



**PA 18-41**—sHB 5384

*Insurance and Real Estate Committee*

## **AN ACT CONCERNING PRESCRIPTION DRUG COSTS**

**SUMMARY:** This act makes several changes related to prescription drugs, pharmacy benefit managers (PBMs), and health carriers (e.g., insurers and HMOs). Among other things, it requires:

1. PBMs to report information about drug formulary rebates to the insurance commissioner, who must report aggregated data to the Insurance and Real Estate Committee;
2. health carriers to submit to the insurance commissioner, and the commissioner to report to the Insurance and Real Estate Committee, information on covered outpatient prescription drugs, including the most frequently prescribed drugs and those provided at the greatest cost;
3. health carriers to certify to the commissioner that they account for all rebates when calculating plan premiums and the commissioner to publicly release a report describing health carrier rebate practices; and
4. health carriers offering individual and small employer group health insurance plans and HMOs to include information on covered outpatient prescription drugs and account for all rebates when filing rates.

The act also requires:

1. entities responsible for prescription drug clinical trials (i.e., sponsors) to notify the Office of Health Strategy (OHS) when they file certain applications for new drugs and
2. OHS to annually identify up to 10 outpatient prescription drugs provided at substantial state cost or critical to public health and the manufacturers of identified drugs to report financial and related information to OHS.

The act also makes minor, technical, and conforming changes.

EFFECTIVE DATE: January 1, 2020

### **§ 2 — PHARMACY BENEFIT MANAGERS**

#### *PBM Reporting*

The act requires PBMs, beginning by March 1, 2021, to annually report certain rebate information to the insurance commissioner. Under the act, a “rebate” is a discount or concession impacting the price of an outpatient prescription drug that a manufacturer provides to a health carrier or PBM, excluding bona fide service fees.

A PBM must report specific rebate information pertaining to health carriers that delivered, issued, renewed, amended, or continued a health care plan that included a pharmacy benefit the PBM managed during the prior calendar year.

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The report must provide the aggregate amount of:

1. drug formulary rebates the PBM collected from pharmaceutical manufacturers of covered outpatient prescription drugs attributable to patient utilization and
2. all rebates, excluding any portion of rebates described above that were received by health carriers.

Under the act, the insurance commissioner must, after consulting with PBMs, establish a single, standardized form for reporting this information in a way that minimizes the administrative burden and cost to both PBMs and the Insurance Department.

### *Regulations and Penalty*

The act authorizes the commissioner to (1) adopt implementing regulations and (2) impose a penalty of up to \$7,500 on PBMs per violation of the reporting requirements.

### *Report to the Insurance and Real Estate Committee*

The commissioner must annually, beginning by March 1, 2022, report an aggregation of the information submitted by PBMs described above and any other information she deems relevant to the Insurance and Real Estate Committee. Beginning by February 1, 2022, the commissioner must annually provide each PBM and any third party impacted by the report's submission with a description of the report's contents.

### *Confidentiality*

The act exempts the rebate information submitted to the commissioner from disclosure under the Freedom of Information Act (FOIA), except to the extent it is aggregated and included in the commissioner's report described above. The act also prohibits the commissioner from disclosing the information in a way that:

1. enables a third party to identify a health care plan, health carrier, PBM, pharmaceutical manufacturer, or the value of a rebate provided for a particular outpatient prescription drug or therapeutic class of outpatient prescription drugs or
2. is likely to compromise the information's financial, competitive, or proprietary nature.

## §§ 3 & 5 — HEALTH CARRIERS' PRESCRIPTION DRUG REPORTING

### *Health Carrier Reporting (§ 3)*

The act requires each health carrier that delivers, issues, renews, amends, or continues a health care plan on or after January 1, 2021, to submit certain information about the plan to the insurance commissioner for the preceding calendar year. A carrier must submit the information when it submits the plan's rate filing. Under the act, the information a carrier must submit includes the following:

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1. for covered outpatient prescription drugs prescribed under the plan, the 25 (a) most frequently prescribed outpatient prescription drugs; (b) outpatient prescription drugs covered at the greatest annual cost, according to the plan's total annual outpatient drug spending; (c) outpatient prescription drugs with the greatest increase in annual cost compared to the prior year; and (d) most frequently prescribed outpatient drugs for which the health carrier received pharmaceutical manufacturer rebates;
2. the portion of the premium attributable to outpatient brand name, generic, and specialty drugs prescribed under the plan and the annual increase in the total annual cost of such drugs, calculated on a per member per month basis and expressed as a percentage;
3. a comparison, calculated on a per member per month basis, of the year-over-year increase in the cost of covered outpatient drugs to the year-over-year increase in the costs of other plan premium components; and
4. the names of each specialty drug covered during the year.

