(5-fluoropentyl)-N-(2-phenylpropan-2-yl)-1 H-pyrrolo[2,3-B]pyridine-3-carboxamide (5F-CUMYL-P7AICA);

~~(B)~~ (ii) 1-(4-cyanobutyl)-N-(2- phenylpropan-2-yl)-1 H-indazole-3-carboxamide (4-CN-Cumyl-Butinaca);

~~(C)~~ (iii) naphthalen-1-yl-1-(5-fluoropentyl)-1-H-indole-3-carboxylate (NM2201; CBL2201);

~~(D)~~ (iv) N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-1 H-indazole-3-carboxamide (5F-ABPINACA);

~~(E)~~ (v) methyl-2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate (MDMB CHMICA);

~~(F)~~ (vi) methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate (5F-ADB; 5F-MDMB-PINACA); and

~~(G)~~ (vii) N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl) 1H-indazole-3-carboxamide (ADB-FUBINACA).

(i) A controlled substance analog, to the extent that it is implicitly or explicitly intended for human consumption.

EFFECTIVE DATE. This section is effective the day following final enactment.

Chapter 63, Article 8, Sec. 2. Minnesota Statutes 2022, section 152.02, subdivision 4, is amended to read:

Subd. 4. **Schedule III.** (a) Schedule III consists of the substances listed in this subdivision.

(b) Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a potential for abuse associated with a stimulant effect on the central nervous system, including its salts, isomers, and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) benzphetamine;

(2) chlorphentermine;

(3) clortermine;

(4) phendimetrazine.

(c) Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a potential for abuse associated with a depressant effect on the central nervous system:

(1) any compound, mixture, or preparation containing amobarbital, secobarbital, pentobarbital or any salt thereof and one or more other active medicinal ingredients which are not listed in any schedule;

(2) any suppository dosage form containing amobarbital, secobarbital, pentobarbital, or any salt of any of these drugs and approved by the food and drug administration for marketing only as a suppository;

(3) any substance which contains any quantity of a derivative of barbituric acid, or any salt of a derivative of barbituric acid, except those substances which are specifically listed in other schedules;

(4) any drug product containing gamma hydroxybutyric acid, including its salts, isomers, and salts of isomers, for which an application is approved under section 505 of the federal Food, Drug, and Cosmetic Act;

(5) any of the following substances:

(i) chlorhexadol;

(ii) ketamine, its salts, isomers and salts of isomers;

(iii) lysergic acid;

(iv) lysergic acid amide;

(v) methyprylon;

(vi) sulfondiethylmethane;

(vii) sulfonenthylmethane;

(viii) sulfonmethane;

(ix) tiletamine and zolazepam and any salt thereof;

(x) embutramide;

(xi) Perampanel [2-(2-oxo-1-phenyl-5-pyridin-2-yl-1,2-Dihydropyridin-3-yl) benzonitrile].

(d) Nalorphine.

(e) Narcotic drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as follows:

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(1) not more than 1.80 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium;

(2) not more than 1.80 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;

(3) not more than 1.80 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;

(4) not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;

(5) not more than 500 milligrams of opium per 100 milliliters or per 100 grams, or not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;

(6) not more than 50 milligrams of morphine per 100 milliliters or per 100 grams with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(f) Anabolic steroids, human growth hormone, and chorionic gonadotropin.

(1) Anabolic steroids, for purposes of this subdivision, means any drug or hormonal substance, chemically and pharmacologically related to testosterone, other than estrogens, progestins, corticosteroids, and dehydroepiandrosterone, and includes:

(i) 3[beta],17[beta]-dihydroxy-5[alpha]-androstane;

(ii) 3[alpha],17[beta]-dihydroxy-5[alpha]-androstane;

(iii) androstanedione (5[alpha]-androstan-3,17-dione);

(iv) 1-androstenediol (3[beta],17[beta]-dihydroxy-5[alpha]-androst-l-ene;

(v) 3[alpha],17[beta]-dihydroxy-5[alpha]-androst-1-ene);

(vi) 4-androstenediol (3[beta],17[beta]-dihydroxy-androst-4-ene);

(vii) 5-androstenediol (3[beta],17[beta]-dihydroxy-androst-5-ene);

(viii) 1-androstenedione (5[alpha]-androst-1-en-3,17-dione);

(ix) 4-androstenedione (androst-4-en-3,17-dione);

(x) 5-androstenedione (androst-5-en-3,17-dione);

(xi) bolasterone (7[alpha],17[alpha]-dimethyl-17[beta]-hydroxyandrost-4-en-3-one);

(xii) boldenone (17[beta]-hydroxyandrost-1,4-diene-3-one);

(xiii) boldione (androsta-1,4-diene-3,17-dione);

(xiv) calusterone (7[beta],17[alpha]-dimethyl-17[beta]-hydroxyandrost-4-en-3-one);

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(xv) clostebol (4-chloro-17[beta]-hydroxyandrost-4-en-3-one);

(xvi) dehydrochloromethyltestosterone (4-chloro-17[beta]-hydroxy-17[alpha]-methylandrost-1,4-dien-3-one);

(xvii) desoxymethyltestosterone (17[alpha]-methyl-5[alpha]-androst-2-en-17[beta]-ol);

(xviii) [delta]1-dihydrotestosterone- (17[beta]-hydroxy-5[alpha]-androst-1-en-3-one);

(xix) 4-dihydrotestosterone (17[beta]-hydroxy-androstan-3-one);

(xx) drostanolone (17[beta]hydroxy-2[alpha]-methyl-5[alpha]-androstan-3-one);

(xxi) ethylestrenol (17[alpha]-ethyl-17[beta]-hydroxyestr-4-ene);

(xxii) fluoxymesterone (9-fluoro-17[alpha]-methyl-11[beta],17[beta]-dihydroxyandrost-4-en-3-one);

(xxiii) formebolone (2-formyl-17[alpha]-methyl-11[alpha],17[beta]-dihydroxyandrost-1,4-dien-3-one);

(xxiv) furazabol (17[alpha]-methyl-17[beta]-hydroxyandrostano[2,3-c]-furazan)13[beta]-ethyl-17[beta] -hydroxygon-4-en-3-one;

(xxv) 4-hydroxytestosterone (4,17[beta]-dihydroxyandrost-4-en-3-one);

(xxvi) 4-hydroxy-19-nortestosterone (4,17[beta]-dihydroxyestr-4-en-3-one);

(xxvii) mestanolone (17[alpha]-methyl-17[beta]-hydroxy-5[alpha]-androstan-3-one);

(xxviii) mesterolone (1[alpha]-methyl-17[beta]-hydroxy-5[alpha]-androstan-3-one);

(xxix) methandienone (17[alpha]-methyl-17[beta]-hydroxyandrost-1,4-dien-3-one);

(xxx) methandriol (17[alpha]-methyl-3[beta],17[beta]-dihydroxyandrost-5-ene);

(xxxi) methasterone (2 alpha-17 alpha-dimethyl-5 alpha-androstan-17beta-ol-3-one);

(xxxii) methenolone (1-methyl-17[beta]-hydroxy-5[alpha]-androst-1-en-3-one);

(xxxiii) 17[alpha]-methyl-3[beta],17[beta]-dihydroxy-5[alpha]-androstane;

(xxxiv) 17[alpha]-methyl-3[alpha],17[beta]-dihydroxy-5[alpha]-androstane;

(xxxv) 17[alpha]-methyl-3[beta],17[beta]-dihydroxyandrost-4-ene;

(xxxvi) 17[alpha]-methyl-4-hydroxynandrolone (17[alpha]-methyl-4-hydroxy-17[beta]-hydroxyestr-4-en-3-one);

