House of Representatives

General Assembly

File No. 317

February Session, 2018

Substitute House Bill No. 5384

House of Representatives, April 9, 2018

The Committee on Insurance and Real Estate reported through REP. SCANLON of the 98th Dist., Chairperson of the Committee on the part of the House, that the substitute bill ought to pass.

AN ACT CONCERNING PRESCRIPTION DRUG COSTS.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. Section 38a-479aaa of the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2019*):

As used in this section and sections 38a-479bbb to 38a-479iii, inclusive, and sections 2 and 3 of this act:

(1) "Commissioner" means the Insurance Commissioner;

(2) "Department" means the Insurance Department;

(3) "Drug" means drug, as defined in section 21a-92;

(4) "Person" means person, as defined in section 38a-1;

(5) "Pharmacist services" includes (A) drug therapy and other patient care services provided by a licensed pharmacist intended to

achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, and (B) education or intervention by a licensed pharmacist intended to arrest or slow a disease process;

(6) "Pharmacist" means an individual licensed to practice pharmacy under section 20-590, 20-591, 20-592 or 20-593, and who is thereby recognized as a health care provider by the state of Connecticut;

(7) "Pharmacy" means a place of business where drugs may be sold at retail and for which a pharmacy license has been issued to an applicant pursuant to section 20-594; and

(8) "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 benefit plan on behalf of plan sponsors such as self-insured employers, insurance companies, labor unions and health care centers.

Sec. 2. (NEW) (*Effective January 1, 2019*) (a) As used in this section:

(1) "Health benefit plan" means a health benefit plan, as defined in section 38a-591a of the general statutes, that includes a pharmacy benefit;

(2) "Health carrier" means a health carrier, as defined in section 38a-591a of the general statutes; and

(3) "Rebate" means a discount or concession, including a volume-based discount or concession, which affects the price of a prescription drug, and is provided by a pharmaceutical manufacturer, directly or indirectly, to a pharmacy benefits manager after the pharmacy benefits manager processes a claim from a pharmacy for a prescription drug manufactured by such pharmaceutical manufacturer.

(b) Not later than March 1, 2019, and annually thereafter, each pharmacy benefits manager shall file a report with the Office of Health

Strategy, established pursuant to section 19a-754a of the general statutes, as amended by this act, for the immediately preceding calendar year. The report shall contain the following information for each health benefit plan that included a pharmacy benefit managed by the pharmacy benefits manager during such calendar year:

(1) The total dollar amount of all rebates that such pharmacy benefits manager received from pharmaceutical manufacturers that manufactured drugs covered by such health benefit plan during such calendar year;

(2) The total dollar amount of all rebates that such pharmacy benefits manager received from pharmaceutical manufacturers that manufactured drugs covered by such health benefit plan during such calendar year, excluding any portion of such rebates received by the health carrier that delivered, issued for delivery, renewed, amended or continued such plan; and

(3) The total dollar amount of all administrative fees that such pharmacy benefits manager received during such calendar year from the health carrier that delivered, issued for delivery, renewed, amended or continued such health benefit plan.

(c) 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, 2019*) (a) Each pharmacy benefits manager shall, for each health benefit plan that includes a pharmacy benefit managed by such pharmacy benefits manager, publish on such pharmacy benefits manager's Internet web site (1) such health benefit plan's drug formulary, and (2) timely notice regarding any (A) change to such formulary, or (B) exclusion from such formulary.

(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, 2019*) (a) Each insurer, health care center, hospital service corporation, medical service corporation or fraternal benefit society that delivers, issues for delivery, renews, amends or continues an individual or group health insurance policy in this state on or after January 1, 2019, providing coverage of the type specified in subdivisions (1), (2), (4), (11) and (12) of section 38a-469 of the general statutes shall, on or before May 1, 2019, and annually thereafter, submit a report to the Insurance Commissioner containing statistical information for the immediately preceding calendar year, including, but not limited to, information concerning:

(1) Decisions on requests for coverage of noncovered benefits; and

(2) Prior authorizations, including, but not limited to, (A) the ratio of prior authorizations denied to prior authorizations requested, (B) for each level of review, the ratio of prior authorization appeals denied to prior authorization appeals conducted, and (C) the maximum, minimum and average number of hours that passed between submission of a request for prior authorization and entry of a decision regarding such request, including any internal or external appeals from such decision.

(b) Each report submitted pursuant to subsection (a) of this section shall be in a format that permits the Insurance Commissioner to make a comparison between health insurance policies.

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

Sec. 5. (NEW) (*Effective January 1, 2019*) (a) For the purposes of this section:

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

(2) "Health benefit plan" means a health benefit plan, as defined in section 38a-591a of the general statutes, that includes prescription drug

coverage;

(3) "Health carrier" has the same meaning as provided in section 38a-591a of the general statutes;

(4) "Rebate" means any direct or indirect rebate, discount or other price concession that the state or a health carrier receives, or expects to receive, from a pharmaceutical manufacturer related to use of a prescription drug manufactured by such pharmaceutical manufacturer;

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

(6) "Wholesale acquisition cost" has the same meaning as provided in 42 USC 1395w-3a.

