General Assembly

# *Amendment*

***February Session, 2022***

LCO No. **6461**

* H B 0 5 4 0 0 0 6 4 6 1 H D O *

Offered by:
REP. WOOD K., 29th Dist.
REP. PAVALOCK-D'AMATO, 77th Dist.
REP. COOK, 65th Dist.
REP. CARPINO, 32nd Dist.
REP. NUCCIO, 53rd Dist.
REP. COMEY, 102nd Dist.

To: House Bill No. **5400** File No. 302 Cal. No. 232

***"AN ACT CONCERNING THE REGULATION OF INSURANCE IN THE STATE."***

Strike everything after the enacting clause and substitute the following in lieu thereof:

"Section 1. Subdivision (1) of subsection (b) of section 38a-510 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2022*):

(b) (1) Notwithstanding the sixty-day period set forth in subdivision (2) of subsection (a) of this section, each insurance company, hospital service corporation, medical service corporation, health care center or other entity that uses step therapy for such prescription drugs shall establish and disclose to its health care providers a process by which an insured's treating health care provider may request at any time an

override of the use of any step therapy drug regimen. Such disclosure shall be made to health care providers in writing at least once each calendar year, and such health care provider shall display in a conspicuous and prominent location, including the provider's Internet web site and on a bulletin board in the provider's office, information regarding the override process. Any such override process shall be convenient to use by health care providers and an override request shall be expeditiously granted when an insured's treating health care provider demonstrates that the drug regimen required under step therapy (A) has been ineffective in the past for treatment of the insured's medical condition, (B) is expected to be ineffective based on the known relevant physical or mental characteristics of the insured and the known characteristics of the drug regimen, (C) will cause or will likely cause an adverse reaction by or physical harm to the insured, or (D) is not in the best interest of the insured, based on medical necessity. Until October 1, 2025, in the case of a prescribed drug for the treatment of schizophrenia, major depressive disorder or bipolar disorder, as defined in the most recent edition of the Diagnostic and Statistical Manual of Mental Disorders, such override request shall be granted not later than twenty-four hours from the time of request.

Sec. 2. (*Effective from passage*) (a) There is established a task force to study data collection efforts regarding step therapy. Such study shall include, but need not be limited to, data collection regarding step therapy edits, rejections and appeals of behavioral health drugs and the best methods to collect such data.

(b) The task force shall consist of the following members:

(1) One appointed by the speaker of the House of Representatives;

(2) One appointed by the president pro tempore of the Senate;

(3) One appointed by the minority leader of the House of Representatives;

(4) One appointed by the minority leader of the Senate;

(5) The chairpersons and ranking members of the joint standing committees of the General Assembly having cognizance of matters relating to public health and insurance, or their designees;

(6) The executive director of the Office of Health Strategy, or the executive director's designee;

(7) The Insurance Commissioner, or the Insurance Commissioner's designee;

(8) The Commissioner of Consumer Protection, or the commissioner's designee;

(9) One representative of the insurance industry, to be appointed by the House chairperson of the joint standing committee of the General Assembly having cognizance of matters relating to insurance;

(10) One representative of the pharmaceutical industry, to be appointed by the House ranking member of the joint standing committee of the General Assembly having cognizance of matters relating to insurance;

(11) One mental health care provider, to be appointed by the House chairperson of the joint standing committee of the General Assembly having cognizance of matters relating to insurance; and

(12) One representative of a mental health advocacy group, who shall be an impacted individual, to be appointed by the House ranking member of the joint standing committee of the General Assembly having cognizance of matters relating to public health.

(c) The administrative staff of the joint standing committee of the General Assembly having cognizance of matters relating to public health shall serve as administrative staff of the task force.

(d) Not later than July 1, 2023, the task force shall submit a report on its findings and recommendations to the joint standing committees of the General Assembly having cognizance of matters relating to

insurance and public health, in accordance with the provisions of section 11-4a of the general statutes. The task force shall terminate on the date that it submits such report or on July 1, 2023, whichever is earlier.