(xxxvii) methyldienolone (17[alpha]-methyl-17[beta]-hydroxyestra-4,9(10)-dien-3-one);

(xxxviii) methyltrienolone (17[alpha]-methyl-17[beta]-hydroxyestra-4,9-11-trien-3-one);

(xxxix) methyltestosterone (17[alpha]-methyl-17[beta]-hydroxyandrost-4-en-3-one);

(xl) mibolerone (7[alpha],17[alpha]-dimethyl-17[beta]-hydroxyestr-4-en-3-one);

(xli) 17[alpha]-methyl-[delta]1-dihydrotestosterone (17[beta]-hydroxy-17[alpha]-methyl-5[alpha]-androst-1-en-3-one);

(xlii) nandrolone (17[beta]-hydroxyestr-4-en-3-one);

(xliii) 19-nor-4-androstenediol (3[beta],17[beta]-dihydroxyestr-4-ene;

(xliv) 3[alpha],17[beta]-dihydroxyestr-4-ene); 19-nor-5-androstenediol (3[beta],17[beta]-dihydroxyestr-5-ene;

(xlv) 3[alpha],17[beta]-dihydroxyestr-5-ene);

(xlvi) 19-nor-4,9(10)-androstadienedione (estra-4,9(10)-diene-3,17-dione);

(xlvii) 19-nor-5-androstenedione (estr-5-en-3,17-dione);

(xlviii) norbolethone (13[beta],17[alpha]-diethyl-17[beta]-hydroxygon-4-en-3-one);

(xlix) norclostebol (4-chloro-17[beta]-hydroxyestr-4-en-3-one);

(l) norethandrolone (17[alpha]-ethyl-17[beta]-hydroxyestr-4-en-3-one);

(li) normethandrolone (17[alpha]-methyl-17[beta]-hydroxyestr-4-en-3-one);

(lii) oxandrolone (17[alpha]-methyl-17[beta]-hydroxy-2-oxa-5[alpha]-androstan-3-one);

(liii) oxymesterone (17[alpha]-methyl-4,17[beta]-dihydroxyandrost-4-en-3-one);

(liv) oxymetholone (17[alpha]-methyl-2-hydroxymethylene-17[beta]-hydroxy-5[alpha]-androstan-3-one);

(lv) prostanozol (17 beta-hydroxy-5 alpha-androstano[3,2-C]pryazole;

(lvi) stanozolol (17[alpha]-methyl-17[beta]-hydroxy-5[alpha]-androst-2-eno[3,2-c]-pyrazole);

(lvii) stenbolone (17[beta]-hydroxy-2-methyl-5[alpha]-androst-1-en-3-one);

(lviii) testolactone (13-hydroxy-3-oxo-13,17-secoandrosta-1,4-dien-17-oic acid lactone);

(lix) testosterone (17[beta]-hydroxyandrost-4-en-3-one);

(lx) tetrahydrogestrinone (13[beta],17[alpha]-diethyl-17[beta]-hydroxygon-4,9,11-trien-3-one);

(lxi) trenbolone (17[beta]-hydroxyestr-4,9,11-trien-3-one);

(lxii) any salt, ester, or ether of a drug or substance described in this paragraph.

Anabolic steroids are not included if they are: (A) expressly intended for administration through implants to cattle or other nonhuman species; and (B) approved by the United States Food and Drug Administration for that use;

(2) Human growth hormones.

(3) Chorionic gonadotropin, except that a product containing chorionic gonadotropin is not included if it is:

(i) expressly intended for administration to cattle or other nonhuman species; and

(ii) approved by the United States Food and Drug Administration for that use.

(g) Hallucinogenic substances. Dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a United States Food and Drug Administration approved product.

(h) Any material, compound, mixture, or preparation containing the following narcotic drug or its salt: buprenorphine.

(i) Marijuana, tetrahydrocannabinols, and synthetic cannabinoids. Unless specifically excepted or unless listed in another schedule, any natural or synthetic material, compound, mixture, or preparation that contains any quantity of the following substances, their analogs, isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of the isomers, esters, ethers, or salts is possible:

(1) marijuana;

(2) tetrahydrocannabinols naturally contained in a plant of the genus Cannabis, except that tetrahydrocannabinols do not include any material, compound, mixture, or preparation that qualifies as industrial hemp as defined in section 18K.02, subdivision 3; synthetic equivalents of the substances contained in the cannabis plant or in the resinous extractives of the plant; or synthetic substances with similar chemical structure and pharmacological activity to those substances contained in the plant or resinous extract, including but not limited to 1 cis or trans tetrahydrocannabinol, 6 cis or trans tetrahydrocannabinol, and 3,4 cis or trans tetrahydrocannabinol.

EFFECTIVE DATE. This section is effective the day following final enactment.

152.126, subd. 4 PRESCRIPTION MONITORING PROGRAM *(amended)*

Chapter 70, Article 6, Sec. 30. Minnesota Statutes 2022, section 152.126, subdivision 4, is amended to read:

Subd. 4. **Reporting requirements; notice.** (a) Each dispenser must submit the following data to the board or its designated vendor:

(1) name of the prescriber;

(2) national provider identifier of the prescriber;

(3) name of the dispenser;

(4) national provider identifier of the dispenser;

(5) prescription number;

(6) name of the patient for whom the prescription was written;

(7) address of the patient for whom the prescription was written;

(8) date of birth of the patient for whom the prescription was written;

(9) date the prescription was written;

(10) date the prescription was filled;

(11) name and strength of the controlled substance;

(12) quantity of controlled substance prescribed;

(13) quantity of controlled substance dispensed; and

(14) number of days supply.

(b) The dispenser must submit the required information by a procedure and in a format established by the board. The board may allow dispensers to omit data listed in this subdivision or may require the submission of data not listed in this subdivision provided the omission or submission is necessary for the purpose of complying with the electronic reporting or data transmission standards of the American Society for Automation in Pharmacy, the National Council on Prescription Drug Programs, or other relevant national standard-setting body.

(c) A dispenser is not required to submit this data for those controlled substance prescriptions dispensed for:

(1) individuals residing in a health care facility as defined in section 151.58, subdivision 2, paragraph (b), when a drug is distributed through the use of an automated drug distribution system according to section 151.58; ~~and~~

(2) individuals receiving a drug sample that was packaged by a manufacturer and provided to the dispenser for dispensing as a professional sample pursuant to Code of Federal Regulations, title 21, part 203, subpart D~~.~~; and

(3) individuals whose prescriptions are being mailed, shipped, or delivered from Minnesota to another state, so long as the data are reported to the prescription drug monitoring program of that state.

(d) A dispenser must provide notice to the patient for whom the prescription was written ~~a conspicuous notice~~, or to that patient's authorized representative, of the reporting requirements of this section and notice that the information may be used for program administration purposes.

(e) The dispenser must submit the required information within the time frame specified by the board; if no reportable prescriptions are dispensed or sold on any day, a report indicating that fact must be filed with the board.

(f) The dispenser must submit accurate information to the database and must correct errors identified during the submission process within seven calendar days.

(g) For the purposes of this paragraph, the term "subject of the data" means the individual reported as being the patient, the practitioner reported as being the prescriber, the client when an animal is reported as being the patient, or an authorized agent of these

individuals. The dispenser must correct errors brought to its attention by the subject of the data within seven calendar days, unless the dispenser verifies that an error did not occur and the data were correctly submitted. The dispenser must notify the subject of the data that either the error was corrected or that no error occurred.

