General Assembly

Amendment

February Session, 2018

LCO No. **5048**

* H B 0 5 3 8 4 0 5 0 4 8 H D O *

Offered by:
REP. SCANLON, 98th Dist.

To: Subst. House Bill No. **5384** File No. 317 Cal. No. 212

"AN ACT CONCERNING PRESCRIPTION DRUG COSTS."

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

"Section 1. (NEW) (*Effective January 1, 2020*) For the purposes of this section and sections 2 to 6, inclusive, of this act:

(1) "Commissioner" means the Insurance Commissioner.

(2) "Department" means the Insurance Department.

(3) "Drug" has the same meaning as provided in section 21a-92 of the general statutes.

(4) "Health care plan" means an individual or a group health insurance policy that provides coverage of the types specified in subdivisions (1), (2), (4), (11) and (12) of section 38a-469 of the general statutes and includes coverage for outpatient prescription drugs.

(5) "Health carrier" means an insurance company, health care center,

hospital service corporation, medical service corporation, fraternal benefit society or other entity that delivers, issues for delivery, renews, amends or continues a health care plan in this state.

(6) "Person" has the same meaning as provided in section 38a-1 of the general statutes.

(7) "Pharmacist" has the same meaning as provided in section 38a-479aaa of the general statutes.

(8) "Pharmacist services" has the same meaning as provided in section 38a-479aaa of the general statutes.

(9) "Pharmacy" has the same meaning as provided in section 38a-479aaa of the general statutes.

(10) "Pharmacy benefits manager" or "manager" means any person that administers the prescription drug, prescription device, pharmacist services or prescription drug and device and pharmacist services portion of a health care plan on behalf of a health carrier.

(11) (A) "Rebate" means a discount or concession, which affects the price of an outpatient prescription drug, that a pharmaceutical manufacturer directly provides to a (1) health carrier for an outpatient prescription drug manufactured by the pharmaceutical manufacturer, or (2) pharmacy benefits manager after the manager processes a claim from a pharmacy or a pharmacist for an outpatient prescription drug manufactured by the pharmaceutical manufacturer.

(B) "Rebate" does not mean a bona fide service fee, as such term is defined in Section 447.502 of Title 42 of the Code of Federal Regulations, as amended from time to time.

(12) "Specialty drug" means a prescription outpatient specialty drug covered under the Medicare Part D program established pursuant to Public Law 108-173, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, as amended from time to time, that exceeds the specialty tier cost threshold established by the Centers for

Medicare and Medicaid Services.

Sec. 2. (NEW) (*Effective January 1, 2020*) (a) Not later than March 1, 2021, and annually thereafter, each pharmacy benefits manager shall file a report with the commissioner for the immediately preceding calendar year. The report shall contain the following information for health carriers that delivered, issued for delivery, renewed, amended or continued health care plans that included a pharmacy benefit managed by the pharmacy benefits manager during such calendar year:

(1) The aggregate dollar amount of all rebates concerning drug formularies used by such health carriers that such manager collected from pharmaceutical manufacturers that manufactured outpatient prescription drugs that (A) were covered by such health carriers during such calendar year, and (B) are attributable to patient utilization of such drugs during such calendar year; and

(2) The aggregate dollar amount of all rebates, excluding any portion of the rebates received by such health carriers, concerning drug formularies that such manager collected from pharmaceutical manufacturers that manufactured outpatient prescription drugs that (A) were covered by such health carriers during such calendar year, and (B) are attributable to patient utilization of such drugs by covered persons under such health care plans during such calendar year.

(b) The commissioner shall establish a standardized form for reporting information pursuant to subsection (a) of this section after consultation with pharmacy benefits managers. The form shall be designed to minimize the administrative burden and cost of reporting on the department and pharmacy benefits managers.

(c) All information submitted to the commissioner pursuant to subsection (a) of this section shall be exempt from disclosure under the Freedom of Information Act, as defined in section 1-200 of the general statutes, except to the extent such information is included on an aggregated basis in the report required by subsection (d) of this

section. The commissioner shall not disclose information submitted pursuant to subdivision (1) of subsection (a) of this section, or information submitted pursuant to subdivision (2) of said subsection in a manner that (1) is likely to compromise the financial, competitive or proprietary nature of such information, or (2) would enable a third party to identify a health care plan, health carrier, pharmacy benefits manager, pharmaceutical manufacturer, or the value of a rebate provided for a particular outpatient prescription drug or therapeutic class of outpatient prescription drugs.

