2019 DRAFTING REQUEST

Bill

For:	**Administration-Budget**	Drafter:	**tdodge**
By:	**Ames**	Secondary Drafters:	
Date:	**1/31/2019**	May Contact:	

Same as LRB:

Submit via email: **YES**
Requester's email:
Carbon copy (CC) to: **doasbostatlanguage@wisconsin.gov**
tamara.dodge@legis.wisconsin.gov

Pre Topic:

DOA:.....Ames, BB0219 -

Topic:

Prescription drug transparency

Instructions:

See attached

Drafting History:

Vers.	Drafted	Reviewed	Submitted	Jacketed	Required
/?	tdodge 2/12/2019	ccarmich 2/13/2019			
/P1	tdodge 2/14/2019	ccarmich 2/15/2019	jmurphy 2/13/2019		State
/P2	tdodge 2/17/2019	ccarmich 2/18/2019	dwalker 2/15/2019		State
/P3			lparisi 2/18/2019		State Insurance

FE Sent For: **<END>**

Dodge, Tamara

From: Cathlene Hanaman <cathleneh@gmail.com>
Sent: Thursday, January 31, 2019 10:15 AM
To: Dodge, Tamara; Walkenhorst Barber, Sarah
Subject: Fwd: Statutory Language Drafting Request - 2019-21

Sent from my iPhone

Begin forwarded message:

Biennial Budget: 2019-21

Topic: Prescription Drug Transparency

Tracking Code: BB0219

SBO Team: HSI

SBO Analyst: Ames, Kyle
Phone: 608-266-2214
E-mail: kyle.ames@wisconsin.gov

Agency Acronym: 435

Agency Number: 435

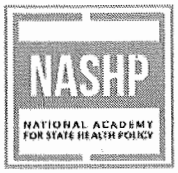
Priority: Low

Intent:

> Draft legislation to require drug manufacturers and pharmacy benefit managers to report drug prices under certain conditions. Please review draft legislation as a model. The language should include the draft legislation's thresholds. Edit: Please also include in draft language that require pharmacy benefit managers to register with the state and disclose rebate amounts and price concessions received from drug companies. Also, language should include the requirement for insurers to identify their 25 highest-cost drugs and the 25 with the greatest cost increases when they file their annual rate requests with the state.

Attachments: True

Please send completed drafts to SBOStatlanguage@spmail.enterprise.wistate.us



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 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.

"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).

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

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.

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
2019 - 2020 LEGISLATURE

LRB-1726(?)
TJD:...
epi
cdc

In: 2/12

DOA:.....Ames, BB0219 - Prescription drug transparency

FOR 2019-2021 BUDGET -- NOT READY FOR INTRODUCTION

HEALTH AND HUMAN SERVICES

GENERAL HEALTH AND HUMAN SERVICES

#. Registration of pharmacy benefit managers; drug cost reporting

s/A
x-ref
s/cr

AN ACT ...; **relating to:** the budget.

Analysis by the Legislative Reference Bureau

This bill generally requires certain prescription drug cost reporting by drug manufacturers, pharmacy benefit managers, insurers, and hospitals. The bill also requires pharmacy benefit managers to register with OCI in order to perform activities of a pharmacy benefit manager in Wisconsin.

Under the bill, each insurer that offers a disability insurance policy that covers prescription drugs must submit to OCI an annual report that identifies the 25 prescription drugs that are the highest cost to the insurer and the 25 prescription drugs that have the highest cost increases over the 12 months before the submission of the report.

The bill requires a drug manufacturer to notify DHS and OCI if it increases the wholesale acquisition cost of a brand-name or generic drug on the market in this state by more that an amount specified in the bill, or if it intends to introduce to market a brand-name or generic drug that has an annual wholesale acquisition cost of more than a specified amount. The manufacturer must include with the notice justification for and documentation regarding the price increase. The bill requires each manufacturer to provide DHS and OCI an annual description of each manufacturer-sponsored patient assistance program in effect during the previous year. Each manufacturer must also report to DHS and OCI the value of price concessions provided to each pharmacy benefit manager for each drug sold.