Chapter 70, Article 6, Sec. 31. Minnesota Statutes 2022, section 152.126, subdivision 5, is amended to read:

Subd. 5. **Use of data by board.** (a) The board shall develop and maintain a database of the data reported under subdivision 4. The board shall maintain data that could identify an individual prescriber or dispenser in encrypted form. Except as otherwise allowed under subdivision 6, the database may be used by permissible users identified under subdivision 6 for the identification of:

(1) individuals receiving prescriptions for controlled substances from prescribers who subsequently obtain controlled substances from dispensers in quantities or with a frequency inconsistent with generally recognized standards of use for those controlled substances, including standards accepted by national and international pain management associations; and

(2) individuals presenting forged or otherwise false or altered prescriptions for controlled substances to dispensers.

(b) No permissible user identified under subdivision 6 may access the database for the sole purpose of identifying prescribers of controlled substances for unusual or excessive prescribing patterns without a valid search warrant or court order.

(c) No personnel of a state or federal occupational licensing board or agency may access the database for the purpose of obtaining information to be used to initiate a disciplinary action against a prescriber.

(d) Data reported under subdivision 4 shall be made available to permissible users for a 12-month period beginning the day the data was received and ending 12 months from the last day of the month in which the data was received, except that permissible users defined in subdivision 6, paragraph (b), clauses ~~(6)~~ (7) and ~~(7)~~ (8), may use all data collected under this section for the purposes of administering, operating, and maintaining the prescription monitoring program and conducting trend analyses and other studies necessary to evaluate the effectiveness of the program.

(e) Data reported during the period January 1, 2015, through December 31, 2018, may be retained through December 31, 2019, in an identifiable manner. Effective January 1, 2020, data older than 24 months must be destroyed. Data reported for prescriptions dispensed on or after January 1, 2020, must be destroyed no later than 12 months from the date the ~~data~~ prescription was ~~received~~ reported as dispensed.

Appendix A

Chapter 70, Article 6, Sec. 32. Minnesota Statutes 2022, section 152.126, subdivision 6, is amended to read:

Subd. 6. **Access to reporting system data.** (a) Except as indicated in this subdivision, the data submitted to the board under subdivision 4 is private data on individuals as defined in section 13.02, subdivision 12, and not subject to public disclosure.

(b) Except as specified in subdivision 5, the following persons shall be considered permissible users and may access the data submitted under subdivision 4 in the same or similar manner, and for the same or similar purposes, as those persons who are authorized to access similar private data on individuals under federal and state law:

(1) a prescriber or an agent or employee of the prescriber to whom the prescriber has delegated the task of accessing the data, to the extent the information relates specifically to a current patient, to whom the prescriber is:

(i) prescribing or considering prescribing any controlled substance;

(ii) providing emergency medical treatment for which access to the data may be necessary;

(iii) providing care, and the prescriber has reason to believe, based on clinically valid indications, that the patient is potentially abusing a controlled substance; or

(iv) providing other medical treatment for which access to the data may be necessary for a clinically valid purpose and the patient has consented to access to the submitted data, and with the provision that the prescriber remains responsible for the use or misuse of data accessed by a delegated agent or employee;

(2) a dispenser or an agent or employee of the dispenser to whom the dispenser has delegated the task of accessing the data, to the extent the information relates specifically to a current patient to whom that dispenser is dispensing or considering dispensing any controlled substance and with the provision that the dispenser remains responsible for the use or misuse of data accessed by a delegated agent or employee;

(3) a licensed dispensing practitioner or licensed pharmacist to the extent necessary to determine whether corrections made to the data reported under subdivision 4 are accurate;

(4) a licensed pharmacist who is providing pharmaceutical care for which access to the data may be necessary to the extent that the information relates specifically to a current patient for whom the pharmacist is providing pharmaceutical care: (i) if the patient has consented to access to the submitted data; or (ii) if the pharmacist is consulted by a prescriber who is requesting data in accordance with clause (1);

~~(4)~~ (5) an individual who is the recipient of a controlled substance prescription for which data was submitted under subdivision 4, or a guardian of the individual, parent or guardian of a

minor, or health care agent of the individual acting under a health care directive under chapter 145C. For purposes of this clause, access by individuals includes persons in the definition of an individual under section 13.02;

~~(5)~~ (6) personnel or designees of a health-related licensing board listed in section 214.01, subdivision 2, or of the Emergency Medical Services Regulatory Board, assigned to conduct a bona fide investigation of a complaint received by that board that alleges that a specific licensee is impaired by use of a drug for which data is collected under subdivision 4, has engaged in activity that would constitute a crime as defined in section 152.025, or has engaged in the behavior specified in subdivision 5, paragraph (a);

~~(6)~~ (7) personnel of the board engaged in the collection, review, and analysis of controlled substance prescription information as part of the assigned duties and responsibilities under this section;

~~(7)~~ (8) authorized personnel ~~of a vendor~~ under contract with the board, or under contract with the state of Minnesota and approved by the board, who are engaged in the design, evaluation, implementation, operation, ~~and~~ or maintenance of the prescription monitoring program as part of the assigned duties and responsibilities of their employment, provided that access to data is limited to the minimum amount necessary to carry out such duties and responsibilities, and subject to the requirement of de-identification and time limit on retention of data specified in subdivision 5, paragraphs (d) and (e);

~~(8)~~ (9) federal, state, and local law enforcement authorities acting pursuant to a valid search warrant;

~~(9)~~ (10) personnel of the Minnesota health care programs assigned to use the data collected under this section to identify and manage recipients whose usage of controlled substances may warrant restriction to a single primary care provider, a single outpatient pharmacy, and a single hospital;

~~(10)~~ (11) personnel of the Department of Human Services assigned to access the data pursuant to paragraph (k);

~~(11)~~ (12) personnel of the health professionals services program established under section 214.31, to the extent that the information relates specifically to an individual who is currently enrolled in and being monitored by the program, and the individual consents to access to that information. The health professionals services program personnel shall not provide this data to a health-related licensing board or the Emergency Medical Services Regulatory Board, except as permitted under section 214.33, subdivision 3; ~~and~~

~~(12)~~ (13) personnel or designees of a health-related licensing board other than the Board of Pharmacy listed in section 214.01, subdivision 2, assigned to conduct a bona fide investigation of a complaint received by that board that alleges that a specific licensee is

inappropriately prescribing controlled substances as defined in this section. For the purposes of this clause, the health-related licensing board may also obtain utilization data; and

(14) personnel of the board specifically assigned to conduct a bona fide investigation of a specific licensee or registrant. For the purposes of this clause, the board may also obtain utilization data.

(c) By July 1, 2017, every prescriber licensed by a health-related licensing board listed in section 214.01, subdivision 2, practicing within this state who is authorized to prescribe controlled substances for humans and who holds a current registration issued by the federal Drug Enforcement Administration, and every pharmacist licensed by the board and practicing within the state, shall register and maintain a user account with the prescription monitoring program. Data submitted by a prescriber, pharmacist, or their delegate during the registration application process, other than their name, license number, and license type, is classified as private pursuant to section 13.02, subdivision 12.

(d) Notwithstanding paragraph (b), beginning January 1, 2021, a prescriber or an agent or employee of the prescriber to whom the prescriber has delegated the task of accessing the data, must access the data submitted under subdivision 4 to the extent the information relates specifically to the patient:

(1) before the prescriber issues an initial prescription order for a Schedules II through IV opiate controlled substance to the patient; and

(2) at least once every three months for patients receiving an opiate for treatment of chronic pain or participating in medically assisted treatment for an opioid addiction.