(d) Not later than March 1, 2022, and annually thereafter, the commissioner shall 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. The report shall contain (1) an aggregation of the information submitted to the commissioner pursuant to subsection (a) of this section for the immediately preceding calendar year, and (2) such other information as the commissioner, in the commissioner's discretion, deems relevant for the purposes of this section. Not later than February 1, 2022, and annually thereafter, the commissioner shall provide each pharmacy benefits manager and any third party affected by submission of a report required by this subsection with a written notice describing the content of the report.

(e) The commissioner may impose a penalty of not more than seven thousand five hundred dollars on a pharmacy benefits manager for each violation of this section.

(f) The commissioner may adopt regulations, in accordance with the provisions of chapter 54 of the general statutes, to implement the provisions of this section.

Sec. 3. (NEW) (*Effective January 1, 2020*) (a) Each health carrier that delivers, issues for delivery, renews, amends or continues a health care plan on or after January 1, 2021, shall submit the following information and data to the commissioner, for such health care plan for the

immediately preceding calendar year, at the time that such health carrier submits a rate filing for such health care plan pursuant to sections 38a-183 of the general statutes, as amended by this act, 38a-481 of the general statutes, as amended by this act, or 38a-513 of the general statutes, as amended by this act, as applicable:

(1) For covered outpatient prescription drugs that were prescribed to insureds under such health care plan during such calendar year, the names of:

(A) The twenty-five most frequently prescribed outpatient prescription drugs;

(B) The twenty-five outpatient prescription drugs that the health care plan covered at the greatest cost, calculated by using the total annual plan spending by such health care plan for each outpatient prescription drug; and

(C) The twenty-five outpatient prescription drugs that experienced the greatest year-over-year increase in cost, calculated by using the total annual plan spending by such health care plan for each outpatient prescription drug.

(2) The portion of the premium for such health care plan that is attributable to each of the following categories of covered outpatient prescription drugs that were prescribed to insureds under such health care plan during such calendar year:

(A) Brand name drugs;

(B) Generic drugs; and

(C) Specialty drugs.

(3) The year-over-year increase, calculated on a per member, per month basis and expressed as a percentage, in the total annual cost of each category of covered outpatient prescription drugs set forth in subdivision (2) of this subsection.

(4) A comparison, calculated on a per member, per month basis, of the year-over-year increase in the cost of covered outpatient prescription drugs to the year-over-year increase in the costs of other contributors to the premium cost of such health care plan.

(5) The name of each specialty drug covered during such calendar year.

(6) The names of the twenty-five most frequently prescribed outpatient prescription drugs for which the health carrier received rebates from pharmaceutical manufacturers during such calendar year.

(b) The commissioner may adopt regulations, in accordance with the provisions of chapter 54 of the general statutes, to implement the provisions of this section.

Sec. 4. (NEW) (*Effective January 1, 2020*) Beginning on March 1, 2022, and annually thereafter, each health carrier shall submit to the commissioner, in a form and manner prescribed by the commissioner, a written certification for the immediately preceding calendar year, certifying that the health carrier accounted for all rebates in calculating the premium for health care plans that such health carrier delivered, issued for delivery, renewed, amended or continued during such calendar year.

Sec. 5. (NEW) (*Effective January 1, 2020*) Not later than March 1, 2022, and annually thereafter, the commissioner shall 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. The report shall contain (1) an aggregation of the information and data submitted to the commissioner pursuant to section 3 of this act for the immediately preceding calendar year, (2) a description of the impact of the cost of outpatient prescription drugs on health insurance premiums in this state, and (3) such other information as the commissioner, in the commissioner's discretion, deems relevant to the cost of outpatient prescription drugs in this state.

Sec. 6. (NEW) (*Effective January 1, 2020*) Not later than March 1, 2021, and annually thereafter, the commissioner shall prepare a report, for the immediately preceding calendar year, describing the rebate practices of health carriers. The report shall contain (1) an explanation of the manner in which health carriers accounted for rebates in calculating premiums for health care plans delivered, issued for delivery, renewed, amended or continued during such year, (2) a statement disclosing whether, and describing the manner in which, health carriers made rebates available to insureds at the point of purchase during such year, (3) any other manner in which health carriers applied rebates during such year, and (4) such other information as the commissioner, in the commissioner's discretion, deems relevant for the purposes of this section. The commissioner shall publish a copy of the report on the department's Internet web site.

