OLR Bill Analysis

sHB 5384 (as amended by House "A")*

AN ACT CONCERNING PRESCRIPTION DRUG COSTS.

SUMMARY

This bill 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;

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

5. OHS to annually identify up to 10 outpatient prescription drugs provided at substantial state cost or critical to public health and drug manufacturers to report information to OHS on those drugs.

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

*House Amendment "A" replaces the underlying bill with similar provisions. In doing so, it, among other things, eliminates provisions

(1) allowing health carriers to submit complaints to the insurance commissioner when prescription drugs increase by 25% or more and the increase raises a plan's per member per month premium by over $1, (2) requiring all PBMs to register with the insurance commissioner, and (3) requiring health carriers to report certain prior authorization data.

EFFECTIVE DATE: January 1, 2020

§ 2 — PHARMACY BENEFIT MANAGERS

PBM Reporting

The bill requires PBMs, beginning by March 1, 2021, to annually report certain rebate information to the insurance commissioner. Under the bill, 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, but excludes bona fide service fees.

A PBM's report must contain, for health carriers that delivered, issued, renewed, amended, or continued a health care plan for which the PBM managed pharmacy benefits during the calendar year, 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.

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

Penalty and Regulations

The bill authorizes the commissioner to (1) adopt implementing regulations and (2) impose a penalty of up to $7,500 on PBMs per violation of these provisions.

Required 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 bill exempts information submitted to the commissioner under these provisions from disclosure under the Freedom of Information Act (FOIA), except to the extent it is included in the commissioner's report described above. The bill 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 bill 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. The carrier must submit the information when it submits the plan's rate filing, as applicable. Under the bill, the information a carrier must submit includes the following:

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 spending, and (c) outpatient prescription drugs with the greatest increase in annual cost compared to the prior year;

2. the portion of the premium attributable to outpatient brand name, generic, and specialty drugs prescribed under the plan and the year-over-year 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;

4. the names of each specialty drug covered during the year; and

5. the 25 most frequently prescribed outpatient drugs for which the health carrier received pharmaceutical manufacturer rebates.

The bill authorizes the commissioner to adopt implementing regulations.

Insurance Commissioner Report (§ 5)

Beginning by March 1, 2022, the commissioner must annually submit a report to the Insurance and Real Estate Committee containing (1) aggregate information and data submitted under these provisions from the prior year, (2) a description of the impact of outpatient prescription drug costs on health insurance premiums in Connecticut, and (3) any other information she deems relevant to the cost of outpatient prescription drugs in Connecticut.

§§ 4 & 6 — REBATES

Health Carrier Certification (§ 4)

The bill 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 Reports (§ 6)

The commissioner must annually, beginning by March 1, 2021, 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 bill requires HMOs, when submitting rate filings to the commissioner, to include in the filing the information listed above (see § 3). It similarly requires health carriers, when filing individual and small employer group health insurance plans to include in the filing the above information.

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

The bill 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 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 or

2. 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.

§ 10(c) — STATE IMPACT STUDY

Beginning January 1, 2020, the bill 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 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 review.

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 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 bill 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 under $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 such 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 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, 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 bill 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 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 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.

COMMITTEE ACTION

Insurance and Real Estate Committee

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