(b) (1) Not later than March 1, 2019, and annually thereafter, a health carrier may submit a written complaint to the Insurance Commissioner, in a form and manner prescribed by the commissioner, regarding a prescription drug if:

(A) The health carrier delivered, issued for delivery, renewed, amended or continued a health benefit plan in this state during the immediately preceding calendar year;

(B) The health carrier included the prescription drug in the health benefit plan's drug formulary;

(C) The wholesale acquisition cost of the prescription drug increased by at least twenty-five per cent during the immediately preceding calendar year; and

(D) The health carrier determines, through an actuarial analysis

performed by an independent third-party actuary (i) that the increase in the wholesale acquisition cost of the prescription drug, less all rebates paid to the health carrier during the immediately preceding calendar year for such prescription drug and controlling for all other changes in expenses and costs incurred under the terms of the health benefit plan, caused the premium of such health benefit plan to increase by at least one dollar per member, per month, (ii) the dollar amount of such increase, and (iii) the dollar amount of such increase attributable to increased utilization of such prescription drug.

(2) Each health carrier that submits a complaint to the commissioner pursuant to subdivision (1) of this subsection shall simultaneously submit a copy of such complaint to the pharmaceutical manufacturer that manufactured the prescription drug that is the subject of such complaint.

(c) Not later than thirty days after a pharmaceutical manufacturer receives a complaint submitted pursuant to subsection (b) of this section, the pharmaceutical manufacturer shall submit to the Insurance Commissioner, in a form and manner prescribed by the commissioner, a written response to the complaint. The response shall include information regarding (1) all rebates that the pharmaceutical manufacturer paid, directly or indirectly, to the health carrier during the year for the prescription drug that is the subject of such complaint, and (2) utilization of the prescription drug that is the subject of the complaint under the relevant health benefit plan.

(d) (1) The Insurance Commissioner shall (A) review each complaint and response submitted pursuant to subsections (b) and (c) of this section, and (B) determine whether the increase in the cost of the prescription drug caused the premium of the health benefit plan to increase by at least one dollar per member, per month.

(2) If the commissioner determines, pursuant to subdivision (1) of this subsection, that the increase in the cost of the prescription drug caused the premium of the health benefit plan to increase by at least one dollar per member, per month, the commissioner shall (A) certify

such determination, and (B) issue written notice of such determination, in a form and manner prescribed by the commissioner, to the health carrier and the pharmaceutical manufacturer.

(e) If the wholesale acquisition cost of a prescription drug increases by at least twenty-five per cent during the immediately preceding calendar year, the pharmaceutical manufacturer that manufactured such drug shall submit to the Insurance Commissioner, in a form and manner prescribed by the commissioner, (1) aggregate, company-level research and development costs and such other capital expenditures that the commissioner, in the commissioner's discretion, deems relevant for the most recent year for which final audited data are available, and (2) a written, narrative description, suitable for public release, of all factors that contributed to the increase in the cost of such drug.

(f) The quality and types of information and data that a pharmaceutical manufacturer submits to the Insurance Commissioner pursuant to this section shall be consistent with the quality and types of information and data that the pharmaceutical manufacturer includes in (1) such pharmaceutical manufacturer's annual consolidated report on Securities and Exchange Commission Form 10-K, or (2) any other public disclosure.

(g) The Insurance Commissioner shall consult with pharmaceutical manufacturers to establish a single standardized form for reporting information and data pursuant to this section. The form shall minimize the administrative burden and cost imposed by this section on the state and pharmaceutical manufacturers.

(h) Except as otherwise provided in subsection (e) of this section, information and data submitted to the Insurance Commissioner pursuant to this section shall not be available for public inspection, and the commissioner shall withhold such information and data from public disclosure under the Freedom of Information Act, as defined in section 1-200 of the general statutes. The commissioner shall not disclose such information and data in a manner that would enable a

third party to identify an individual drug, therapeutic class of drugs or pharmaceutical manufacturer, or that is likely to compromise the financial, competitive or proprietary nature of such information and data.

Sec. 6. Section 19a-754a of the 2018 supplement to the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2019*):

(a) For the purposes of this section:

(1) "Abbreviated new drug application" has the same meaning as provided in Section 314.3 of Title 21 of the Code of Federal Regulations.

(2) "Accelerated approval" has the same meaning as provided in 21 USC 356.

(3) "Biologics license application" means an application filed pursuant to Section 601.2 of Title 21 of the Code of Federal Regulations.

(4) "Breakthrough therapy" has the same meaning as provided in 21 USC 356.

(5) "Drug" has the same meaning as provided in section 21a-92.

(6) "Exchange" means the Connecticut Health Insurance Exchange established pursuant to section 38a-1081.

(7) "Fast track product" has the same meaning as provided in 21 USC 356.