(e) Paragraph (d) does not apply if:

(1) the patient is receiving palliative care, or hospice or other end-of-life care;

(2) the patient is being treated for pain due to cancer or the treatment of cancer;

(3) the prescription order is for a number of doses that is intended to last the patient five days or less and is not subject to a refill;

(4) the prescriber and patient have a current or ongoing provider/patient relationship of a duration longer than one year;

(5) the prescription order is issued within 14 days following surgery or three days following oral surgery or follows the prescribing protocols established under the opioid prescribing improvement program under section 256B.0638;

(6) the controlled substance is prescribed or administered to a patient who is admitted to an inpatient hospital;

(7) the controlled substance is lawfully administered by injection, ingestion, or any other means to the patient by the prescriber, a pharmacist, or by the patient at the direction of a prescriber and in the presence of the prescriber or pharmacist;

(8) due to a medical emergency, it is not possible for the prescriber to review the data before the prescriber issues the prescription order for the patient; or

(9) the prescriber is unable to access the data due to operational or other technological failure of the program so long as the prescriber reports the failure to the board.

(f) Only permissible users identified in paragraph (b), clauses (1), (2), (3), ~~(6)~~ (4), (7), ~~(9), and~~ (8), (10), and (11), may directly access the data electronically. No other permissible users may directly access the data electronically. If the data is directly accessed electronically, the permissible user shall implement and maintain a comprehensive information security program that contains administrative, technical, and physical safeguards that are appropriate to the user's size and complexity, and the sensitivity of the personal information obtained. The permissible user shall identify reasonably foreseeable internal and external risks to the security, confidentiality, and integrity of personal information that could result in the unauthorized disclosure, misuse, or other compromise of the information and assess the sufficiency of any safeguards in place to control the risks.

(g) The board shall not release data submitted under subdivision 4 unless it is provided with evidence, satisfactory to the board, that the person requesting the information is entitled to receive the data.

(h) The board shall maintain a log of all persons who access the data for a period of at least three years and shall ensure that any permissible user complies with paragraph (c) prior to attaining direct access to the data.

(i) Section 13.05, subdivision 6, shall apply to any contract the board enters into pursuant to subdivision 2. A vendor shall not use data collected under this section for any purpose not specified in this section.

(j) The board may participate in an interstate prescription monitoring program data exchange system provided that permissible users in other states have access to the data only as allowed under this section, and that section 13.05, subdivision 6, applies to any contract or memorandum of understanding that the board enters into under this paragraph.

(k) With available appropriations, the commissioner of human services shall establish and implement a system through which the Department of Human Services shall routinely access the data for the purpose of determining whether any client enrolled in an opioid treatment program licensed according to chapter 245A has been prescribed or dispensed a controlled substance in addition to that administered or dispensed by the opioid treatment

program. When the commissioner determines there have been multiple prescribers or multiple prescriptions of controlled substances, the commissioner shall:

(1) inform the medical director of the opioid treatment program only that the commissioner determined the existence of multiple prescribers or multiple prescriptions of controlled substances; and

(2) direct the medical director of the opioid treatment program to access the data directly, review the effect of the multiple prescribers or multiple prescriptions, and document the review.

If determined necessary, the commissioner of human services shall seek a federal waiver of, or exception to, any applicable provision of Code of Federal Regulations, title 42, section 2.34, paragraph (c), prior to implementing this paragraph.

(l) The board shall review the data submitted under subdivision 4 on at least a quarterly basis and shall establish criteria, in consultation with the advisory task force, for referring information about a patient to prescribers and dispensers who prescribed or dispensed the prescriptions in question if the criteria are met.

(m) The board shall conduct random audits, on at least a quarterly basis, of electronic access by permissible users, as identified in paragraph (b), clauses (1), (2), (3), ~~(6)~~ (4), (7), ~~(9), and~~ (8), (10), and (11), to the data in subdivision 4, to ensure compliance with permissible use as defined in this section. A permissible user whose account has been selected for a random audit shall respond to an inquiry by the board, no later than 30 days after receipt of notice that an audit is being conducted. Failure to respond may result in deactivation of access to the electronic system and referral to the appropriate health licensing board, or the commissioner of human services, for further action. The board shall report the results of random audits to the chairs and ranking minority members of the legislative committees with jurisdiction over health and human services policy and finance and government data practices.

(n) A permissible user who has delegated the task of accessing the data in subdivision 4 to an agent or employee shall audit the use of the electronic system by delegated agents or employees on at least a quarterly basis to ensure compliance with permissible use as defined in this section. When a delegated agent or employee has been identified as inappropriately accessing data, the permissible user must immediately remove access for that individual and notify the board within seven days. The board shall notify all permissible users associated with the delegated agent or employee of the alleged violation.

(o) A permissible user who delegates access to the data submitted under subdivision 4 to an agent or employee shall terminate that individual's access to the data within three business days of the agent or employee leaving employment with the permissible user. The board may conduct random audits to determine compliance with this requirement.

Appendix A

62J.84 PRESCRIPTION DRUG PRICE TRANSPARENCY

Chapter 70, Article 2, Sec. 8. Minnesota Statutes 2022, section 62J.84, subdivision 2, is amended to read:

Subd. 2. **Definitions.** (a) For purposes of this section, the terms defined in this subdivision have the meanings given.

(b) "Biosimilar" means a drug that is produced or distributed pursuant to a biologics license application approved under United States Code, title 42, section 262(K)(3).

(c) "Brand name drug" means a drug that is produced or distributed pursuant to:

(1) ~~an original,~~ a new drug application approved under United States Code, title 21, section 355(c), except for a generic drug as defined under Code of Federal Regulations, title 42, section 447.502; or

(2) a biologics license application approved under United States Code, title ~~45~~ 42, section 262(a)(c).

(d) "Commissioner" means the commissioner of health.

(e) "Generic drug" means a drug that is marketed or distributed pursuant to:

(1) an abbreviated new drug application approved under United States Code, title 21, section 355(j);

(2) an authorized generic as defined under Code of Federal Regulations, title ~~45~~ 42, section 447.502; or

(3) a drug that entered the market the year before 1962 and was not originally marketed under a new drug application.

(f) "Manufacturer" means a drug manufacturer licensed under section 151.252.

(g) "New prescription drug" or "new drug" means a prescription drug approved for marketing by the United States Food and Drug Administration (FDA) for which no previous wholesale acquisition cost has been established for comparison.

(h) "Patient assistance program" means a program that a manufacturer offers to the public in which a consumer may reduce the consumer's out-of-pocket costs for prescription drugs by using coupons, discount cards, prepaid gift cards, manufacturer debit cards, or by other means.

(i) "Prescription drug" or "drug" has the meaning provided in section 151.441, subdivision 8.

(j) "Price" means the wholesale acquisition cost as defined in United States Code, title 42, section 1395w-3a(c)(6)(B).

(k) "30-day supply" means the total daily dosage units of a prescription drug recommended by the prescribing label approved by the FDA for 30 days. If the FDA-approved prescribing label includes more than one recommended daily dosage, the 30-day supply is based on the maximum recommended daily dosage on the FDA-approved prescribing label.

(l) "Course of treatment" means the total dosage of a single prescription for a prescription drug recommended by the FDA-approved prescribing label. If the FDA-approved prescribing label includes more than one recommended dosage for a single course of treatment, the course of treatment is the maximum recommended dosage on the FDA-approved prescribing label.

(m) "Drug product family" means a group of one or more prescription drugs that share a unique generic drug description or nontrade name and dosage form.

(n) "Individual salable unit" means the smallest container of product introduced into commerce by the manufacturer or repackager that is intended by the manufacturer or repackager for individual sale to a dispenser.

(o) "National drug code" means the three-segment code maintained by the federal Food and Drug Administration that includes a labeler code, a product code, and a package code for a drug product and that has been converted to an 11-digit format consisting of five digits in the first segment, four digits in the second segment, and two digits in the third segment. A three-segment code shall be considered converted to an 11-digit format when, as necessary, at least one "0" has been added to the front of each segment containing less than the specified number of digits such that each segment contains the specified number of digits.