Sec. 3. Section 38a-477ff of the 2022 supplement to the general statutes is repealed and the following is substituted in lieu thereof (*Effective from passage and applicable to policies delivered, issued for delivery, renewed, amended or continued on or after January 1, 2022*):

(a) Each insurer, health care center, hospital service corporation, medical service corporation, fraternal benefit society or other entity that delivers, issues for delivery, renews, amends or continues an individual or group health insurance policy in this state on or after January 1, 2022, providing coverage of the type specified in subdivisions (1), (2), (4), (11) and (12) of section 38a-469 shall, when calculating an insured's liability for a coinsurance, copayment, deductible or other out-of-pocket expense for a covered benefit, give credit for any discount provided or payment made by a third party for the amount of, or any portion of the amount of, the coinsurance, copayment, deductible or other out-of-pocket expense for the covered benefit.

(b) If, under federal law, application of subsection (a) of this section would result in health savings account ineligibility under Section 223 of the Internal Revenue Code of 1986, or any subsequent corresponding internal revenue code of the United States, as amended from time to time, this requirement shall apply for health savings account-qualified, high deductible health plans with respect to the deductible of such a plan after the enrollee has satisfied the minimum deductible under Section 223 of said internal revenue code, except for items or services that are preventive care pursuant to Section 223(c)(2)(C) of said internal revenue code, in which case the requirements of subsection (a) of this section shall apply regardless of whether the minimum deductible under Section 223 of said internal revenue code is satisfied.

Sec. 4. Section 38a-477gg of the 2022 supplement to the general

statutes is repealed and the following is substituted in lieu thereof (*Effective from passage and applicable to contracts entered into on or after January 1, 2022*):

(a) On and after January 1, 2022, each contract entered into between a health carrier, as defined in section 38a-591a, and a pharmacy benefits manager, as defined in section 38a-479aaa, for the administration of the pharmacy benefit portion of a health benefit plan in this state on behalf of plan sponsors shall require that the pharmacy benefits manager, when calculating an insured's or enrollee's liability for a coinsurance, copayment, deductible or other out-of-pocket expense for a covered prescription drug benefit, give credit for any discount provided or payment made by a third party for the amount of, or any portion of the amount of, the coinsurance, copayment, deductible or other out-of-pocket expense for the covered prescription drug benefit.

(b) If, under federal law, application of subsection (a) of this section would result in health savings account ineligibility under Section 223 of the Internal Revenue Code of 1986, or any subsequent corresponding internal revenue code of the United States, as amended from time to time, this requirement shall apply for health savings account-qualified, high deductible health plans with respect to the deductible of such a plan after the enrollee has satisfied the minimum deductible under Section 223 of said internal revenue code, except for items or services that are preventive care pursuant to Section 223(c)(2)(C) of said internal revenue code, in which case the requirements of subsection (a) of this section shall apply regardless of whether the minimum deductible under Section 223 of said internal revenue code is satisfied.

Sec. 5. Section 38a-478w of the 2022 supplement to the general statutes is repealed and the following is substituted in lieu thereof (*Effective from passage and applicable to contracts delivered, issued for delivery, renewed, amended or continued on or after January 1, 2022*):

(a) For any contract delivered, issued for delivery, renewed, amended or continued in this state on or after January 1, 2022, each managed care

organization shall, when calculating an enrollee's liability for a coinsurance, copayment, deductible or other out-of-pocket expense for a covered benefit, give credit for any discount provided or payment made by a third party for the amount of, or any portion of the amount of, the coinsurance, copayment, deductible or other out-of-pocket expense for the covered benefit.

(b) If, under federal law, application of subsection (a) of this section would result in health savings account ineligibility under Section 223 of the Internal Revenue Code of 1986, or any subsequent corresponding internal revenue code of the United States, as amended from time to time, this requirement shall apply for health savings account-qualified, high deductible health plans with respect to the deductible of such a plan after the enrollee has satisfied the minimum deductible under Section 223 of said internal revenue code, except for items or services that are preventive care pursuant to Section 223(c)(2)(C) of said internal revenue code, in which case the requirements of subsection (a) of this section shall apply regardless of whether the minimum deductible under Section 223 of said internal revenue code is satisfied.