The bill requires pharmacy benefit managers to report to DHS and OCI the amount received from manufacturers as drug rebates and the value of price

concessions provided by manufacturers for each drug. The bill also requires each hospital participating in the federal drug pricing program, known as the 340B program, to report to DHS and to OCI the per unit margin for each drug covered under the 340B program dispensed in the previous year, the total margin, and how the margin revenue was used. DHS is required under the bill to publicly post information submitted, analyze data collected, publish a report on emerging trends in prescription prices and price increases, and annually conduct a public hearing based on that analysis. DHS must also conduct a statistically-valid survey of pharmacies in this state regarding whether the pharmacy agreed to not disclose that customer drug benefit cost sharing exceeds the cost of the dispensed drug.

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. (1) DEFINITIONS. In this section:

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

(b) "Covered hospital" means an entity described in 42 USC 256b (a) (4) (L) to (N) that participates in the federal drug-pricing program under 42 USC 256b.

(c) "Generic drug" means a prescription drug approved under 21 USC 355 (j).

(d) "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.

(e) "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.

(f) "Margin" means, for a covered hospital, the difference between the net cost of a brand-name drug or generic drug covered under the federal drug-pricing program under 42 USC 256b and the net payment by the covered hospital for that brand-name drug or generic drug.

(g) "Net payment" means the amount paid for a brand-name drug or generic drug after all discounts and rebates have been applied.

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

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

(j) "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 10 percent or by more than $10,000 during any 12-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.

****NOTE: This draft requires the notifications and reports to be sent to both the Department of Health Services and the Office of the Commissioner of Insurance. Please advise if you want to eliminate one of the agencies or include a different agency.

(b) A manufacturer shall notify the department and the office if it is increasing the wholesale acquisition cost 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 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 with a justification that includes all documents and research related to the manufacturer's selection of the cost increase or introduction price and a description of life cycle management, market competition and context, and estimated value or cost-effectiveness of the product.

(3) NET PRICES PAID BY PHARMACY BENEFIT MANAGERS. By March 1 annually, the 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.

(4) REBATES AND PRICE CONCESSIONS. By March 1 annually, each pharmacy benefit manager shall report to the department and to the office the amount received from manufacturers as drug rebates and the value of price concessions, expressed as a percentage of the wholesale acquisition cost, provided by manufacturers for each drug.

(5) HOSPITAL MARGIN SPENDING. By March 1 annually, each covered hospital operating in this state shall report to the department and to the office the per unit margin for each drug covered under the federal drug pricing program under 42 USC 256b dispensed in the previous year multiplied by the number of units dispensed at that margin and how the margin revenue was used.

(6) MANUFACTURER-SPONSORED ASSISTANCE PROGRAMS. By March 1 annually, each manufacturer shall provide the department and the office with a description of each manufacturer-sponsored patient assistance program in effect during the previous year that includes all of the following:

(a) 1. The terms of the programs.

(b) (2) The number of prescriptions provided to state residents under the program.

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

(7) CERTIFICATION AND PENALTIES FOR NONCOMPLIANCE. Each manufacturer and covered hospital that is required to report under this section shall certify each report as accurate under the penalty of perjury. A manufacturer or covered hospital that fails to submit a report required under this section is subject to a forfeiture of no more than $10,000 each day the report is overdue.

(8) HEARING AND PUBLIC REPORTING. (a) The department shall publicly post manufacturer price justification documents and covered hospital documentation of how each hospital spends the margin revenue. The department shall keep any trade secret or proprietary information confidential.

(b) The department shall analyze data collected under this section and publish annually a report on emerging trends in prescription prices and price increases and shall annually conduct a public hearing based on the analysis under this paragraph. The report under this paragraph shall include analysis of manufacturer prices and price increases, analysis of hospital-specific margins and how that revenue is spent or allocated on a hospital-specific basis, and analysis of how pharmacy benefit manager discounts and net costs compare to retail prices paid by patients.