(p) "Pharmacy" or "pharmacy provider" means a community/outpatient pharmacy as defined in Minnesota Rules, part 6800.0100, subpart 2, that is also licensed as a pharmacy by the Board of Pharmacy under section 151.19.

(q) "Pharmacy benefit manager" or "PBM" means an entity licensed to act as a pharmacy benefit manager under section 62W.03.

(r) "Pricing unit" means the smallest dispensable amount of a prescription drug product that could be dispensed.

(s) "Rebate" means a discount, chargeback, or other price concession that affects the price of a prescription drug product, regardless of whether conferred through regular aggregate payments, on a claim-by-claim basis at the point of sale, as part of retrospective financial reconciliations, including reconciliations that also reflect other contractual arrangements, or by any other method. "Rebate" does not mean a bona fide service fee as defined in Code of Federal Regulations, title 42, section 447.502.

(t) "Reporting entity" means any manufacturer, pharmacy, pharmacy benefit manager, wholesale drug distributor, or any other entity required to submit data under this section.

(u) "Wholesale drug distributor" or "wholesaler" means an entity that:

(1) is licensed to act as a wholesale drug distributor under section 151.47; and

(2) distributes prescription drugs, for which it is not the manufacturer, to persons or entities, or both, other than a consumer or patient in the state.

Chapter 70, Article 2, Sec. 9. Minnesota Statutes 2022, section 62J.84, subdivision 3, is amended to read:

Subd. 3. **Prescription drug price increases reporting.** (a) Beginning January 1, 2022, a drug manufacturer must submit to the commissioner the information described in paragraph (b) for each prescription drug for which the price was $100 or greater for a 30-day supply or for a course of treatment lasting less than 30 days and:

(1) for brand name drugs where there is an increase of ten percent or greater in the price over the previous 12-month period or an increase of 16 percent or greater in the price over the previous 24-month period; and

(2) for generic or biosimilar drugs where there is an increase of 50 percent or greater in the price over the previous 12-month period.

(b) For each of the drugs described in paragraph (a), the manufacturer shall submit to the commissioner no later than 60 days after the price increase goes into effect, in the form and manner prescribed by the commissioner, the following information, if applicable:

(1) the ~~name~~ description and price of the drug and the net increase, expressed as a percentage~~;~~, with the following listed separately:

(i) the national drug code;

(ii) the product name;

(iii) the dosage form;

(iv) the strength; and

(v) the package size;

(2) the factors that contributed to the price increase;

(3) the name of any generic version of the prescription drug available on the market;

(4) the introductory price of the prescription drug when it was ~~approved for marketing by the Food and Drug Administration and the net yearly increase, by calendar year, in the price of the prescription drug during the previous five years~~ introduced for sale in the United

States and the price of the drug on the last day of each of the five calendar years preceding the price increase;

(5) the direct costs incurred during the previous 12-month period by the manufacturer that are associated with the prescription drug, listed separately:

(i) to manufacture the prescription drug;

(ii) to market the prescription drug, including advertising costs; and

(iii) to distribute the prescription drug;

(6) the total sales revenue for the prescription drug during the previous 12-month period;

(7) the manufacturer's net profit attributable to the prescription drug during the previous 12-month period;

(8) the total amount of financial assistance the manufacturer has provided through patient prescription assistance programs during the previous 12-month period, if applicable;

(9) any agreement between a manufacturer and another entity contingent upon any delay in offering to market a generic version of the prescription drug;

(10) the patent expiration date of the prescription drug if it is under patent;

(11) the name and location of the company that manufactured the drug; and

(12) if a brand name prescription drug, the ten highest prices price paid for the prescription drug during the previous calendar year in any country other than the ten countries, excluding the United States., that charged the highest single price for the prescription drug; and

(13) if the prescription drug was acquired by the manufacturer during the previous 12-month period, all of the following information:

(i) price at acquisition;

(ii) price in the calendar year prior to acquisition;

(iii) name of the company from which the drug was acquired;

(iv) date of acquisition; and

(v) acquisition price.

(c) The manufacturer may submit any documentation necessary to support the information reported under this subdivision.

Appendix A

Chapter 70, Article 2, Sec. 10. Minnesota Statutes 2022, section 62J.84, subdivision 4, is amended to read:

Subd. 4. **New prescription drug price reporting.** (a) Beginning January 1, 2022, no later than 60 days after a manufacturer introduces a new prescription drug for sale in the United States that is a new brand name drug with a price that is greater than the tier threshold established by the Centers for Medicare and Medicaid Services for specialty drugs in the Medicare Part D program for a 30-day supply or for a course of treatment lasting fewer than 30 days or a new generic or biosimilar drug with a price that is greater than the tier threshold established by the Centers for Medicare and Medicaid Services for specialty drugs in the Medicare Part D program for a 30-day supply or for a course of treatment lasting fewer than 30 days and is not at least 15 percent lower than the referenced brand name drug when the generic or biosimilar drug is launched, the manufacturer must submit to the commissioner, in the form and manner prescribed by the commissioner, the following information, if applicable:

(1) the description of the drug, with the following listed separately:

(i) the national drug code;

(ii) the product name;

(iii) the dosage form;

(iv) the strength; and

(v) the package size;

~~(1)~~ (2) the price of the prescription drug;

~~(2)~~ (3) whether the Food and Drug Administration granted the new prescription drug a breakthrough therapy designation or a priority review;

~~(3)~~ (4) the direct costs incurred by the manufacturer that are associated with the prescription drug, listed separately:

(i) to manufacture the prescription drug;

(ii) to market the prescription drug, including advertising costs; and

(iii) to distribute the prescription drug; and

~~(4)~~ (5) the patent expiration date of the drug if it is under patent.

(b) The manufacturer may submit documentation necessary to support the information reported under this subdivision.

Chapter 70, Article 2, Sec. 11. Minnesota Statutes 2022, section 62J.84, subdivision 6, is amended to read:

Subd. 6. **Public posting of prescription drug price information.** (a) The commissioner shall post on the department's website, or may contract with a private entity or consortium that satisfies the standards of section 62U.04, subdivision 6, to meet this requirement, the following information:

(1) a list of the prescription drugs reported under subdivisions 3, 4, and ~~5~~, 11 to 14 and the manufacturers of those prescription drugs; and

(2) information reported to the commissioner under subdivisions 3, 4, and ~~5~~ 11 to 14.

(b) The information must be published in an easy-to-read format and in a manner that identifies the information that is disclosed on a per-drug basis and must not be aggregated in a manner that prevents the identification of the prescription drug.

(c) The commissioner shall not post to the department's website or a private entity contracting with the commissioner shall not post any information described in this section if the information is not public data under section 13.02, subdivision 8a; or is trade secret information under section 13.37, subdivision 1, paragraph (b); or is trade secret information pursuant to the Defend Trade Secrets Act of 2016, United States Code, title 18, section 1836, as amended. If a ~~manufacturer~~ reporting entity believes information should be withheld from public disclosure pursuant to this paragraph, the ~~manufacturer~~ reporting entity must clearly and specifically identify that information and describe the legal basis in writing when the ~~manufacturer~~ reporting entity submits the information under this section. If the commissioner disagrees with the ~~manufacturer's~~ reporting entity's request to withhold information from public disclosure, the commissioner shall provide the ~~manufacturer~~ reporting entity written notice that the information will be publicly posted 30 days after the date of the notice.

(d) If the commissioner withholds any information from public disclosure pursuant to this subdivision, the commissioner shall post to the department's website a report describing the nature of the information and the commissioner's basis for withholding the information from disclosure.

(e) To the extent the information required to be posted under this subdivision is collected and made available to the public by another state, by the University of Minnesota, or through an online drug pricing reference and analytical tool, the commissioner may reference the availability of this drug price data from another source including, within existing appropriations, creating the ability of the public to access the data from the source for purposes of meeting the reporting requirements of this subdivision.