Sec. 6. Section 38a-490 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2023*):

(a) Each individual health insurance policy delivered, issued for delivery, renewed, amended or continued in this state providing coverage of the type specified in subdivisions (1), (2), (4), (6), (10), (11) and (12) of section 38a-469 for a family member of the insured or subscriber shall, as to such family member's coverage, also provide that the health insurance benefits applicable for children shall be payable with respect to a newly born child of the insured or subscriber from the moment of birth.

(b) Coverage for such newly born child shall consist of coverage for injury and sickness including necessary care and treatment of medically diagnosed congenital defects and birth abnormalities within the limits of the policy.

(c) If payment of a specific premium or subscription fee is required to provide coverage for a child, the policy or contract may require that notification of birth of such newly born child and payment of the required premium or fees shall be furnished to the insurer, hospital service corporation, medical service corporation or health care center not later than **[**sixty-one**]** ninety-one days after the date of birth in order to continue coverage beyond such **[**sixty-one-day**]** period, provided failure to furnish such notice or pay such premium or fees shall not prejudice any claim originating within such **[**sixty-one-day**]** period.

Sec. 7. Section 38a-516 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2023*):

(a) Each group health insurance policy delivered, issued for delivery, renewed, amended or continued in this state providing coverage of the type specified in subdivisions (1), (2), (4), (6), (11) and (12) of section 38a-469 for a family member of the insured or subscriber shall, as to such family member's coverage, also provide that the health insurance benefits applicable for children shall be payable with respect to a newly born child of the insured or subscriber from the moment of birth.

(b) Coverage for such newly born child shall consist of coverage for injury and sickness including necessary care and treatment of medically diagnosed congenital defects and birth abnormalities within the limits of the policy.

(c) If payment of a specific premium fee is required to provide coverage for a child, the policy may require that notification of birth of such newly born child and payment of the required premium or fees shall be furnished to the insurer, hospital service corporation, medical service corporation or health care center not later than **[**sixty-one**]** ninety-one days after the date of birth in order to continue coverage beyond such **[**sixty-one-day**]** period, provided failure to furnish such notice or pay such premium shall not prejudice any claim originating within such **[**sixty-one-day**]** period.

Sec. 8 (NEW) (*Effective July 1, 2022*) For the purposes of this section

and sections 9 to 13, inclusive, of this act unless the context otherwise requires:

(1) "Commissioner" means the Commissioner of Consumer Protection;

(2) "Drug" means an article that is (A) recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States or official National Formulary, or any supplement thereto, (B) intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans, (C) not food and intended to affect the structure or any function of the human body, and (D) not a device and intended for use as a component of any other article specified in subparagraphs (A) to (C), inclusive, of this subdivision;

(3) "Drug Quality and Security Act" means the Drug Quality and Security Act, 21 USC 351, et seq., as amended from time to time;

(4) "Food, Drug and Cosmetic Act" means the Food, Drug and Cosmetic Act, 21 USC 301, et seq., as amended by the Drug Quality and Security Act, as both may be amended from time to time;

(5) "Importation program" means the Canadian legend drug importation program established by the commissioner pursuant to section 9 of this act;

(6) "Institutional pharmacy" has the same meaning as provided in section 20-571 of the general statutes;

(7) "Laboratory testing" means a quantitative and qualitative analysis of a prescription drug consistent with the official United States Pharmacopoeia;

(8) "Legend drug" means a drug that (A) any applicable federal or state law provides shall only be (i) dispensed pursuant to a prescription, or (ii) used by a prescribing practitioner, or (B) applicable federal law requires to bear the following legend: "RX ONLY" IN ACCORDANCE WITH GUIDELINES ESTABLISHED IN THE FEDERAL FOOD, DRUG

AND COSMETIC ACT;

(9) "Manufacturer" means (A) an applicant as defined in 21 CFR 314.3, as amended from time to time, (B) a person who owns or operates an establishment that manufactures an eligible prescription drug, or (C) a holder of a drug master file containing information necessary to conduct the Statutory Testing, prepare the manufacturer's attestation and information statement, or comply with Section 804 of the Food, Drug and Cosmetic Act, 21 USC 360(b), as amended from time to time;

