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)