The act authorizes the commissioner to adopt implementing regulations.

### *Insurance Commissioner Report to Insurance and Real Estate Committee (§ 5)*

Beginning by March 1, 2022, the commissioner must annually submit a report to the Insurance and Real Estate Committee that (1) aggregates the information and data she received from the carriers for the prior year, (2) describes the impact of outpatient prescription drug costs on health insurance premiums in Connecticut, and (3) includes any other information she deems relevant to the cost of outpatient prescription drugs in Connecticut.

### §§ 4 & 6 — REBATES

#### *Health Carrier Certification (§ 4)*

The act requires health carriers, beginning March 1, 2022, to annually certify to the commissioner, in a form and manner she prescribes, that they accounted for all rebates when calculating premiums for plans delivered, issued, renewed, amended, or continued in the previous year.

#### *Insurance Commissioner Rebate Practices Reports (§ 6)*

Beginning by March 1, 2021, the commissioner must annually prepare a report describing health carrier rebate practices for the prior year. The report must contain (1) an explanation of how carriers accounted for rebates when calculating premiums, (2) a statement disclosing whether and how carriers made rebates available to insureds at the point of purchase, (3) any other way carriers applied rebates, and (4) any other information the commissioner deems relevant. The report must be published on the department's web site.

### §§ 7-9 — HMOS, INDIVIDUAL HEALTH INSURANCE PLANS, AND SMALL EMPLOYER GROUP HEALTH INSURANCE PLANS

The act requires HMOs, when submitting rate filings to the commissioner, to

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include the prescription drug information listed above in § 3 of the act (e.g., the 25 most frequently prescribed outpatient drugs). It similarly requires health carriers to include this information when filing individual and small employer group health insurance plans.

Additionally, the act requires HMOs and individual and small employer group health insurance carriers to account for all rebates when calculating premium rates offered on or after January 1, 2021.

The act also allows, rather than requires, the commissioner to adopt regulations establishing a procedure for reviewing individual policies.

### § 10(b) — DRUG AND BIOLOGIC APPLICATION REPORTING

Beginning January 1, 2020, the act 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 or
2. a biologics license application for a biosimilar drug, within 60 days of receiving an action date from the FDA.

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 one that contains a new molecular entity for which the sponsor has filed an application with, and received an action date from, the FDA.

### § 10(c) — STATE IMPACT STUDY

#### *Pipeline Drugs*

Beginning January 1, 2020, the act allows OHS’s executive director to study, with the comptroller’s assistance and no more often than annually, each pharmaceutical manufacturer of a pipeline drug that, in the executive director’s opinion and in consultation with the comptroller and social services commissioner, may have a significant impact on state outpatient prescription drug expenditures. OHS may work with the comptroller to use existing state resources or contracts, or 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 pertaining 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. each 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

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

### *Applicable Pipeline Drugs*

Under the act, 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 address 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*

“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 before 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.

### § 10(d) — DRUGS WITH SUBSTANTIAL COSTS TO THE STATE

Beginning by March 1, 2020, the act requires OHS’s executive director, in consultation with the comptroller and the social services and public health commissioners, to annually prepare a list of up to 10 outpatient 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 outpatient prescription drugs from different therapeutic classes and at least one generic outpatient prescription drug. However, it cannot include an outpatient prescription drug unless the wholesale acquisition cost, less all associated rebates paid to the state during the prior year, (1) increased by at least 20% over the prior year or 50% over the prior three years and (2) was at least \$60 for a 30-day supply or a course of treatment lasting under 30 days.

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

1. for the most recent year for which final audited data are available, aggregate company-level research and development costs and other capital expenditures that the OHS executive director deems relevant and
2. a written, narrative description of all factors that contributed to the drug’s cost increase, suitable for public release.

The act 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.

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The act requires OHS, after consulting with pharmaceutical manufacturers, to establish a single, standardized form for reporting the required information that minimizes the administrative burden and cost of reporting on OHS and manufacturers.

### §§ 10(e) & (f) — PENALTY AND REGULATIONS

The act allows OHS to impose a penalty of up to \$7,500 on a pharmaceutical manufacturer or sponsor for each violation of the provisions relating to drug and biologic reporting, the state impact study, and the substantial state cost list. It also authorizes OHS to adopt implementing regulations.

### § 11 — 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 act 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 noncovered outpatient prescription drug.

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.