Sec. 7. Section 38a-183 of the 2018 supplement to the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2020*):

(a) (1) A health care center governed by sections 38a-175 to 38a-194, inclusive, shall not enter into any agreement with subscribers unless and until it has filed with the commissioner a full schedule of the amounts to be paid by the subscribers and has obtained the commissioner's approval thereof. Such filing shall include the information and data required under section 3 of this act if the contract or policy is subject to said section, and an actuarial memorandum that includes, but is not limited to, pricing assumptions and claims experience, and premium rates and loss ratios from the inception of the contract or policy. The commissioner may refuse such approval if the commissioner finds such amounts to be excessive, inadequate or discriminatory. As used in this subsection, "loss ratio" means the ratio of incurred claims to earned premiums by the number of years of policy duration for all combined durations.

(2) Premium rates offered to individuals shall be consistent with the

requirements set forth in section 38a-481, as amended by this act.

(3) Premium rates offered to small employers, as defined in section 38a-564, shall be consistent with the requirements set forth in section 38a-567.

(4) No such health care center shall enter into any agreement with subscribers unless and until it has filed with the commissioner a copy of such agreement or agreements, including all riders and endorsements thereon, and until the commissioner's approval thereof has been obtained. The commissioner shall, within a reasonable time after the filing of any request for an approval of the amounts to be paid, any agreement or any form, notify the health care center of the commissioner's approval or disapproval thereof.

(b) A health care center may establish rates of payment by any method permitted by the Federal Health Maintenance Organization Act and the regulations adopted thereunder from time to time unless otherwise determined by the commissioner by regulation.

(c) Each such health care center may include as a component of its rate a sum up to ten per cent of such rate to be used for the objects and purposes set forth in section 38a-184. An amount not exceeding ten per cent of the annual net premium income of such center may be set aside annually as a capital reserve fund and may be accumulated from year to year by such health care center, to be expended for the objects and purposes as set forth and in accordance with said section.

(d) Each such health care center shall, if such health care center intends to account for rebates, as defined in section 1 of this act in the manner specified in section 4 of this act, account for such rebates in calculating premium rates offered on or after January 1, 2021, if such health care center is subject to section 4 of this act.

Sec. 8. Subsection (a) of section 38a-481 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2020*):

(a) No individual health insurance policy shall be delivered or issued for delivery to any person in this state, nor shall any application, rider or endorsement be used in connection with such policy, until a copy of the form thereof and of the classification of risks and the premium rates have been filed with the commissioner. Rate filings shall include the information and data required under section 3 of this act if the policy is subject to said section, and an actuarial memorandum that includes, but is not limited to, pricing assumptions and claims experience, and premium rates and loss ratios from the inception of the policy. Each premium rate filed on or after January 1, 2021, shall, if the insurer intends to account for rebates, as defined in section 1 of this act in the manner specified in section 4 of this act, account for such rebates in such manner, if the policy is subject to section 4 of this act. The commissioner **[**shall**]** may adopt regulations, in accordance with the provisions of chapter 54, to establish a procedure for reviewing such policies. The commissioner shall disapprove the use of such form at any time if it does not comply with the requirements of law, or if it contains a provision or provisions that are unfair or deceptive or that encourage misrepresentation of the policy. The commissioner shall notify, in writing, the insurer that has filed any such form of the commissioner's disapproval, specifying the reasons for disapproval, and ordering that no such insurer shall deliver or issue for delivery to any person in this state a policy on or containing such form. The provisions of section 38a-19 shall apply to such orders. As used in this subsection, "loss ratio" means the ratio of incurred claims to earned premiums by the number of years of policy duration for all combined durations.