Chapter 70, Article 2, Sec. 12. Minnesota Statutes 2022, section 62J.84, subdivision 7, is amended to read:

Subd. 7. **Consultation.** (a) The commissioner may consult with a private entity or consortium that satisfies the standards of section 62U.04, subdivision 6, the University of

Minnesota, or the commissioner of commerce, as appropriate, in issuing the form and format of the information reported under this section; in posting information pursuant to subdivision 6; and in taking any other action for the purpose of implementing this section.

(b) The commissioner may consult with representatives of the ~~manufacturers~~ reporting entities to establish a standard format for reporting information under this section and may use existing reporting methodologies to establish a standard format to minimize administrative burdens to the state and ~~manufacturers~~ reporting entities.

Chapter 70, Article 2, Sec. 13. Minnesota Statutes 2022, section 62J.84, subdivision 8, is amended to read:

Subd. 8. **Enforcement and penalties.** (a) A ~~manufacturer~~ reporting entity may be subject to a civil penalty, as provided in paragraph (b), for:

(1) failing to register under subdivision 15;

~~(1)~~ (2) failing to submit timely reports or notices as required by this section;

~~(2)~~ (3) failing to provide information required under this section; or

~~(3)~~ (4) providing inaccurate or incomplete information under this section.

(b) The commissioner shall adopt a schedule of civil penalties, not to exceed $10,000 per day of violation, based on the severity of each violation.

(c) The commissioner shall impose civil penalties under this section as provided in section 144.99, subdivision 4.

(d) The commissioner may remit or mitigate civil penalties under this section upon terms and conditions the commissioner considers proper and consistent with public health and safety.

(e) Civil penalties collected under this section shall be deposited in the health care access fund.

Chapter 70, Article 2, Sec. 14. Minnesota Statutes 2022, section 62J.84, subdivision 9, is amended to read:

Subd. 9. **Legislative report.** (a) No later than May 15, 2022, and by January 15 of each year thereafter, the commissioner shall report to the chairs and ranking minority members of the legislative committees with jurisdiction over commerce and health and human services policy and finance on the implementation of this section, including but not limited to the effectiveness in addressing the following goals:

(1) promoting transparency in pharmaceutical pricing for the state and other payers;

(2) enhancing the understanding on pharmaceutical spending trends; and

(3) assisting the state and other payers in the management of pharmaceutical costs.

(b) The report must include a summary of the information submitted to the commissioner under subdivisions 3, 4, and ~~5~~ 11 to 14.

Chapter 70, Article 2, Sec. 15. Minnesota Statutes 2022, section 62J.84, is amended by adding a subdivision to read:

Subd. 10. **Notice of prescription drugs of substantial public interest.** (a) No later than January 31, 2024, and quarterly thereafter, the commissioner shall produce and post on the department's website a list of prescription drugs that the commissioner determines to represent a substantial public interest and for which the commissioner intends to request data under subdivisions 11 to 14, subject to paragraph (c). The commissioner shall base its inclusion of prescription drugs on any information the commissioner determines is relevant to providing greater consumer awareness of the factors contributing to the cost of prescription drugs in the state, and the commissioner shall consider drug product families that include prescription drugs:

(1) that triggered reporting under subdivision 3 or 4 during the previous calendar quarter;

(2) for which average claims paid amounts exceeded 125 percent of the price as of the claim incurred date during the most recent calendar quarter for which claims paid amounts are available; or

(3) that are identified by members of the public during a public comment process.

(b) Not sooner than 30 days after publicly posting the list of prescription drugs under paragraph (a), the department shall notify, via email, reporting entities registered with the department of the requirement to report under subdivisions 11 to 14.

(c) The commissioner must not designate more than 500 prescription drugs as having a substantial public interest in any one notice.

Chapter 70, Article 2, Sec. 16. Minnesota Statutes 2022, section 62J.84, is amended by adding a subdivision to read:

Subd. 11. **Manufacturer prescription drug substantial public interest reporting.** (a) Beginning January 1, 2024, a manufacturer must submit to the commissioner the information described in paragraph (b) for any prescription drug:

(1) included in a notification to report issued to the manufacturer by the department under subdivision 10;

(2) which the manufacturer manufactures or repackages;

(3) for which the manufacturer sets the wholesale acquisition cost; and

(4) for which the manufacturer has not submitted data under subdivision 3 during the 120-day period prior to the date of the notification to report.

(b) For each of the drugs described in paragraph (a), the manufacturer shall submit to the commissioner no later than 60 days after the date of the notification to report, in the form and manner prescribed by the commissioner, the following information, if applicable:

(1) a description of the drug with the following listed separately:

(i) the national drug code;

(ii) the product name;

(iii) the dosage form;

(iv) the strength; and

(v) the package size;

(2) the price of the drug product on the later of:

(i) the day one year prior to the date of the notification to report;

(ii) the introduced to market date; or

(iii) the acquisition date;

(3) the price of the drug product on the date of the notification to report;

(4) the introductory price of the prescription drug when it was introduced for sale in the United States and the price of the drug on the last day of each of the five calendar years preceding the date of the notification to report;

(5) the direct costs incurred during the 12-month period prior to the date of the notification to report by the manufacturers that are associated with the prescription drug, listed separately:

(i) to manufacture the prescription drug;

(ii) to market the prescription drug, including advertising costs; and

(iii) to distribute the prescription drug;

(6) the number of units of the prescription drug sold during the 12-month period prior to the date of the notification to report;

(7) the total sales revenue for the prescription drug during the 12-month period prior to the date of the notification to report;

(8) the total rebate payable amount accrued for the prescription drug during the 12-month period prior to the date of the notification to report;

(9) the manufacturer's net profit attributable to the prescription drug during the 12-month period prior to the date of the notification to report;

(10) the total amount of financial assistance the manufacturer has provided through patient prescription assistance programs during the 12-month period prior to the date of the notification to report, if applicable;

(11) any agreement between a manufacturer and another entity contingent upon any delay in offering to market a generic version of the prescription drug;

(12) the patent expiration date of the prescription drug if the prescription drug is under patent;

(13) the name and location of the company that manufactured the drug;

(14) if the prescription drug is a brand name prescription drug, the ten countries other than the United States that paid the highest prices for the prescription drug during the previous calendar year and their prices; and

(15) if the prescription drug was acquired by the manufacturer within a 12-month period prior to the date of the notification to report, all of the following information:

(i) the price at acquisition;

(ii) the price in the calendar year prior to acquisition;

(iii) the name of the company from which the drug was acquired;

(iv) the date of acquisition; and

(v) the acquisition price.

(c) The manufacturer may submit any documentation necessary to support the information reported under this subdivision.

Chapter 70, Article 2, Sec. 17. Minnesota Statutes 2022, section 62J.84, is amended by adding a subdivision to read:

Subd. 12. **Pharmacy prescription drug substantial public interest reporting.** (a) Beginning January 1, 2024, a pharmacy must submit to the commissioner the information described in paragraph (b) for any prescription drug included in a notification to report issued to the pharmacy by the department under subdivision 10.

(b) For each of the drugs described in paragraph (a), the pharmacy shall submit to the commissioner no later than 60 days after the date of the notification to report, in the form and manner prescribed by the commissioner, the following information, if applicable:

(1) a description of the drug with the following listed separately:

(i) the national drug code;

(ii) the product name;

(iii) the dosage form;

(iv) the strength; and

(v) the package size;

(2) the number of units of the drug acquired during the 12-month period prior to the date of the notification to report;

(3) the total spent before rebates by the pharmacy to acquire the drug during the 12-month period prior to the date of the notification to report;

(4) the total rebate receivable amount accrued by the pharmacy for the drug during the 12-month period prior to the date of the notification to report;

(5) the number of pricing units of the drug dispensed by the pharmacy during the 12-month period prior to the date of the notification to report;

(6) the total payment receivable by the pharmacy for dispensing the drug including ingredient cost, dispensing fee, and administrative fees during the 12-month period prior to the date of the notification to report;

(7) the total rebate payable amount accrued by the pharmacy for the drug during the 12-month period prior to the date of the notification to report; and

(8) the average cash price paid by consumers per pricing unit for prescriptions dispensed where no claim was submitted to a health care service plan or health insurer during the 12-month period prior to the date of the notification to report.