SECTION 2. 632.865 (3) of the statutes is created to read:

632.865 **(3)** REGISTRATION REQUIRED. (a) No person may perform any activities of a pharmacy benefit manager in this state without first registering with the commissioner under this subsection.

(b) The commissioner shall establish a registration procedure for pharmacy benefit managers. The commissioner may promulgate any rules necessary to implement the registration procedure under this paragraph.

resort draft

SECTION 3. 632.796 of the statutes is created to read:

632.796 Drug cost report. (1) DEFINITION. In this section, "disability insurance policy" has the meaning given in s. 632.895 (1) (a).

(2) REPORT REQUIRED. Annually, at the time the insurer files its rate request with the commissioner, each insurer that offers a disability insurance policy that covers prescription drugs shall submit to the commissioner a report that identifies the 25 prescription drugs that are the highest cost to the insurer and the 25 prescription drugs that have the highest cost increases over the 12 months before the submission of the report.

SECTION 9119. Nonstatutory provisions; Health Services.

(1) PRESCRIPTION DRUG COST SURVEY. The department of health services shall conduct a statistically-valid survey of pharmacies in this state regarding whether the pharmacy agreed to not disclose that customer drug benefit cost sharing exceeds the cost of the dispensed drug.

(END)

Dodge, Tamara

From: Ames, Kyle - DOA
Sent: Thursday, February 14, 2019 6:05 PM
To: Dodge, Tamara
Cc: Dombrowski, Cynthia A - DOA
Subject: RE: LRB-1726/P1

Tami:

OCI should have that requirement.

Thanks!
Kyle

From: Dodge, Tami - LEGIS <tamara.dodge@legis.wisconsin.gov>
Sent: Thursday, February 14, 2019 5:36 PM
To: Ames, Kyle - DOA <Kyle.Ames@wisconsin.gov>
Subject: RE: LRB-1726/P1

Kyle,

I will remove DHS from the draft. There is a requirement that the agency (was DHS) do an analysis and public reporting of the information provided to it. Do you want that eliminated? Or do you want that requirement put on OCI?

Tami

Tamara J. Dodge
Senior Legislative Attorney
Wisconsin Legislative Reference Bureau
P.O. Box 2037
Madison, WI 53701-2037
(608) 504 - 5808
tamara.dodge@legis.wisconsin.gov

Please note my new direct phone number (as of June 13, 2018).

From: Ames, Kyle - DOA <Kyle.Ames@wisconsin.gov>
Sent: Thursday, February 14, 2019 5:29 PM
To: Dodge, Tamara <Tamara.Dodge@legis.wisconsin.gov>
Subject: LRB-1726/P1

Tami:

For the prescription drug transparency program, please remove the DHS reporting requirement. OCI will have the sole responsibility of administering this program and all reporting of the initiative will be directed to OCI.

Please let me know if you have any questions.

Best,
Kyle

KYLE AMES | Executive Budget and Policy Analyst
Department of Administration
Division of Executive Budget and Finance
Kyle.Ames@wisconsin.gov
Main: (608) 266-2214 |

State of Wisconsin
2019 - 2020 LEGISLATURE

LRB-1726/P1 & P2
TJD:cdc

In. 2/14

DOA:.....Ames, BB0219 - Prescription drug transparency

FOR 2019-2021 BUDGET -- NOT READY FOR INTRODUCTION

INSURANCE

AN ACT ...; **relating to:** the budget.

Analysis by the Legislative Reference Bureau

HEALTH AND HUMAN SERVICES

GENERAL HEALTH AND HUMAN SERVICES

1. Registration of pharmacy benefit managers; drug cost reporting

This bill generally requires certain prescription drug cost reporting by drug manufacturers, pharmacy benefit managers, insurers, and hospitals. The bill also requires pharmacy benefit managers to register with OCI in order to perform activities of a pharmacy benefit manager in Wisconsin.