(8) "Health benefit plan" means a health benefit plan, as defined in section 38a-591a, that includes prescription drug coverage.

(9) "Health carrier" has the same meaning as provided in section 38a-591a.

(10) "New drug application" has the same meaning as provided in Section 314.3 of Title 21 of the Code of Federal Regulations.

(11) "New molecular entity" has the same meaning as such term is used in 21 USC 355-1.

(12) "Office" means the Office of Health Strategy established in subsection (b) of this section.

(13) "Orphan drug" has the same meaning as provided in Section 316.3 of Title 21 of the Code of Federal Regulations.

(14) (A) "Payer" means (i) each department, agency and institution supported, in whole or in part, by the state that provides prescription drugs at state expense, (ii) a health carrier, (iii) an insurer, as described in section 38a-1, or health care center, as defined in section 38a-175, that provides coverage under Part C or Part D of Title XVIII of the Social Security Act, as amended from time to time, to residents of this state, (iv) a third-party administrator, as defined in section 38a-720, (v) a pharmacy benefits manager, as defined in section 38a-479aaa, as amended by this act, (vi) a nonprofit medical service corporation, as defined in section 38a-214, (vii) a dental plan organization, as defined in section 38a-577, (viii) a preferred provider network, as defined in section 38a-479aa, and (ix) any other person who administers health care claims and payments pursuant to a contract or agreement or is required by statute to administer such claims and payments.

(B) "Payer" does not include an employee welfare benefit plan, as defined in the federal Employee Retirement Income Security Act of 1974, as amended from time to time, that is also a trust established pursuant to collective bargaining subject to the federal Labor Management Relations Act.

(15) "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.

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

(17) "Priority review" has the same meaning as such term is used in 21 USC 356.

(18) "Rebate" means a rebate, discount or other price concession that the state or a health carrier receives or expects to receive, directly or indirectly, from a pharmaceutical manufacturer relating to the use of a prescription drug manufactured by the pharmaceutical manufacturer.

(19) "Research and development cost" means any cost that a pharmaceutical manufacturer incurs during a calendar year in researching and developing a new product, process or service, including, but not limited to, any 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.

(20) "Sponsor" has the same meaning as provided in Section 316.3 of Title 21 of the Code of Federal Regulations.

(21) "Wholesale acquisition cost" has the same meaning as provided in 42 USC 1395w-3a.

[(a)**]** (b) There is established an Office of Health Strategy, which shall be within the Department of Public Health for administrative purposes only. The department head of said office shall be the executive director of the **[**Office of Health Strategy**]** office, who shall be appointed by the Governor in accordance with the provisions of sections 4-5 to 4-8, inclusive, with the powers and duties therein prescribed.

[(b)**]** (c) On or before July 1, 2018, the **[**Office of Health Strategy**]** office shall be responsible for the following:

(1) Developing and implementing a comprehensive and cohesive health care vision for the state, including, but not limited to, a

coordinated state health care cost containment strategy;

(2) Directing and overseeing (A) the all-payers claims database program established pursuant to section 19a-755a, and (B) the State Innovation Model Initiative and related successor initiatives;

(3) Coordinating the state's health information technology initiatives;

(4) Directing and overseeing the Office of Health Care Access and all of its duties and responsibilities as set forth in chapter 368z; and

(5) Convening forums and meetings with state government and external stakeholders, including, but not limited to, the **[**Connecticut Health Insurance Exchange**]** exchange, to discuss health care issues designed to develop effective health care cost and quality strategies.

(d) Beginning on January 1, 2019, each sponsor shall submit to the office, in a form and manner specified by the office, written notice informing the office that the 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's receipt of an action date from the federal Food and Drug Administration regarding such application;

(2) An abbreviated new drug application for a generic drug not later than sixty days after such sponsor filed such application; or

(3) 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.

(e) (1) Beginning on January 1, 2019, the office may conduct a study, not more frequently than once annually, of each pharmaceutical manufacturer of a pipeline drug that, in the opinion of the executive director of the office, may have a significant impact on state

expenditures for drugs. The office may 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 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.

(f) (1) On or before March 1, 2019, and annually thereafter, the office, in consultation with the Comptroller, Commissioner of Social Services, Insurance Commissioner and Commissioner of Public Health, shall prepare a list of not more than ten prescription drugs that the executive director of the office, 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 prescription drugs from different therapeutic classes of drugs and at least one generic prescription drug. The office shall not list any prescription drug under this subdivision unless the

wholesale acquisition cost of the prescription drug, less all rebates paid to the state for such prescription drug during the immediately preceding calendar year, increased by at least twenty-five per cent during the immediately preceding calendar year.

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

(3) The office shall consult with pharmaceutical manufacturers to establish a single standardized form for reporting information and data pursuant to this subsection. The form shall minimize the administrative burden and cost imposed by this subsection on the state and pharmaceutical manufacturers.

(g) Not later than May 1, 2019, and annually thereafter, the office shall post the information the office receives pursuant to subsection (b) of section 2 of this act on the office's Internet web site.

