2017 DRAFTING REQUEST

Bill

For: **Debra Kolste (608) 266-7503**

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Secondary Drafters:

Date: **6/1/2017**

May Contact:

Same as LRB: **-4449**

Submit via email: **YES**
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Pre Topic:

No specific pre topic given

Topic:

Reporting of prescription drug costs by manufacturers

Instructions:

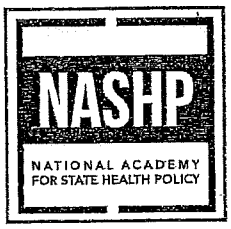
See attached

Drafting History:

Vers.	Drafted	Reviewed	Submitted	Jacketed	Required
/?	tdodge 6/29/2017	anienaja 6/30/2017			
/P1	tdodge 8/16/2017	anienaja 8/16/2017	mbarman 6/30/2017		State
/1			dwalker 8/16/2017	mbarman 10/6/2017	State

FE Sent For: 2 at intro

<END>



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

DHS

"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.

"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).

[redacted] medicaid + OCI

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. ; 25% over a 24 mo. period

(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.

a) price + effectiveness of similar drugs on the market, ~~relative to~~ anticipated sales performance

b)

c) impact of ~~mandatory~~ negotiated or mandated discounts to PBM's or insurers

SECTION 3. NET PRICES PAID BY PHARMACY BENEFITS MANAGERS

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 publically post manufacturer price justification documents and 340B hospital documentation of how each hospital spends its aggregate 340B margin. 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.

SECTION 9. EFFECTIVE DATE

This Act shall take effect on [date].

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[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

State of Wisconsin
2017 - 2018 LEGISLATURE

LRB-3681/?
TJD:...

In. 6/29

Due Fri 6/30 (H)

PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION

SA ✓
Xref.

Genl. ✓

AN ACT ...; **relating to:** prescription drug cost reporting by manufacturers and providing a penalty.

Analysis by the Legislative Reference Bureau

This is a preliminary draft. An analysis will be provided in a subsequent version of this draft.

For further information see the ***state*** fiscal estimate, which will be printed as an appendix to this bill.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

SECTION 1. 146.901 of the statutes is created to read:

146.901 Prescription drug cost reporting by manufacturers. (1) DEFINITIONS. In this section:

(a) "Brand-name drug" is a prescription drug approved under 21 USC 355 (b) or 42 USC 262. (CHECK)

(b) "Generic drug" is a prescription drug approved under 21 USC 355 (j).

(c) "Manufacturer" has the meaning given in s. 450.01 (12). "Manufacturer" does not include an entity that is engaged only in the dispensing, as defined in s. 450.01 (7), of a brand-name drug or a generic drug.

(d) "Manufacturer-sponsored assistance program" means a program offered by a manufacturer or an intermediary under contract with a manufacturer through which a brand-name drug or a generic drug is provided to a patient at no charge or at a discount.

(e) "Office" means the office of the commissioner of insurance.

(f) "Pharmacy benefit manager" has the meaning given in s. 632.865 (1) (c).

(g) "Wholesale acquisition cost" means the most recently reported manufacturer list or catalog price for a brand-name drug or a generic drug available to wholesalers or direct purchasers in the United States, before application of discounts, rebates, or reductions in price.

(2) PRICE INCREASE OR INTRODUCTION NOTICE; JUSTIFICATION REPORT. (a) A manufacturer shall notify the department and the office if it is increasing the wholesale acquisition cost of a brand-name drug on the market in this state by more than 25 percent or more over a 24-month period or if it intends to introduce to market in this state a brand-name drug in this state that has a annual wholesale acquisition cost of $30,000 or more annually.

(b) A manufacturer shall notify the department and the office if it is increasing the wholesale acquisition cost of a generic drug on the market in this state by more than 25 percent or by more than $300 during any 12-month period or if it intends to introduce to market in this state a generic drug that has a annual wholesale acquisition cost of $3,000 or more annually.

(c) The manufacturer shall provide the notice under this par. (a) or (b) in writing at least 30 days before the planned effective date of the cost increase or drug introduction and shall provide a justification that includes all documents and research related to the manufacturer's selection of the price increase or introduction price and includes a description of all of the following:

1. The estimated cost-effectiveness of the drug.

2. The price and effectiveness of similar drugs available in this state and the anticipated sales performance of the drug as compared to similar drugs.

3. The impact of negotiated or mandated discounts to pharmacy benefit managers, insurers, and other health cost payers on the pricing determination for the drug.

(d) By March 1 annually, each manufacturer shall report to the department and the office the value of price concessions, expressed as a percentage of the wholesale acquisition cost, provided to each pharmacy benefit manager for each drug for which a notice was required under par. (a) or (b) sold in this state in the previous calendar year.

(3) MANUFACTURER-SPONSORED ASSISTANCE PROGRAMS. By March 1 annually, each manufacturer of a brand-name drug or generic drug sold in this state shall submit to the department and the office a report containing a description of each manufacturer-sponsored patient assistance program in effect during the previous calendar year including all of the following:

1. The criteria for participation in the program and the program terms.

2. The number of prescriptions provided to residents of this state under the program.

3. The total market value of assistance provided to residents of this state under the program.

(4) PENALTY. The manufacturer shall certify the information reported under sub. (2) or (3) as accurate under penalty of perjury. A manufacturer that fails to provide the notice or report under sub. (2) or (3) is subject to a forfeiture as determined by the department but not to exceed $10,000 for each day after the notice is required or the deadline of the report is past due.