Under the bill, each insurer that offers a disability insurance policy that covers prescription drugs must submit to OCI an annual report that identifies the 25 prescription drugs that are the highest cost to the insurer and the 25 prescription drugs that have the highest cost increases over the 12 months before the submission of the report.

The bill requires a drug manufacturer to notify DHS and OCI if it increases the wholesale acquisition cost of a brand-name or generic drug on the market in this state by more that an amount specified in the bill, or if it intends to introduce to market a brand-name or generic drug that has an annual wholesale acquisition cost of more than a specified amount. The manufacturer must include with the notice justification for and documentation regarding the price increase. The bill requires each manufacturer to provide DHS and OCI an annual description of each

manufacturer-sponsored patient assistance program in effect during the previous year. Each manufacturer must also report to DHS and OCI the value of price concessions provided to each pharmacy benefit manager for each drug sold.

The bill requires pharmacy benefit managers to report to DHS and OCI the amount received from manufacturers as drug rebates and the value of price concessions provided by manufacturers for each drug. The bill also requires each hospital participating in the federal drug-pricing program, known as the 340B program, to report to DHS and OCI the per unit margin for each drug covered under the 340B program dispensed in the previous year, the total margin, and how the margin revenue was used. DHS is required under the bill to publicly post information submitted, analyze data collected, publish a report on emerging trends in prescription prices and price increases, and annually conduct a public hearing based on that analysis. DHS must also conduct a statistically-valid survey of pharmacies in this state regarding whether the pharmacy agreed to not disclose that customer drug benefit cost sharing exceeds the cost of the dispensed drug.

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:

632.866

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

632.866

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

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

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(c) "Generic drug" means a prescription drug approved under 21 USC 355 (j).

(d) "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.

(e) "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.

(f) "Margin" means, for a covered hospital, the difference between the net cost of a brand-name drug or generic drug covered under the federal drug-pricing program under 42 USC 256b and the net payment by the covered hospital for that brand-name drug or generic drug.

(g) "Net payment" means the amount paid for a brand-name drug or generic drug after all discounts and rebates have been applied.

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

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

(i) (j) "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.

Commissioner

(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 10 percent or by more than $10,000 during any 12-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.

****NOTE: This draft requires the notifications and reports to be sent to both the Department of Health Services and the Office of the Commissioner of Insurance. Please advise if you want to eliminate one of the agencies or include a different agency.

(b) A manufacturer shall notify the department and the office if it is increasing the wholesale acquisition cost of a generic drug by more than 25 percent or by more

Commissioner

than $300 during any 12-month period or if it intends to introduce to market 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 with a justification that includes all documents and research related to the manufacturer's selection of the cost increase or introduction price and a description of life cycle management, market competition and context, and estimated value or cost-effectiveness of the product.

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(4) REBATES AND PRICE CONCESSIONS. By March 1 annually, each pharmacy benefit manager shall report to the department and to the office the amount received from manufacturers as drug rebates and the value of price concessions, expressed as a percentage of the wholesale acquisition cost, provided by manufacturers for each drug.

(5) HOSPITAL MARGIN SPENDING. By March 1 annually, each covered hospital operating in this state shall report to the department and to the office the per unit margin for each drug covered under the federal drug pricing program under 42 USC 256b dispensed in the previous year multiplied by the number of units dispensed at that margin and how the margin revenue was used.

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each manufacturer-sponsored patient assistance program in effect during the previous year that includes all of the following:

(a) The terms of the programs.

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

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

(7) CERTIFICATION AND PENALTIES FOR NONCOMPLIANCE. Each manufacturer and covered hospital that is required to report under this section shall certify each report as accurate under the penalty of perjury. A manufacturer or covered hospital that fails to submit a report required under this section is subject to a forfeiture of no more than $10,000 each day the report is overdue.