(10) "Participating Canadian supplier" means a manufacturer or wholesale drug distributor within Canada that (A) holds an active Drug Establishment License to wholesale drugs by Health Canada, (B) is registered with provincial regulatory authorities to distribute HPFB-approved drugs, (C) is not licensed by a provincial regulatory authority with an international pharmacy license that allows it to distribute drugs that are approved by countries other than Canada and that are not HPFB-approved for distribution in Canada, (D) is properly registered, if such Canadian supplier is required to be registered, with the United States Food and Drug Administration, or any successor agency, and (E) exports legend drugs, in the manufacturer's original container, to a participating wholesaler for distribution in this state under the importation program;

(11) "Participating wholesaler" means a wholesaler as defined in 21 CFR 251.2, as amended from time to time, that is designated by the commissioner to participate in the importation program in this state. Participating wholesaler does not include a person authorized to import drugs under Section 801 (d) (1) of the Food, Drug and Cosmetic Act, 21 USC 381, as amended from time to time;

(12) "Pharmacy" has the same meaning as provided in section 20-571 of the general statutes;

(13) "Prescription" means a lawful oral, written or electronic order by a prescribing practitioner for a drug for a specific patient;

(14) "Qualified laboratory" means a laboratory in this state that has been approved by the United States Food and Drug Administration for the purposes of Section 804 of the Food, Drug and Cosmetic Act, 21 USC 360(b), as amended from time to time;

(15) "Qualified wholesaler" means a wholesaler, as defined in section 21a-70 of the general statutes, that has received a certificate of registration from the commissioner pursuant to said section; and

(16) "Track-and-trace" means the product tracing process for the components of the pharmaceutical distribution supply chain, as described in Title II of the Drug Quality and Security Act.

Sec. 9. (NEW) (*Effective July 1, 2022*) (a) The commissioner shall establish a program to be known as the "Canadian legend drug importation program". Under such importation program, the commissioner shall, notwithstanding any provision of the general statutes:

(1) Provide for the importation from Canada of safe and effective legend drugs that have the highest potential for cost savings for patients in this state;

(2) Develop and implement an application and approval process for qualified wholesalers to be designated as participating wholesalers; and

(3) Designate one or more participating wholesalers to distribute in this state legend drugs, imported from Canada, from a participating Canadian supplier and in the manufacturer's original container, to a licensed pharmacy or institutional pharmacy or a qualified laboratory.

(b) (1) Not later than July 1, 2023, the commissioner shall submit a request to the federal Secretary of Health and Human Services seeking approval for the importation program under 21 USC 384, as amended from time to time. Such request shall, at a minimum:

(A) Describe the commissioner's plans for operating the importation program;

(B) Demonstrate that the legend drugs to be imported and distributed in this state under the importation program shall:

(i) Meet all applicable federal and state standards for safety and effectiveness; and

(ii) Comply with all federal tracing procedures and federal supply chain security requirements as set forth in 21 CFR 251.14, as amended from time to time;

(C) Disclose the costs of implementing the importation program;

(D) Meet all review and authorization criteria as set forth in 21 CFR 251.4, as amended from time to time; and

(E) Satisfy all pre-importation requirements as set forth in 21 CFR 251.5.

(2) (A) If the federal Secretary of Health and Human Services approves the commissioner's request, the commissioner shall:

(i) Submit to (I) the Commissioner of Public Health a notice disclosing that the federal Secretary of Health and Human Services has approved such request, and (II) the joint standing committees of the General Assembly having cognizance of matters relating to appropriations, general law, human services, insurance and public health a notice disclosing that the federal Secretary of Health and Human Services has approved such request; and

(ii) Begin operating the importation program not later than one hundred eighty days after the date of such approval.

(B) Except as otherwise provided in this subsection, the commissioner shall not operate the importation program unless the federal Secretary of Health and Human Services approves the commissioner's request.