(h) Not later than June 1, 2019, and annually thereafter, the office shall publish a report that includes the following information:

(1) All information that the office received pursuant to subsections (e) and (f) of this section;

(2) Any information that the office has collected from any commissioner, officer or agency of the state concerning the cost of prescription drugs, including, but not limited to, information concerning the historical cost of prescription drugs in this state, any legal action against pharmaceutical manufacturers implicating the cost of prescription drugs, and the marketing budgets of pharmaceutical manufacturers; and

(3) Any other publicly available information that the executive director of the office, in the executive director's discretion, deems relevant to the cost of prescription drugs in this state.

(i) Except as otherwise provided in this section, information and data submitted to the office pursuant to this section shall not be available for public inspection, and the office shall withhold such information and data from public disclosure under the Freedom of Information Act, as defined in section 1-200. The office shall not disclose such information and data in a manner (1) that is likely to compromise the financial, competitive or proprietary nature of information and data, or (2) would enable a third party to identify a pharmaceutical manufacturer, health carrier, health benefit plan, an individual drug, therapeutic class of drugs, the prices charged for any particular drug or therapeutic class of drugs, or the value of any rebate provided for any particular drug or therapeutic class of drugs.

[(c)**]** (j) The **[**Office of Health Strategy**]** office shall constitute a successor, in accordance with the provisions of sections 4-38d, 4-38e and 4-39, to the functions, powers and duties of the following:

(1) The **[**Connecticut Health Insurance Exchange, established pursuant to section 38a-1081,**]** exchange relating to the administration of the all-payer claims database pursuant to section 19a-755a; and

(2) The Office of the Lieutenant Governor, relating to the (A)

development of a chronic disease plan pursuant to section 19a-6q, (B) housing, chairing and staffing of the Health Care Cabinet pursuant to section 19a-725, and (C) (i) appointment of the health information technology officer pursuant to section 19a-755, and (ii) oversight of the duties of such health information technology officer as set forth in sections 17b-59, 17b-59a and 17b-59f.

[(d)**]** (k) Any order or regulation of the entities listed in subdivisions (1) and (2) of subsection **[**(c)**]** (j) of this section that is in force on July 1, 2018, shall continue in force and effect as an order or regulation until amended, repealed or superseded pursuant to law.

(l) The Commissioner of Public Health may impose a penalty of not more than fifteen thousand dollars for a violation of this section.

(m) The Commissioner of Public Health may adopt regulations, in accordance with the provisions of chapter 54, to implement the provisions of this section.

Sec. 7. 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, 2019*):

(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 health care service on the grounds that such service is medically necessary;

(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.

Sec. 8. Section 38a-478j of the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2019*):

(a) Each managed care plan that requires a percentage coinsurance payment by the insured shall calculate the insured's coinsurance payment on the lesser of the provider's or vendor's charges for the goods or services or the amount payable by the managed care organization for such goods or services, except as otherwise required by the laws of a foreign state when applicable to providers, vendors or patients in such foreign state.

(b) (1) For the purposes of this subsection, "rebate" means (A) any price concession received by a managed care organization regarding use of a prescription drug, and (B) any fee or other administrative cost that reduces a managed care organization's prescription drug costs.

(2) Beginning on March 1, 2019, and annually thereafter, each managed care organization shall submit to the commissioner, in a form and manner prescribed by the commissioner, a certification that (A) during the immediately preceding calendar year, the managed care organization made available to each enrollee that purchased a covered

prescription drug, at the time that such enrollee purchased the covered prescription drug, the majority of any rebate for such covered prescription drug, and (B) the managed care organization accounted for all rebates in calculating the premium for each managed care plan issued by such managed care organization.

(3) Except as set forth in subdivision (2) of this subsection, neither the commissioner nor any managed care organization that submits a certification to the commissioner pursuant to subdivision (2) of this subsection shall publish or otherwise reveal any information regarding the value of any rebate received by such managed care organization. The commissioner shall withhold such information from public disclosure under the Freedom of Information Act, as defined in section 1-200.

(4) Each managed care organization that receives a rebate shall require that each party to a contract delivered, issued for delivery, renewed, amended or continued by such managed care organization on or after January 1, 2019, not publish or otherwise reveal any information regarding the value of any rebate received by such managed care organization.

Sec. 9. Section 38a-479bbb of the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2019*):

(a) **[**Except as provided in subsection (d) of this section, no**]** No person shall act as a pharmacy benefits manager in this state without first obtaining a certificate of registration from the commissioner.

(b) Any person seeking a certificate of registration shall apply to the commissioner, in writing, on a form provided by the commissioner. The application form shall state (1) the name, address, official position and professional qualifications of each individual responsible for the conduct of the affairs of the pharmacy benefits manager, including all members of the board of directors, board of trustees, executive committee, other governing board or committee, the principal officers in the case of a corporation, the partners or members in the case of a

partnership or association and any other person who exercises control or influence over the affairs of the pharmacy benefits manager, and (2) the name and address of the applicant's agent for service of process in this state.