(c) The pharmacy may submit any documentation necessary to support the information reported under this subdivision.

(d) The commissioner may grant extensions, exemptions, or both to compliance with the requirements of paragraphs (a) and (b) by small or independent pharmacies, if compliance with paragraphs (a) and (b) would represent a hardship or undue burden to the pharmacy. The commissioner may establish procedures for small or independent pharmacies to request extensions or exemptions under this paragraph.

Chapter 70, Article 2, Sec. 18. Minnesota Statutes 2022, section 62J.84, is amended by adding a subdivision to read:

Subd. 13. **PBM prescription drug substantial public interest reporting.** (a) Beginning January 1, 2024, a PBM must submit to the commissioner the information described in paragraph (b) for any prescription drug included in a notification to report issued to the PBM by the department under subdivision 10.

(b) For each of the drugs described in paragraph (a), the PBM shall submit to the commissioner no later than 60 days after the date of the notification to report, in the form and manner prescribed by the commissioner, the following information, if applicable:

(1) a description of the drug with the following listed separately:

(i) the national drug code;

(ii) the product name;

(iii) the dosage form;

(iv) the strength; and

(v) the package size;

(2) the number of pricing units of the drug product filled for which the PBM administered claims during the 12-month period prior to the date of the notification to report;

(3) the total reimbursement amount accrued and payable to pharmacies for pricing units of the drug product filled for which the PBM administered claims during the 12-month period prior to the date of the notification to report;

(4) the total reimbursement or administrative fee amount, or both, accrued and receivable from payers for pricing units of the drug product filled for which the PBM administered claims during the 12-month period prior to the date of the notification to report;

(5) the total rebate receivable amount accrued by the PBM for the drug product during the 12-month period prior to the date of the notification to report; and

(6) the total rebate payable amount accrued by the PBM for the drug product during the 12-month period prior to the date of the notification to report.

(c) The PBM may submit any documentation necessary to support the information reported under this subdivision.

Chapter 70, Article 2, Sec. 19. Minnesota Statutes 2022, section 62J.84, is amended by adding a subdivision to read:

Subd. 14. **Wholesale drug distributor prescription drug substantial public interest reporting.** (a) Beginning January 1, 2024, a wholesale drug distributor must submit to the commissioner the information described in paragraph (b) for any prescription drug included in a notification to report issued to the wholesale drug distributor by the department under subdivision 10.

(b) For each of the drugs described in paragraph (a), the wholesale drug distributor shall submit to the commissioner no later than 60 days after the date of the notification to report, in the form and manner prescribed by the commissioner, the following information, if applicable:

(1) a description of the drug with the following listed separately:

(i) the national drug code;

(ii) the product name;

(iii) the dosage form;

(iv) the strength; and

(v) the package size;

(2) the number of units of the drug product acquired by the wholesale drug distributor during the 12-month period prior to the date of the notification to report;

(3) the total spent before rebates by the wholesale drug distributor to acquire the drug product during the 12-month period prior to the date of the notification to report;

(4) the total rebate receivable amount accrued by the wholesale drug distributor for the drug product during the 12-month period prior to the date of the notification to report;

(5) the number of units of the drug product sold by the wholesale drug distributor during the 12-month period prior to the date of the notification to report;

(6) gross revenue from sales in the United States generated by the wholesale drug distributor for this drug product during the 12-month period prior to the date of the notification to report; and

(7) total rebate payable amount accrued by the wholesale drug distributor for the drug product during the 12-month period prior to the date of the notification to report.

(c) The wholesale drug distributor may submit any documentation necessary to support the information reported under this subdivision.

Chapter 70, Article 2, Sec. 20. Minnesota Statutes 2022, section 62J.84, is amended by adding a subdivision to read:

Subd. 15. **Registration requirements.** Beginning January 1, 2024, a reporting entity subject to this chapter shall register with the department in a form and manner prescribed by the commissioner.

Chapter 70, Article 2, Sec. 21. Minnesota Statutes 2022, section 62J.84, is amended by adding a subdivision to read:

Subd. 16. **Rulemaking.** For the purposes of this section, the commissioner may use the expedited rulemaking process under section 14.389.

Appendix A

62J.841 DEFINITIONS *(added)*

Chapter 57, Article 2, Sec. 22. **[62J.841] DEFINITIONS.**

Subdivision 1. **Scope**. For purposes of sections 62J.841 to 62J.845, the following definitions apply.

Subd. 2. **Consumer Price Index**. "Consumer Price Index" means the Consumer Price Index, Annual Average, for All Urban Consumers, CPI-U: U.S. City Average, All Items, reported by the United States Department of Labor, Bureau of Labor Statistics, or its successor or, if the index is discontinued, an equivalent index reported by a federal authority or, if no such index is reported, "Consumer Price Index" means a comparable index chosen by the Bureau of Labor Statistics.

Subd. 3. **Generic or off-patent drug.** "Generic or off-patent drug" means any prescription drug for which any exclusive marketing rights granted under the Federal Food, Drug, and Cosmetic Act, section 351 of the federal Public Health Service Act, and federal patent law have expired, including any drug-device combination product for the delivery of a generic drug.

Subd. 4. **Manufacturer**. "Manufacturer" has the meaning given in section 151.01, subdivision 14a, but does not include an entity that must be licensed solely because the entity repackages or relabels drugs.

Subd. 5. **Prescription drug.** "Prescription drug" means a drug for human use subject to United States Code, title 21, section 353(b)(1).

Subd. 6**. Wholesale acquisition cost.** "Wholesale acquisition cost" has the meaning provided in United States Code, title 42, section 1395w-3a.

Subd. 7. **Wholesale distributor.** "Wholesale distributor" has the meaning provided in section 151.441, subdivision 14.

62J.842 EXCESSIVE PRICE INCREAESES PROHIBITED *(added)*

Chapter 57, Article 2, Sec. 23. **[62J.842] EXCESSIVE PRICE INCREASES PROHIBITED.**

Subdivision 1. **Prohibition**. No manufacturer shall impose, or cause to be imposed, an excessive price increase, whether directly or through a wholesale distributor, pharmacy, or similar intermediary, on the sale of any generic or off-patent drug sold, dispensed, or delivered to any consumer in the state.

Subd. 2. **Excessive price increase.** A price increase is excessive for purposes of this section when:

(1) the price increase, adjusted for inflation utilizing the Consumer Price Index, exceeds:

(i) 15 percent of the wholesale acquisition cost over the immediately preceding calendar year; or

(ii) 40 percent of the wholesale acquisition cost over the immediately preceding three calendar years; and

(2) the price increase, adjusted for inflation utilizing the Consumer Price Index, exceeds $30 for:

(i) a 30-day supply of the drug; or

(ii) a course of treatment lasting less than 30 days.

Subd. 3. **Exemption**. It is not a violation of this section for a wholesale distributor or pharmacy to increase the price of a generic or off-patent drug if the price increase is directly attributable to additional costs for the drug imposed on the wholesale distributor or pharmacy by the manufacturer of the drug.