Sec. 10. (NEW) (*Effective July 1, 2022*) (a) Each participating

wholesaler may, subject to the provisions of this section and sections 9 and 12 of this act, import into this state a legend drug from a participating Canadian supplier, and distribute such legend drug to a licensed pharmacy or institutional pharmacy, or a qualified laboratory in this state, under the importation program if:

(1) Such participating wholesaler:

(A) Is registered with the federal Secretary of Health and Human Services pursuant to 21 CFR 251, as amended from time to time; and

(B) Holds a valid labeler code that was issued to such participating wholesaler by the United States Food and Drug Administration, or any successor agency; and

(2) Such legend drug:

(A) May be imported into this state in accordance with applicable federal patent laws;

(B) Meets the United States Food and Drug Administration's, or any successor agency's, standards concerning drug safety, effectiveness, misbranding and adulteration; and

(C) Is not:

(i) A controlled substance, as defined in 21 USC 802, as amended from time to time;

(ii) A biological product, as defined in 42 USC 262, as amended from time to time;

(iii) An infused drug;

(iv) An intravenously, intradermally, intrathecally, intramuscularly or subcutaneously injected drug;

(v) A drug that is inhaled during surgery;

(vi) A drug that is a parenteral drug, the importation of which is determined by the federal Secretary of Health and Human Services to pose a threat to the public health; or

(vii) A drug that is a compound which is not commercially available.

(b) Each participating wholesaler shall:

(1) Comply with all applicable track-and-trace requirements, and make available to the commissioner all track-and-trace records not later than forty-eight hours after said commissioner requests such records;

(2) Not import into, or distribute, dispense or sell, in this state any legend drugs under the importation program except in accordance with the provisions of this section and sections 9 and 12 of this act;

(3) Not distribute, dispense or sell outside of this state any legend drugs that are imported into this state under the importation program;

(4) Ensure the safety and quality of each legend drug that is imported and distributed in this state under the importation program;

(5) Comply with federal pre-importation request requirements as set forth in 21 CFR 251.5, as amended from time to time;

(6) For each initial shipment of any legend drug that is imported into this state by such participating wholesaler, ensure that a qualified laboratory engaged by such participating wholesaler tests a statistically valid sample size for each batch of such legend drug in such shipment for authenticity and degradation in a manner that is consistent with the Food, Drug and Cosmetic Act and 21 CFR 251.16, as both may be amended from time to time;

(7) For each subsequent shipment of a legend drug that is imported into this state by such participating wholesaler, and sampled and tested pursuant to subdivision (6) of this subsection, ensure that a qualified laboratory engaged by such participating wholesaler tests a statistically valid sample of such legend drug in such shipment for authenticity and

degradation in a manner that is consistent with the Food, Drug and Cosmetic Act and 21 CFR 251.16, as both may be amended from time to time, and quarantine such shipment until the results of such test conducted pursuant to this subdivision indicate that such legend drug is consistent with its labeling;

(8) Certify to the commissioner that each legend drug imported into this state under the importation program:

(A) Is approved for marketing in the United States and not adulterated or misbranded;

(B) Meets all labeling requirements under 21 USC 352, as amended from time to time;

(C) Meets all labeling requirements as set forth in 21 CFR 251.12, 21 CFR 251.13 and 21 CFR 251.14, as amended from time to time;

(9) Either:

(A) Propose a national drug code for each drug imported into this state in accordance with sections 8 to 13, inclusive, of this act, pursuant to the procedures under 21 CFR 207.33, as amended from time to time, and list such drug pursuant to the procedures set forth in 21 CFR 207.53, as amended from time to time; or

(B) Ensure that the entity performing relabeling on such wholesaler's behalf lists each eligible prescription drug and incorporates the national drug code such wholesaler proposed for assignment in accordance with the labeling requirements set forth in 21 CFR 207, as amended from time to time;

(10) Maintain laboratory records, including, but not limited to, complete data derived from all tests necessary to ensure that each legend drug imported into this state under the importation program satisfies the requirements of subdivisions (6) and (7) of this subsection;

(11) Maintain documentation demonstrating that the testing required

by subdivisions (6) and (7) of this subsection was conducted at a qualified laboratory in accordance with the Food, Drug and Cosmetic Act, and all other applicable federal and state laws and regulations concerning laboratory qualifications;