(c) Each application for a certificate of registration shall be accompanied by (1) a nonrefundable fee of fifty dollars, and (2) evidence of a surety bond in an amount equivalent to ten per cent of one month of claims in this state over a twelve-month average, except that such bond shall not be less than twenty-five thousand dollars or more than one million dollars.

[(d) Any pharmacy benefits manager operating as a line of business or affiliate of a health insurer, health care center, hospital service corporation, medical service corporation or fraternal benefit society licensed in this state or any affiliate of such health insurer, health care center, hospital service corporation, medical service corporation or fraternal benefit society shall not be required to obtain a certificate of registration. Such health insurer, health care center, hospital service corporation, medical service corporation or fraternal benefit society shall notify the commissioner annually, in writing, on a form provided by the commissioner, that it is affiliated with or operating a business as a pharmacy benefits manager.**]**

This act shall take effect as follows and shall amend the following sections:		
Section 1	*January 1, 2019*	38a-479aaa
Sec. 2	*January 1, 2019*	New section
Sec. 3	*January 1, 2019*	New section
Sec. 4	*January 1, 2019*	New section
Sec. 5	*January 1, 2019*	New section
Sec. 6	*January 1, 2019*	19a-754a
Sec. 7	*January 1, 2019*	38a-477d(a)
Sec. 8	*January 1, 2019*	38a-478j
Sec. 9	*January 1, 2019*	38a-479bbb

Statement of Legislative Commissioners:
Section 2(a)(3) was rewritten for clarity; in Section 4(b), "the Insurance Commissioner to make a" was inserted for clarity; in Section 5(b)(1), "Beginning on" was changed to "Not later than" for clarity; and in Section 5(e) "an amount that is not less than the amount specified in subparagraph (C) of subdivision (1) of subsection (b) of this section" was changed to "at least twenty-five per cent during the immediately preceding calendar year" for conciseness.

INS *Joint Favorable Subst.*

The following Fiscal Impact Statement and Bill Analysis are prepared for the benefit of the members of the General Assembly, solely for purposes of information, summarization and explanation and do not represent the intent of the General Assembly or either chamber thereof for any purpose. In general, fiscal impacts are based upon a variety of informational sources, including the analyst's professional knowledge. Whenever applicable, agency data is consulted as part of the analysis, however final products do not necessarily reflect an assessment from any specific department.

OFA Fiscal Note

State Impact:

Agency Affected	Fund-Effect	FY 19 $	FY 20 $
Insurance Dept.	IF - Cost	approx. 100,000	None
Insurance Dept.	IF - Potential Cost	None	approx. 160,000
Office of Health Strategy	GF - Cost	approx. 35,000	approx. 70,000
State Comptroller - Fringe Benefits[1]	GF - Cost	approx. 13,000	approx. 25,000
Resources of the GF	GF - Potential Revenue Gain	Minimal	Minimal

Note: IF=Insurance Fund; GF=General Fund

Municipal Impact:

Municipalities	Effect	FY 19 $	FY 20 $
Various Municipalities	Potential Cost	See Below	See Below

Explanation

The bill establishes new requirements for state agencies and various entities that impact the prices of prescription drugs, resulting in the fiscal impact described below.

Section 1 provides definitions and has no fiscal impact.

Sections 2 and 3 allow the Insurance Commissioner to adopt

[1]The fringe benefit costs for most state employees are budgeted centrally in accounts administered by the Comptroller. The estimated active employee fringe benefit cost associated with most personnel changes is 36.33% of payroll in FY 19 and FY 20.

regulations concerning reporting and web site posting requirements for PBMs and are not anticipated to have a fiscal impact as the Insurance Department has personnel for regulation development.

Section 4 requires certain health carriers to submit information on requests for coverage of non-covered benefits and prior authorizations to the Insurance Department in the form of an annual report beginning on or before 5/1/19 and has no fiscal impact as the Department already collects this information from such parties to prepare the Consumer Report Card on Health Insurance Carriers in Connecticut.

Section 5 creates a health carrier complaint review process and expands Insurance Department requirements as described in the bill. The Department does not currently oversee pharmaceutical manufacturers or have expertise in this area, therefore it is anticipated that they will need to hire consultants, an actuary and an analyst, to set up these programs at a cost to the Insurance Fund of approximately $100,000 in FY 19. To the extent that such expertise and additional personnel are required on an ongoing basis to assist with complaint reviews, there is a potential cost of approximately $160,000 to the Insurance Fund in FY 20 to support the salary and fringe benefit costs of a pharmacy manufacturing analyst.

Section 6 is anticipated to result in a state cost of approximately $50,000 in FY 19 and $100,000 in FY 20, and a potential minimal revenue gain to the General Fund annually. The state cost reflects: (1) approximately $35,000 in FY 19 (half-year) and $70,000 in FY 20 to support a Research Analyst in the Office of Health Strategy to fulfill requirements in this section, and (2) approximately $13,000 in FY 19 and $25,000 in FY 20 for fringe benefits. There is a potential minimal revenue gain to the General Fund from the establishment of a penalty for sponsors/pharmaceutical manufacturers of no more than $15,000 per violation of the section.

