



Center for State **Rx** Drug Pricing

AN ACT TO PROMOTE PRESCRIPTION DRUG PRICE TRANSPARENCY AND COST CONTROL

WHEREAS costs of prescription drugs are rising rapidly, year over year. In 2015, the average branded product increase was 15.5 percent. Spending on specialty drugs increased 21.5 percent from 2014 to 2015, contributing \$150.8 billion to total spending on medicines.ⁱ

WHEREAS, the cost of prescription drugs represents a significant challenge to the State budget for Medicaid, CHIP expenditures, state employee and retiree health insurance, corrections' health and the cost of coverage for the employees of public schools and institutions of public higher education for which the State shares in the cost; and

WHEREAS the cost of prescription drugs represent a 21 percent share of spending for employer sponsored insuranceⁱⁱ, creating a significant challenge to employers across the state who struggle to provide health insurance to employees and their dependents while maintaining a competitive and viable business concern; and

WHEREAS the cost of prescription drugs represents a significant and daily challenge to thousands of the State's residents who experience difficulty accessing affordable medications; and

WHEREAS the unpredictability of new, high cost drug launches and significant price increases for older drugs can strain the ability of state agencies, private payers and consumers to manage their budgets and access treatments;

WHEREAS the lack of transparency in drug price discounts obtained by prescription drug benefits managers and 340B hospitals [include only those entities sponsor decides to include in bill language] prevents policymakers and the public from gaining a true understanding of the cost of the prescription drugs purchased; and

WHEREAS the Legislature finds that greater transparency in the current opaque pricing and payment environment for prescription drugs will be a critical tool in developing strategies to address rising drug prices and managing state budgets in a responsible manner; now, therefore

Be it enacted by the People of the State of _____ as follows:

SECTION 1. DEFINITIONS

"340B Covered Hospital" is an entity described in 42 USC § 256b(a)(4)(L) – (N) that participates in the federal 340B drug-pricing program.

"340B Margin" for a 340B Covered Hospital, is the difference between the net cost of a 340B covered brand-name or generic drug and the net payment received by the 340B covered hospital for that brand-name or generic drug.



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“Brand-Name Drug” is a prescription drug approved under 21 USC § 355(b) or 42 USC § 262.

“Generic Drug” is a prescription drug approved under 21 USC § 355(j).

“Pharmacy Benefits Manager” or “PBM” is a third-party administrator under contract to a health insurance sponsor for management of prescription drug benefits including claims processing and payment, pharmacy contracting, and drug manufacturer price concession negotiation.

“Manufacturer” is an entity engaged in producing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling a brand-name or generic drug, but does not include an entity that is engaged in the preparation and dispensing of a brand-name or generic drug pursuant to a prescription.

“Manufacturer-sponsored assistance program” is a program offered by a manufacturer or a manufacturer-contracted intermediary, through which brand-name or generic drugs are provided to patients at a discount or no charge.

“Net Payment” is the amount paid for a brand-name or generic drug after all discounts and rebates have been applied.

“Wholesale Acquisition Cost” or “WAC” is the manufacturer list or catalogue price for a brand-name or generic drug available to wholesalers or direct purchasers in the United States, before application of discounts, rebates, or reductions in price (for the most recent month for which information is available as reported in wholesale price guides or other publications of drug or biological pricing data).

SECTION 2. PRICE INCREASE AND LAUNCH PRICE JUSTIFICATION

(1) A manufacturer shall notify the [State Agency] if it is increasing the WAC of a brand-name drug by more than 10 percent or by more than \$10,000 during any 12-month period, or if it intends to introduce to market a brand-name drug that has a WAC of \$30,000 or more annually. The notice shall be provided in writing at least 30 days prior to the planned effective date of the increase or launch and include a justification as detailed in Paragraph 3 of this Section.

(2) A manufacturer shall notify the [State Agency] if it is increasing the WAC of a generic drug by more than 25 percent or by more than \$300 during any 12-month period, or if it intends to introduce to market a generic drug that has a WAC of \$3,000 or more annually. The notice shall be provided in writing at least 30 days prior to the planned effective date of the increase or launch and include a justification as detailed in Paragraph 3 of this Section.

(3) Justification for the proposed price or price increase shall include all documents and research related to the manufacturer’s selection of the launch price or price increase, including but not limited to life cycle management, market competition and context, and estimated value/cost-effectiveness of the product.

SECTION 3. NET PRICES PAID BY PHARMACY BENEFITS MANAGERS



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By the first day of the third month of the year, each manufacturer of brand-name or generic drugs sold in the state shall report to the [State Agency] the value of price concessions provided to each PBM for each drug sold to providers or residents in the state in the previous calendar year, expressed as a percentage of the WAC.

SECTION 4. 340B HOSPITAL MARGIN SPENDING

By the first day of the third month following the start of each year, each 340B covered hospital operating in the state shall report to the [State Agency] with the per unit 340B margins for each 340B covered drug dispensed in the previous year multiplied by the number of units dispensed at that margin. Entities shall also report how that margin revenue was used.

SECTION 5. MANUFACTURER-SPONSORED ASSISTANCE PROGRAMS

By the first day of the third month following the start of each year, manufacturers of brand-name or generic drugs sold in the state shall provide the [State Agency] with a description of each manufacturer-sponsored patient assistance program in effect during the previous year, including: (i) the terms of the programs; (ii) the number of prescriptions provided to state residents under the program; and (iii) the total market value of assistance provided to state residents.

SECTION 6. CERTIFICATION AND PENALTIES FOR NON-COMPLIANCE

Required reporting under this Act shall be certified as accurate by the reporting entity under the penalty of perjury. Failure of manufacturers and 340B covered hospital entities to report required information may result in a civil penalty as determined by the [Secretary or Commissioner or head of State Agency], but may not exceed \$10,000 each day after the notification deadline.

SECTION 7.

The [State Agency] shall conduct a one-time statistically valid survey of state pharmacies regarding whether the pharmacy agreed to not disclose that customer drug benefit cost sharing exceeds the cost of the dispensed drug.

SECTION 8. HEARING AND PUBLIC REPORTING

The [State Agency] shall publicly post manufacturer price justification documents and 340B hospital documentation of how each hospital spends its aggregate 340B margin. Proprietary information will be kept confidential. The [State Agency] shall analyze data collected and publish a report on emerging trends in prescription prices and price increases annually and conduct a public hearing based on the report findings. Such report may include analysis of manufacturer prices and price increases, analysis of hospital-specific 340B margins and how that revenue is spent or allocated on a hospital specific basis, and analysis of how PBM discounts and net costs compare to retail prices paid by patients.



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SECTION 9. EFFECTIVE DATE

This Act shall take effect on [date].

ⁱ IMS Institute for Healthcare Informatics. "Medicines Use and Spending in the US: Review of 2015 and Outlook to 2020." April 2016. Accessed [online](#) February 24, 2017

ⁱⁱ Cox, C. Anthony Damico, Gary Claxton, Larry Levitt. "Examining high prescription drug spending for people with employer sponsored health insurance." *Peterson-Kaiser Health System Tracker*. October 27, 2016. Accessed [online](#) February 24, 2017