(12) Maintain the following information for each legend drug that such participating wholesaler imports and distributes in this state under the importation program, and submit such information to the commissioner upon request by the commissioner:

(A) The name and quantity of the active ingredient of such legend drug;

(B) A description of the dosage form of such legend drug;

(C) The date on which such participating wholesaler received such legend drug;

(D) The quantity of such legend drug that such participating wholesaler received;

(E) The point of origin and destination of such legend drug;

(F) The price paid by such participating wholesaler for such legend drug;

(G) A report for each legend drug that fails laboratory testing under subdivision (6) or (7) of this subsection; and

(H) Such additional information and documentation that the commissioner deems necessary to ensure the protection of the public health;

(13) Ensure that any legend drug that fails laboratory testing under subdivision (6) or (7) of this subsection is appropriately quarantined and destroyed; and

(14) Maintain all information and documentation that is submitted to the commissioner pursuant to this subsection for a period of not less

than three years.

Sec. 11. (NEW) (*Effective July 1, 2022*) Each participating Canadian supplier shall:

(1) Comply with all applicable track-and-trace requirements;

(2) Not distribute, dispense or sell outside of this state any legend drugs that are imported into this state under the importation program; and

(3) Maintain the following information and documentation and, upon request by the commissioner, submit such information and documentation to the commissioner for each legend drug that such participating Canadian supplier exports into this state under the importation program:

(A) The original source of such legend drug, including, but not limited to:

(i) The name of the manufacturer of such legend drug;

(ii) The date on which such legend drug was manufactured; and

(iii) The location where such legend drug was manufactured;

(B) The date on which such legend drug was shipped to a participating wholesaler;

(C) The quantity of such legend drug that was shipped to a participating wholesaler;

(D) The quantity of each lot of such legend drug that such participating Canadian supplier originally received and the source of such lot;

(E) The lot or control number and the batch number assigned to such legend drug by the manufacturer; and

(F) Such additional information and documentation that the commissioner deems necessary to ensure the protection of the public health.

Sec. 12. (NEW) (*Effective July 1, 2022*) (a) The commissioner shall issue a written order:

(1) Suspending importation and distribution of a legend drug under the importation program if the commissioner discovers that such importation or distribution violates any provision of sections 9 to 11, inclusive, of this act or any other applicable state or federal law or regulation, including post importation requirements as set forth in 21 CFR 251.18;

(2) Suspending all importation and distribution of legend drugs by a participating wholesaler under the importation program if the commissioner discovers that the participating wholesaler has violated any provision of section 9 or 10 of this act or any other applicable state or federal law or regulation;

(3) Suspending all importation and distribution of legend drugs by a participating Canadian supplier under the importation program if the commissioner discovers that the participating Canadian supplier has violated any provision of section 9 or 11 of this act or any other applicable state or federal law or regulation;

(4) Requiring the quarantine, recall or seizure of any legend drug that was imported and distributed under the importation program if such legend drug has been identified as adulterated, within the meaning of section 21a-105 of the general statutes, or misbranded; or

(5) Requiring retesting, at the expense of the participating wholesaler and by a laboratory approved by the commissioner, of any legend drug distributed by the participating wholesaler if the commissioner deems such retesting necessary.

(b) The commissioner shall send a notice to each participating

Canadian supplier and participating wholesaler affected by an order issued pursuant to subsection (a) of this section notifying such participating Canadian supplier or participating wholesaler that:

(1) The commissioner has issued such order, and providing the legal and factual basis for such order; and

(2) Such participating Canadian supplier or participating wholesaler may request, in writing, a hearing before the commissioner, provided such request is received by the commissioner not later than thirty days after the date of such notice.

(c) If a participating Canadian supplier or participating wholesaler timely requests a hearing pursuant to subsection (b) of this section, the commissioner shall, not later than thirty days after the receipt of the request, convene the hearing as a contested case in accordance with the provisions of chapter 54 of the general statutes. Not later than sixty days after the receipt of such request, the commissioner shall issue a final decision vacating, modifying or affirming the commissioner's order. If the participating Canadian supplier or participating wholesaler is aggrieved by such final decision, such participating Canadian supplier or participating wholesaler may appeal such decision in accordance with the provisions of section 4-183 of the general statutes.