Section 7 makes changes to the information certain health carriers must provide to consumers and has no fiscal impact.

Section 8 does not result in a fiscal impact to the state employee and retiree health plan as the state plan currently complies with the rebate pass through requirements. Section 8 may result in an impact to fully-insured municipal plans to the extent rebates are not currently passed through to the consumers at the point of sale or in premiums. The impact will be reflected in fully insured premiums for policies issued on or after January 1, 2019. Due to federal law, this provision does not impact self-insured municipalities.

Section 9 results in a potential minimal revenue gain to the extent that additional PBMs register with the Commissioner and pay the $50 registration fee and any applicable renewal fees.

The Out Years

The annualized ongoing fiscal impact identified above would continue into the future subject to increases in the costs identified above.

Sources: Connecticut Insurance Department

OLR Bill Analysis

sHB 5384

AN ACT CONCERNING PRESCRIPTION DRUG COSTS.

SUMMARY

This bill makes several changes related to prescription drugs, pharmacy benefit managers (PBMs), and managed care organizations. Among other things, it:

1. requires all PBMs operating in Connecticut to register with the insurance commissioner and submit to the Office of Health Strategy (OHS) annual financial reports that include information on prescription drug rebates and administrative fees;

2. establishes a process for health carriers to submit complaints to the insurance commissioner when the cost of a prescription drug increases by 25% or more and the increase raises a plan's per member per month (PMPM) premium by over $1;

3. requires the commissioner to investigate the complaints and drug manufacturers to report specified information to her;

4. requires a prescription drug "sponsor" (i.e., the entity responsible for its clinical trials) to notify OHS when it files certain applications for new drugs;

5. requires (a) OHS to annually identify up to 10 prescription drugs provided at substantial state cost or critical to public health and (b) drug manufacturers to report information on those drugs; and

6. requires managed care organizations to certify to the insurance commissioner that they pass the majority of a prescription drug rebate on to the consumer.

It also makes minor, technical, and conforming changes.

EFFECTIVE DATE: January 1, 2019

§§ 2, 3, 6 & 9 — PHARMACY BENEFIT MANAGERS

Registration (§ 9)

The bill requires all PBMs operating in the state to register with the insurance commissioner. It does so by removing the registration exemption for PBMs operating as a line of business or affiliate of a Connecticut insurer, HMO, hospital or medical service corporation, or fraternal benefit society. By law, to register a PBM must complete an application, pay a $50 fee, and provide evidence of a surety bond.

Annual Reports (§§ 2 & 6)

The bill requires PBMs, annually by March 1, to report certain financial information to OHS for the previous calendar year. The report must contain, for each health benefit plan for which the PBM managed pharmacy benefits, the total amount of all:

1. rebates the PBM received during the year from pharmaceutical manufacturers of covered drugs;

2. rebates the PBM received during the year from pharmaceutical manufacturers of covered drugs, excluding any portion of rebates received by the health carrier; and

3. administrative fees the PBM received during the year from the health carrier.

OHS must post this information on its website by May 1 annually.

Formulary (§ 3)

The bill also requires each PBM, for each health benefit plan it manages, to post on its website its formulary and timely notice of any formulary change or exclusion. A formulary is a list of covered prescription drugs.

Regulations (§§ 2 & 3)

The bill authorizes the commissioner to adopt implementing regulations.

§ 4 — HEALTH CARRIERS

The bill requires certain health carriers to report to the insurance commissioner, annually by May 1, statistical information for the previous calendar year, including decisions on requests for coverage of noncovered benefits and prior authorizations, in a format that allows her to compare policies. For prior authorizations, the reported information must include:

1. the ratio of prior authorizations denied to the total requested;

2. for each level of review, the ratio of prior authorization appeals denied to those conducted; and

3. the maximum, minimum, and average number of hours between when a prior authorization was requested and a decision was reached, including any internal or external appeals of the decision.

The provision applies to each insurer, HMO, hospital or medical service corporation, or fraternal benefit society that delivers, issues, renews, amends, or continues in Connecticut individual or group health insurance policies that cover (1) basic hospital expenses; (2) basic medical-surgical expenses; (3) major medical expenses; or (4) hospital or medical services, including those provided under an HMO plan.

The bill authorizes the commissioner to adopt implementing regulations.

§ 5 — PRESCRIPTION DRUG COSTS

Complaint Process

By March 1, 2019, and annually thereafter, the bill allows a health carrier to submit a written complaint to the insurance commissioner about a prescription drug, in a form and manner she prescribes, if:

1. the health carrier delivered, issued, renewed, amended, or continued a health benefit plan in Connecticut during the previous year that covered the prescription drug in its formulary;

2. the wholesale acquisition cost of the drug increased by 25% or more over the prior year; and

3. the health carrier determines (a) the increased cost of the drug caused the plan's premium to increase by at least $1 PMPM, (b) the amount of such an increase, and (c) how much of it is attributable to increased use of the drug.