62J.843 REGISTERED AGENT AND OFFICE WITHIN THE STATE *(added)*

Chapter 57, Article 2, Sec. 24. [62J.843] REGISTERED AGENT AND OFFICE WITHIN THE STATE.

Any manufacturer that sells, distributes, delivers, or offers for sale any generic or off-patent drug in the state must maintain a registered agent and office within the state.

62J.844 ENFORCEMENT *(added)*

Chapter 57, Article 2, Sec. 25. **[62J.844] ENFORCEMENT.**

Subdivision 1. **Notification**. (a) The commissioner of health shall notify the manufacturer of a generic or off-patent drug and the attorney general of any price increase that the commissioner believes may violate section 62J.842.

(b) The commissioner of management and budget and any other state agency that provides or purchases a pharmacy benefit except the Department of Human Services, and any entity under contract with a state agency to provide a pharmacy benefit other than an entity under contract with the Department of Human Services, may notify the manufacturer of a generic or off-patent drug and the attorney general of any price increase that the commissioner or entity believes may violate section 62J.842.

Subd. 2. **Submission of drug cost statement and other information by manufacturer; investigation by attorney general.**

(a) Within 45 days of receiving a notice under subdivision 1, the manufacturer of the generic or off-patent drug shall submit a drug cost statement to the attorney general. The statement must:

(1) itemize the cost components related to production of the drug;

(2) identify the circumstances and timing of any increase in materials or manufacturing costs that caused any increase during the preceding calendar year, or preceding three calendar years as applicable, in the price of the drug; and

(3) provide any other information that the manufacturer believes to be relevant to a determination of whether a violation of section 62J.842 has occurred.

(b) The attorney general may investigate whether a violation of section 62J.842 has occurred, in accordance with section 8.31, subdivision 2.

Subd. 3. **Petition to court.** (a) On petition of the attorney general, a court may issue an order:

(1) compelling the manufacturer of a generic or off-patent drug to:

(i) provide the drug cost statement required under subdivision 2, paragraph (a); and

(ii) answer interrogatories, produce records or documents, or be examined under oath, as required by the attorney general under subdivision 2, paragraph (b);

(2) restraining or enjoining a violation of sections 62J.841 to 62J.845, including issuing an order requiring that drug prices be restored to levels that comply with section 62J.842;

(3) requiring the manufacturer to provide an accounting to the attorney general of all revenues resulting from a violation of section 62J.842;

(4) requiring the manufacturer to repay to all Minnesota consumers, including any third-party payers, any money acquired as a result of a price increase that violates section 62J.842;

(5) notwithstanding section 16A.151, requiring that all revenues generated from a violation of section 62J.842 be remitted to the state and deposited into a special fund, to be used for initiatives to reduce the cost to consumers of acquiring prescription drugs, if a manufacturer is unable to determine the individual transactions necessary to provide the repayments described in clause (4);

(6) imposing a civil penalty of up to $10,000 per day for each violation of section 62J.842;

(7) providing for the attorney general's recovery of costs and disbursements incurred in bringing an action against a manufacturer found in violation of section 62J.842, including the costs of investigation and reasonable attorney's fees; and

(8) providing any other appropriate relief, including any other equitable relief as determined by the court.

(b) For purposes of paragraph (a), clause (6), every individual transaction in violation of section 62J.842 is considered a separate violation.

Subd. 4. **Private right of action.** Any action brought pursuant to section 8.31, subdivision 3a, by a person injured by a violation of section 62J.842 is for the benefit of the public.

62J.845 PROHIBITION ON WITHDRAWAL OF GENERIC OR OFF-PATENT DRUGS FOR SALE *(added)*

Chapter 57, Article 2, Sec. 26. **[62J.845] PROHIBITION ON WITHDRAWAL OF GENERIC OR OFF-PATENT DRUGS FOR SALE.**

Subdivision 1. **Prohibition**. A manufacturer of a generic or off-patent drug is prohibited from withdrawing that drug from sale or distribution within this state for the purpose of avoiding the prohibition on excessive price increases under section 62J.842.

Subd. 2**. Notice to board and attorney general.** Any manufacturer that intends to withdraw a generic or off-patent drug from sale or distribution within the state shall provide a written notice of withdrawal to the attorney general at least 90 days prior to the withdrawal.

Subd. 3. **Financial penalty**. The attorney general shall assess a penalty of $500,000 on any manufacturer of a generic or off-patent drug that the attorney general determines has failed to comply with the requirements of this section.

62J.846 SEVERABILITY *(added)*

Chapter 57, Article 2, Sec. 27. **[62J.846] SEVERABILITY**.

If any provision of sections 62J.841 to 62J.845 or the application thereof to any person or circumstance is held invalid for any reason in a court of competent jurisdiction, the invalidity does not affect other provisions or any other application of sections 62J.841 to 62J.845 that can be given effect without the invalid provision or application.

62W.02 CLINICIAN ADMINISTERED DRUGS (added)

Chapter 57, Article 2, Sec. 54. [62W.15] CLINICIAN-ADMINISTERED DRUGS.

Subdivision 1. Definition. (a) For purposes of this section, the following definition applies.

(b) "Clinician-administered drug" means an outpatient prescription drug other than a vaccine that:

(1) cannot reasonably be self-administered by the enrollee to whom the drug is prescribed or by an individual assisting the enrollee with self-administration; and

(2) is typically administered:

(i) by a health care provider authorized to administer the drug, including when acting under a physician's delegation and supervision; and

(ii) in a physician's office, hospital outpatient infusion center, or other clinical setting.

Appendix A

Subd. 2.

Safety and care requirements for clinician-administered drugs.

(a) A specialty pharmacy that ships a clinician-administered drug to a health care provider or pharmacy must:

(1) comply with all federal laws regulating the shipment of drugs, including but not limited to the U.S. Pharmacopeia General Chapter 800;

(2) in response to questions from a health care provider or pharmacy, provide access to a pharmacist or nurse employed by the specialty pharmacy 24 hours a day, 7 days a week;

(3) allow an enrollee and health care provider to request a refill of a clinician-administered drug on behalf of an enrollee, in accordance with the pharmacy benefit manager or health carrier's utilization review procedures; and

(4) adhere to the track and trace requirements, as defined by the federal Drug Supply Chain Security Act, United States Code, title 21, section 360eee, et seq., for a clinician-administered drug that needs to be compounded or manipulated.

(b) For any clinician-administered drug dispensed by a specialty pharmacy selected by the pharmacy benefit manager or health carrier, the requesting health care provider or their designee must provide the requested date, approximate time, and place of delivery of a clinician-administered drug at least five business days before the date of delivery. The specialty pharmacy must require a signature upon receipt of the shipment when shipped to a health care provider.

(c) A pharmacy benefit manager or health carrier who requires dispensing of a clinician-administered drug through a specialty pharmacy shall establish and disclose a process which allows the health care provider or pharmacy to appeal and have exceptions to the use of a specialty pharmacy when:

(1) a drug is not delivered as specified in paragraph (b); or

(2) an attending health care provider reasonably believes an enrollee may experience immediate and irreparable harm without the immediate, onetime use of clinician-administered drug that a health care provider or pharmacy has in stock.

(d) A pharmacy benefit manager or health carrier shall not require a specialty pharmacy to dispense a clinician-administered drug directly to an enrollee with the intention that the enrollee will transport the clinician-administered drug to a health care provider for administration.

(e) A pharmacy benefit manager, health carrier, health care provider, or pharmacist shall not require and may not deny the use of a home infusion or infusion site external to the

enrollee's provider office or clinic to administer a clinician-administered drug when requested by an enrollee and such services are covered by the health plan and are available and clinically appropriate as determined by the health care provider and delivered in accordance with state law.

EFFECTIVE DATE. This section is effective January 1, 2024, and applies to health plans offered, issued, or renewed on or after that date.