Sec. 13. (NEW) (*Effective July 1, 2022*) The commissioner may, in consultation with the Commissioner of Public Health, adopt regulations in accordance with the provisions of chapter 54 of the general statutes to implement the provisions of sections 8 to 12, inclusive, of this act.

Sec. 14. (*Effective from passage*) Not later than January 1, 2023, the Office of Health Strategy shall prepare and submit a report, in accordance with section 11-4a of the general statutes, to the joint standing committee of the General Assembly having cognizance of matters relating to insurance. Such report shall include, but need not be limited to, an analysis of pharmacy benefit manager distribution of prescription drug practices regarding spread pricing arrangements, manufacturing rebates and transparency and accountability.

Sec. 15. (*Effective from passage*) Not later than January 1, 2023, the State Comptroller shall prepare and submit a report, in accordance with section 11-4a of the general statutes, to the joint standing committee of the General Assembly having cognizance of matters relating to insurance. Such report shall include an analysis of state purchasing pools for prescription drugs and health care supplies, and shall describe: (1) Whether current pool purchasing arrangements with other states are resulting in cost savings in the state; and (2) whether other potential pool purchasing relationships may result in lower prescription drug and health care costs.

Sec. 16. Subdivision (1) of subsection (b) of section 38a-544 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2022*):

(b) (1) Notwithstanding the sixty-day period set forth in subdivision (2) of subsection (a) of this section, each insurance company, hospital service corporation, medical service corporation, health care center or other entity that uses step therapy for such prescription drugs shall establish and disclose to its health care providers a process by which an insured's treating health care provider may request at any time an override of the use of any step therapy drug regimen. Such disclosure shall be made to health care providers in writing at least once each calendar year, and such health care provider shall display in a conspicuous and prominent location, including on the provider's Internet web site and on a bulletin board in the provider's office, information regarding the override process. Any such override process shall be convenient to use by health care providers and an override request shall be expeditiously granted when an insured's treating health care provider demonstrates that the drug regimen required under step therapy (A) has been ineffective in the past for treatment of the insured's medical condition, (B) is expected to be ineffective based on the known relevant physical or mental characteristics of the insured and the known characteristics of the drug regimen, (C) will cause or will likely cause an adverse reaction by or physical harm to the insured, or (D) is not in the best interest of the insured, based on medical necessity. Until October 1,

2025, in the case of a prescribed drug for the treatment of schizophrenia, major depressive disorder or bipolar disorder, as defined in the most recent edition of the Diagnostic and Statistical Manual of Mental Disorders, such override request shall be granted not later than twenty-four hours from the time of the request."

| This act shall take effect as follows and shall amend the following sections: | | |
|---|---|---|
| Section 1 | *October 1, 2022* | 38a-510(b)(1) |
| Sec. 2 | *from passage* | New section |
| Sec. 3 | *from passage and applicable to policies delivered, issued for delivery, renewed, amended or continued on or after January 1, 2022* | 38a-477ff |
| Sec. 4 | *from passage and applicable to contracts entered into on or after January 1, 2022* | 38a-477gg |
| Sec. 5 | *from passage and applicable to contracts delivered, issued for delivery, renewed, amended or continued on or after January 1, 2022* | 38a-478w |
| Sec. 6 | *January 1, 2023* | 38a-490 |
| Sec. 7 | *January 1, 2023* | 38a-516 |
| Sec. 8 | *July 1, 2022* | New section |
| Sec. 9 | *July 1, 2022* | New section |
| Sec. 10 | *July 1, 2022* | New section |
| Sec. 11 | *July 1, 2022* | New section |
| Sec. 12 | *July 1, 2022* | New section |
| Sec. 13 | *July 1, 2022* | New section |
| Sec. 14 | *from passage* | New section |
| Sec. 15 | *from passage* | New section |
| Sec. 16 | *October 1, 2022* | 38a-544(b)(1) |