In determining the impact on premiums, the health carrier must use an actuarial analysis performed by an independent third-party actuary that (1) takes into account any rebates for the drug paid to the carrier during the preceding year, and (2) controls for all other changes in plan expenses and costs.

Under the bill, the "wholesale acquisition cost" is a drug's list price to wholesalers or direct purchasers in the United States, as reported in a wholesale price guide or publication and for the most recent month in which data is available, excluding any prompt pay, rebates, price reductions, or other discounts. This definition conforms to federal law.

Each carrier that submits a complaint to the commissioner must simultaneously submit a copy to the drug manufacturer. The manufacturer must, within 30 days of receiving a complaint, submit a written response to the commissioner in a form and manner she prescribes. The response must include information about (1) all rebates the manufacturer paid, directly or indirectly, to the health carrier for the drug during the year and (2) utilization of the prescription drug.

Under the bill, the commissioner must review each complaint and drug manufacturer's response to determine if the increase in prescription drug costs caused the plan premium to increase by at least $1 PMPM.

If the commissioner determines the prescription drug's cost increase caused the plan premium to increase above the $1 PMPM threshold, she must (1) certify her determination and (2) issue a written notice to the health carrier and manufacturer in a form and manner she prescribes.

Required Manufacturer Reporting

If a prescription drug's wholesale acquisition cost increases by 25% or more over the prior year, the manufacturer must submit to the commissioner, in a form and manner she prescribes:

1. for the most recent year for which final audited data are available, aggregate company-level research and development costs and any other capital expenditures that she deems relevant and

2. a written, narrative description of all factors that contributed to the drug's cost increase, suitable for public release.

The bill specifies that the quality and types of information and data that a manufacturer submits must be consistent with the quality and types of information submitted in the manufacturer's annual consolidated report (i.e., Security and Exchange Commission Form 10-K) or any other public disclosure.

Under the bill, the insurance commissioner must consult with pharmaceutical manufacturers to establish a single, standardized form for reporting the required information to minimize the administrative burden and cost to the state and manufacturers.

Confidentiality. Except as otherwise provided, the bill makes any information submitted to the commissioner under these provisions confidential, not available for public inspection, and requires the commissioner to withhold such information from disclosure under the Freedom of Information Act (FOIA). The commissioner is also prohibited from disclosing the information in a way that enables a third party to identify an individual drug, therapeutic class of drugs,

or drug manufacturer, or in a way that is likely to compromise the information's financial, competitive, or proprietary nature.

§ 6(d) — DRUG AND BIOLOGIC APPLICATION REPORTING

Beginning January 1, 2019, the bill requires a sponsor to submit to OHS, in a form and manner it specifies, written notice when it files with the U.S. Food and Drug Administration (FDA):

1. an application for a new drug or biologics license for a pipeline drug, within 60 days after receiving an action date from the FDA;

2. an abbreviated new drug application for a generic drug, within 60 days after filing the application; or

3. a biologics license application for a biosimilar drug, within 60 days of receiving an action date from the FDA.

Definitions

Under the bill, a "sponsor" is any entity responsible for a clinical or nonclinical drug investigation, including for legal compliance. A "biologics license application" is an application to use a biologic filed in accordance with federal regulations. (Generally, a biologic is a drug manufactured from living organisms.) A "pipeline drug" is a drug that contains a new molecular entity for which the sponsor has filed an application with, and received an action date from, the FDA. An "abbreviated new drug application" is an application for a generic drug made from a currently licensed drug.

§ 6(e) — STATE IMPACT STUDY

Beginning January 1, 2019, the bill allows OHS to study, no more often than annually, each pharmaceutical manufacturer of a pipeline drug that, in the executive director's opinion, may have a significant impact on state drug expenditures. OHS may contract with a third party, including an accounting firm, to conduct the study.

Each manufacturer being studied must submit to OHS or its

contractor, the following information as it pertains to the pipeline drug:

1. the primary disease, condition, or therapeutic area studied in connection with the drug and whether the drug is therapeutically indicated for it;

2. the administration route studied for the drug;

3. clinical trial comparators (generally, an existing drug currently used to treat the disease or condition against which the new drug's efficacy can be compared), if applicable;

4. estimated market entry year;

5. whether the FDA has designated it as an orphan drug, a fast track product, or a breakthrough therapy; and

6. whether the FDA has designated the drug for accelerated approval and, if it contains a new molecular entity, for priority reviews.

Definitions

Under the bill, an "orphan drug" is a drug intended to treat a rare disease or condition. A "fast track product" is a drug deemed by the U.S. health and human services (HHS) secretary to (1) treat a serious or life-threatening disease or condition and that addresses unmet medical needs for the disease or condition or (2) qualify as an infectious disease product. A "breakthrough therapy" is a drug deemed by the HHS secretary to treat a serious or life-threatening disease or condition for which preliminary clinical evidence indicates that it may demonstrate substantial improvement over existing therapies.