Sec. 9. Subdivision (2) of subsection (a) of section 38a-513 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2020*):

(2) No group health insurance policy or certificate for a small employer, as defined in section 38a-564, shall be delivered or issued for delivery in this state unless the premium rates have been submitted to and approved by the commissioner. Premium rate filings shall include

the information and data required under section 3 of this act if the policy is subject to said section, and an actuarial memorandum that includes, but is not limited to, pricing assumptions and claims experience, and premium rates and loss ratios from the inception of the policy. Each premium rate filed on or after January 1, 2021, shall, if the insurer intends to account for rebates, as defined in section 1 of this act in the manner specified in section 4 of this act, account for such rebates in such manner, if the policy is subject to section 4 of this act. As used in this subdivision, "loss ratio" means the ratio of incurred claims to earned premiums by the number of years of policy duration for all combined durations.

Sec. 10. (NEW) (*Effective January 1, 2020*) (a) For the purposes of this section:

(1) "Accelerated approval" has the same meaning as provided in 21 USC 356, as amended from time to time;

(2) "Biologics license application" means an application filed pursuant to Section 601.2 of Title 21 of the Code of Federal Regulations, as amended from time to time;

(3) "Breakthrough therapy" has the same meaning as provided in 21 USC 356, as amended from time to time;

(4) "Drug" has the same meaning as provided in section 21a-92 of the general statutes;

(5) "Fast track product" has the same meaning as provided in 21 USC 356, as amended from time to time;

(6) "New drug application" has the same meaning as provided in Section 314.3 of Title 21 of the Code of Federal Regulations, as amended from time to time;

(7) "New molecular entity" has the same meaning as such term is used in 21 USC 355-1, as amended from time to time;

(8) "Orphan drug" has the same meaning as provided in Section 316.3 of Title 21 of the Code of Federal Regulations, as amended from time to time;

(9) "Pipeline drug" means a drug containing a new molecular entity for which a sponsor has filed a new drug application or biologics license application with, and received an action date from, the federal Food and Drug Administration;

(10) "Prescription drug" means a drug prescribed by a health care provider to an individual in this state;

(11) "Priority review" has the same meaning as such term is used in 21 USC 356, as amended from time to time;

(12) "Rebate" has the same meaning as provided in section 1 of this act;

(13) "Research and development cost" means a cost that a pharmaceutical manufacturer incurs in researching and developing a new product, process or service, including, but not limited to, a cost that a pharmaceutical manufacturer incurs in researching and developing a product, process or service that the pharmaceutical manufacturer has acquired from another person by license;

(14) "Sponsor" has the same meaning as provided in Section 316.3 of Title 21 of the Code of Federal Regulations, as amended from time to time; and

(15) "Wholesale acquisition cost" has the same meaning as provided in 42 USC 1395w-3a, as amended from time to time.

(b) Beginning on January 1, 2020, each sponsor shall submit to the Office of Health Strategy, established in section 19a-754a of the general statutes, in a form and manner specified by the office, written notice informing the office that such sponsor has filed with the federal Food and Drug Administration:

(1) A new drug application or biologics license application for a pipeline drug, not later than sixty days after such sponsor receives an action date from the federal Food and Drug Administration regarding such application; or

(2) A biologics license application for a biosimilar drug, not later than sixty days after such sponsor's receipt of an action date from the federal Food and Drug Administration regarding such application.

(c) (1) Beginning on January 1, 2020, the executive director of the Office of Health Strategy may conduct a study, with the assistance of the Comptroller and not more frequently than once annually, of each pharmaceutical manufacturer of a pipeline drug that, in the opinion of the executive director in consultation with the Comptroller and the Commissioner of Social Services, may have a significant impact on state expenditures for outpatient prescription drugs. The office may work with the Comptroller to utilize existing state resources and contracts, or contract with a third party, including, but not limited to, an accounting firm, to conduct such study.

(2) Each pharmaceutical manufacturer that is the subject of a study conducted pursuant to subdivision (1) of this subsection shall submit to the office, or any contractor engaged by the office or the Comptroller to perform such study, the following information for the pipeline drug that is the subject of such study:

(A) The primary disease, condition or therapeutic area studied in connection with such drug, and whether such drug is therapeutically indicated for such disease, condition or therapeutic area;

(B) Each route of administration studied for such drug;

(C) Clinical trial comparators, if applicable, for such drug;

(D) The estimated year of market entry for such drug;

(E) Whether the federal Food and Drug Administration has designated such drug as an orphan drug, a fast track product or a

breakthrough therapy; and

(F) Whether the federal Food and Drug Administration has designated such drug for accelerated approval and, if such drug contains a new molecular entity, for priority review.