(5) POSTING OF REPORT; HEARING. (a) The department shall publish on its Internet site the justification documentation provided under sub. (2) (c).

(b) The department shall analyze the information submitted under subs. (2) and (3) and publish a report on its Internet site describing trends in drug pricing. The department shall conduct at least one public hearing annually on the findings of the report.

(END)

State of Wisconsin
2017 - 2018 LEGISLATURE

LRB-3681/P1
TJD:amn

In: 8/16

Due Today if possible

PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION

AN ACT ***to create*** 146.901 of the statutes; **relating to:** prescription drug cost reporting by manufacturers and providing a penalty.

Insert Analysis

Analysis by the Legislative Reference Bureau

This is a preliminary draft. An analysis will be provided in a subsequent version of this draft.

For further information see the ***state*** fiscal estimate, which will be printed as an appendix to this bill.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

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(d) "Manufacturer-sponsored assistance program" means a program offered by a manufacturer or an intermediary under contract with a manufacturer through which a brand-name drug or a generic drug is provided to a patient at no charge or at a discount.

(e) "Office" means the office of the commissioner of insurance.

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(2) PRICE INCREASE OR INTRODUCTION NOTICE; JUSTIFICATION REPORT. (a) A manufacturer shall notify the department and the office if it is increasing the wholesale acquisition cost of a brand-name drug on the market in this state by more than 25 percent over a 24-month period or if it intends to introduce to market in this state a brand-name drug that has an annual wholesale acquisition cost of $30,000 or more.

(b) A manufacturer shall notify the department and the office if it is increasing the wholesale acquisition cost of a generic drug on the market in this state by more than 25 percent or by more than $300 during any 12-month period or if it intends to introduce to market in this state a generic drug that has an annual wholesale acquisition cost of $3,000 or more.

(c) The manufacturer shall provide the notice under par. (a) or (b) in writing at least 30 days before the planned effective date of the cost increase or drug introduction and shall provide a justification that includes all documents and research related to the manufacturer's selection of the price increase or introduction price and includes a description of all of the following:

1. The estimated cost-effectiveness of the drug.

2. The price and effectiveness of similar drugs available in this state and the anticipated sales performance of the drug as compared to similar drugs.

3. The impact of negotiated or mandated discounts to pharmacy benefit managers, insurers, and other payers of health costs on the pricing determination for the drug.

(d) By March 1 annually, each manufacturer shall report to the department and the office the value of price concessions, expressed as a percentage of the wholesale acquisition cost, provided to each pharmacy benefit manager for each drug sold in this state for which a notice is required under par. (a) or (b) in the previous calendar year.

(3) MANUFACTURER-SPONSORED ASSISTANCE PROGRAMS. By March 1 annually, each manufacturer of a brand-name drug or generic drug sold in this state shall submit to the department and the office a report containing a description of each manufacturer-sponsored assistance program in effect during the previous calendar year including all of the following:

(a) The criteria for participation in the program and the program terms.

(b) The number of prescriptions provided to residents of this state under the program.

(c) The total market value of assistance provided to residents of this state under the program.

(4) PENALTY. The manufacturer shall certify the information reported under sub. (2) or (3) as accurate under penalty of perjury. A manufacturer that fails to provide the notice or report under sub. (2) or (3) is subject to a forfeiture as determined by the department but not to exceed $10,000 for each day the notice or report is past due.

(5) POSTING OF REPORT; HEARING. (a) The department shall publish on its Internet site the justification documentation provided under sub. (2) (c).

(b) The department shall analyze the information submitted under subs. (2) and (3) and publish a report on its Internet site describing trends in drug pricing. The department shall conduct at least one public hearing annually on the findings of the report.

(END)

INSERT ANALYSIS

This bill requires certain cost reporting by manufacturers of brand-name and generic drugs. The bill requires a manufacturer to notify the Department of Health Services and the Office of the Commissioner of Insurance if it is 1) increasing the wholesale acquisition cost of a brand-name drug on the market in Wisconsin by more than 25 percent over a 24-month period; 2) intending to introduce in Wisconsin a brand-name drug that has an annual wholesale acquisition cost of $30,000 or more; 3) increasing the wholesale acquisition cost of a generic drug on the market in Wisconsin by more than 25 percent or by more than $300 during any 12-month period; or 4) intending to introduce in Wisconsin a generic drug that has an annual wholesale acquisition cost of $3,000 or more. The manufacturer must provide the notice at least 30 days before the planned date of the increase or introduction and must provide a justification including a description described in the bill. A manufacturer is also required to report annually to DHS and OCI the value of price concessions provided to each pharmacy benefit manager for each drug sold in Wisconsin for which a notice was required. The bill also requires each manufacturer of a brand-name or generic drug sold in Wisconsin to submit to DHS and OCI a report containing a description of each manufacturer-sponsored assistance program in effect during the previous year that includes the criteria for participation, program terms, and the number of prescriptions and the total market value of assistance provided to residents of Wisconsin under the program. The manufacturer must certify the information provided in a notice or report required under the bill under penalty of perjury, and failure to provide the notice or report is subject to a forfeiture determined by DHS but not to exceed $10,000 per day past due.

The bill requires DHS to publish the pricing justification information reported by manufacturers on its Internet site. DHS must also analyze the information and publish a report on its Internet site describing trends in drug pricing.

END INSERT ANALYSIS

Barman, Mike

From: Hoyer-Booth, Andrew
Sent: Friday, October 06, 2017 1:16 PM
To: LRB.Legal
Subject: Draft Review: LRB -3681/1

Please Jacket LRB -3681/1 for the ASSEMBLY.