"Accelerated approval" is an expedited application process for a drug the HHS secretary determines is likely to predict clinical benefits or benefits that can be measured on a clinical endpoint prior to irreversible morbidity or mortality. "Priority review" is a designation assigned to applications for drugs that treat serious conditions and

provide significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions compared to available therapies.

§ 6(f) — DRUGS WITH SUBSTANTIAL COSTS TO THE STATE

The bill requires OHS, annually by March 1, to prepare a list of up to 10 prescription drugs that the executive director determines are (1) provided at substantial cost to the state, considering the drugs' net cost, or (2) critical to public health. The list must include prescription drugs from different therapeutic classes and at least one generic drug. But it cannot include a drug unless the wholesale acquisition cost, less all associated rebates paid to the state during the prior year, increased by 25% or more over the preceding year. The list must be established in consultation with the comptroller and the social services, insurance, and public health commissioners.

The pharmaceutical manufacturer of a prescription drug on the list must provide to OHS, in a form and manner it specifies:

1. for the most recent year for which final audited data are available, aggregate company-level research and development costs and such other capital expenditures that she deems relevant and

2. a written, narrative description of all factors that contributed to the drug's cost increase, suitable for public release.

The bill specifies that the quality and types of information and data that a manufacturer submits must be consistent with the quality and types of information submitted in the manufacturer's annual consolidated report (i.e., Security and Exchange Commission Form 10-K) or any other public disclosure.

The bill requires OHS to consult with pharmaceutical manufacturers to establish a single, standardized form for reporting the required information to minimize the administrative burden and cost to the state and manufacturers.

§ 6(h) — OHS REPORT

Annually by June 1, OHS must publish a report including:

1. information received from manufacturers under the bill's state impact and substantial state cost provisions;

2. any information OHS collected from any commissioner, officer, or state agency about the cost of prescription drugs, including (a) historical cost information, (b) legal action against pharmaceutical manufacturers implicating prescription drug costs, and (c) pharmaceutical manufacturers' marketing budgets; and

3. any other publicly available information that the OHS executive director deems relevant to the cost of prescription drugs in the state.

§ 6(i) — CONFIDENTIALITY

Except as otherwise provided, the bill makes any information submitted to OHS by a sponsor or drug manufacturer confidential. The information is not available for public inspection and OHS must withhold it from disclosure under FOIA. OHS is also prohibited from disclosing the information in a way that:

1. enables a third party to identify a drug manufacturer, health carrier, health benefit plan, individual drug, therapeutic class of drugs, or particular drug or drug class prices or rebates or

2. is likely to compromise the information's financial, competitive, or proprietary nature.

§ 6(l) & (m) — PENALTY AND REGULATIONS

The bill allows the public health commissioner to impose a penalty of up to $15,000 for a violation of the provisions relating to drug and biologic reporting, the state impact study, the substantial state cost list, and the OHS annual report provisions. (Presumably, the penalty only applies to sponsors and drug manufacturers required to report under

these provisions and not to OHS fulfilling its responsibilities.)

It also authorizes the public health commissioner to adopt implementing regulations.

§ 7 — ACCESSIBLE INSURANCE INFORMATION

By law, insurers, HMOs, hospital or medical service corporations, and fraternal benefit societies that deliver, issue, renew, amend, or continue specific health insurance policies in Connecticut must make certain benefit information available to consumers in an easily readable and understandable format. The bill requires the information to (1) also be accessible and (2) include information about any process available to consumers, and all documents necessary, to seek coverage of a health care service on medical necessity grounds.

These provisions apply to individual and group health insurance policies that cover (1) basic hospital expenses; (2) basic medical-surgical expenses; (3) major medical expenses; or (4) hospital or medical services, including those provided under an HMO plan.

§ 8 — MANAGED CARE ORGANIZATIONS

The bill requires each managed care organization to certify to the insurance commissioner by March 1, 2019 and annually thereafter, in a form and manner she prescribes, that the organization:

1. during the prior year, made available to an enrollee the majority of any associated rebate when he or she purchased a covered drug and

2. accounted for all rebates in calculating the premium for each plan it issued.

The bill prohibits the managed care organization and the commissioner from otherwise revealing the value of rebates and exempts such information from disclosures under FOIA. Under the bill, managed care organizations must prohibit each party to a contract it delivers, issues, renews, amends, or continues from publishing or

revealing the value of any rebate.

By law, a "managed care organization" is an insurer, HMO, or other entity that delivers, issues, renews, amends, or continues a managed care plan in the state.

BACKGROUND

Related Bill

sSB 384, favorably reported by the Insurance and Real Estate Committee, also requires health carriers to submit statistical information on benefit denials.

COMMITTEE ACTION

Insurance and Real Estate Committee

Joint Favorable Substitute
Yea 16 Nay 5 (03/20/2018)