(d) (1) On or before March 1, 2020, and annually thereafter, the executive director of the Office of Health Strategy, in consultation with the Comptroller, Commissioner of Social Services and Commissioner of Public Health, shall prepare a list of not more than ten outpatient prescription drugs that the executive director, in the executive director's discretion, determines are (A) provided at substantial cost to the state, considering the net cost of such drugs, or (B) critical to public health. The list shall include outpatient prescription drugs from different therapeutic classes of outpatient prescription drugs and at least one generic outpatient prescription drug.

(2) The executive director shall not list any outpatient prescription drug under subdivision (1) of this subsection unless the wholesale acquisition cost of the drug, less all rebates paid to the state for such drug during the immediately preceding calendar year, (A) increased by at least (i) twenty per cent during the immediately preceding calendar year, or (ii) fifty per cent during the immediately preceding three calendar years, and (B) was not less than sixty dollars for (i) a thirty-day supply of such drug, or (ii) a course of treatment of such drug lasting less than thirty days.

(3) (A) The pharmaceutical manufacturer of an outpatient prescription drug included on a list prepared by the executive director pursuant to subdivision (1) of this subsection shall provide to the office, in a form and manner specified by the executive director, (i) a written, narrative description, suitable for public release, of all factors that caused the increase in the wholesale acquisition cost of the listed outpatient prescription drug, and (ii) aggregate, company-level research and development costs and such other capital expenditures that the executive director, in the executive director's discretion, deems

relevant for the most recent year for which final audited data are available.

(B) The quality and types of information and data that a pharmaceutical manufacturer submits to the office under this subdivision shall be consistent with the quality and types of information and data that the pharmaceutical manufacturer includes in (i) such pharmaceutical manufacturer's annual consolidated report on Securities and Exchange Commission Form 10-K, or (ii) any other public disclosure.

(4) The office shall establish a standardized form for reporting information and data pursuant to this subsection after consulting with pharmaceutical manufacturers. The form shall be designed to minimize the administrative burden and cost of reporting on the office and pharmaceutical manufacturers.

(e) The office may impose a penalty of not more than seven thousand five hundred dollars on a pharmaceutical manufacturer or sponsor for each violation of this section by the pharmaceutical manufacturer or sponsor.

(f) The office may adopt regulations, in accordance with the provisions of chapter 54 of the general statutes, to carry out the purposes of this section.

Sec. 11. Subsection (a) of section 38a-477d of the 2018 supplement to the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2020*):

(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 a health insurance policy providing coverage of the type specified in subdivisions (1), (2), (4), (11) and (12) of section 38a-469 in this state, shall:

(1) Make available to consumers, in an easily readable, accessible and understandable format, the following information for each such policy: (A) Any coverage exclusions; (B) any restrictions on the use or quantity of a covered benefit, including on prescription drugs or drugs administered in a physician's office or a clinic; (C) a specific description of how prescription drugs are included or excluded from any applicable deductible, including a description of other out-of-pocket expenses that apply to such drugs; **[**and**]** (D) the specific dollar amount of any copayment and the percentage of any coinsurance imposed on each covered benefit, including each covered prescription drug; and (E) information regarding any process available to consumers, and all documents necessary, to seek coverage of a noncovered outpatient prescription drug;

(2) Make available to consumers a way to determine accurately (A) whether a specific prescription drug is available under such policy's drug formulary; (B) the coinsurance, copayment, deductible or other out-of-pocket expense applicable to such drug; (C) whether such drug is covered when dispensed by a physician or a clinic; (D) whether such drug requires prior authorization or the use of step therapy; (E) whether specific types of health care specialists are in-network; and (F) whether a specific health care provider or hospital is in-network."

This act shall take effect as follows and shall amend the following sections:		
Section 1	*January 1, 2020*	New section
Sec. 2	*January 1, 2020*	New section
Sec. 3	*January 1, 2020*	New section
Sec. 4	*January 1, 2020*	New section
Sec. 5	*January 1, 2020*	New section
Sec. 6	*January 1, 2020*	New section
Sec. 7	*January 1, 2020*	38a-183
Sec. 8	*January 1, 2020*	38a-481(a)
Sec. 9	*January 1, 2020*	38a-513(a)(2)
Sec. 10	*January 1, 2020*	New section
Sec. 11	*January 1, 2020*	38a-477d(a)