(8) HEARING AND PUBLIC REPORTING. (a) The department shall publicly post manufacturer price justification documents and covered hospital documentation of how each hospital spends the margin revenue. The department shall keep any trade secret or proprietary information confidential.

(b) The department shall analyze data collected under this section and publish annually a report on emerging trends in prescription prices and price increases, and shall annually conduct a public hearing based on the analysis under this paragraph. The report under this paragraph shall include analysis of manufacturer prices and price increases, analysis of hospital-specific margins and how that revenue is spent or allocated on a hospital-specific basis, and analysis of how pharmacy benefit manager discounts and net costs compare to retail prices paid by patients.

SECTION 2. 632.796 of the statutes is created to read:

632.796 Drug cost report. (1) DEFINITION. In this section, "disability insurance policy" has the meaning given in s. 632.895 (1) (a).

(2) REPORT REQUIRED. Annually, at the time the insurer files its rate request with the commissioner, each insurer that offers a disability insurance policy that covers prescription drugs shall submit to the commissioner a report that identifies the 25 prescription drugs that are the highest cost to the insurer and the 25 prescription drugs that have the highest cost increases over the 12 months before the submission of the report.

SECTION 3. 632.865 (3) of the statutes is created to read:

632.865 **(3)** REGISTRATION REQUIRED. (a) No person may perform any activities of a pharmacy benefit manager in this state without first registering with the commissioner under this subsection.

(b) The commissioner shall establish a registration procedure for pharmacy benefit managers. The commissioner may promulgate any rules necessary to implement the registration procedure under this paragraph.

SECTION 9119. Nonstatutory provisions; Health Services.

(1) PRESCRIPTION DRUG COST SURVEY. The department of health services shall conduct a statistically-valid survey of pharmacies in this state regarding whether the pharmacy agreed to not disclose that customer drug benefit cost sharing exceeds the cost of the dispensed drug.

(END)

Dodge, Tamara

From: Ames, Kyle - DOA
Sent: Sunday, February 17, 2019 2:48 PM
To: Dodge, Tamara
Cc: Dombrowski, Cynthia A - DOA
Subject: LRB-1726/P2

Follow Up Flag: FollowUp
Flag Status: Flagged

Tami, could you please add the following language or language similar to the following:

A [insert OCI] organization "shall ensure that each prescription drug plan or MA–PD plan offered by the sponsor or organization does not restrict a pharmacy that dispenses a prescription drug or biological from informing, nor penalize such pharmacy for informing, an enrollee in such plan of any differential between the negotiated price of, or copayment or coinsurance for, the drug or biological to the enrollee under the plan and a lower price the individual would pay for the drug or biological if the enrollee obtained the drug without using any health insurance coverage."

This is language taken from the Know The Lowest Price Act passed through Congress last year banning gag orders on pharmacies. The intent is to preserve the meaning in the drug transparency language.

Please let me know if you have any questions.

Best,
Kyle

State of Wisconsin
2019 - 2020 LEGISLATURE

LRB-1726/P2 ep3
TJD:cdc

DOA:.....Ames, BB0219 - Prescription drug transparency

FOR 2019-2021 BUDGET -- NOT READY FOR INTRODUCTION

AN ACT ...; **relating to:** the budget.

Analysis by the Legislative Reference Bureau

INSURANCE

1. Registration of pharmacy benefit managers; drug cost reporting

This bill generally requires certain prescription drug cost reporting by drug manufacturers, pharmacy benefit managers, insurers, and hospitals. The bill also requires pharmacy benefit managers to register with OCI in order to perform activities of a pharmacy benefit manager in Wisconsin.

Under the bill, each insurer that offers a disability insurance policy that covers prescription drugs must submit to OCI an annual report that identifies the 25 prescription drugs that are the highest cost to the insurer and the 25 prescription drugs that have the highest cost increases over the 12 months before the submission of the report.

The bill requires a drug manufacturer to notify OCI if it increases the wholesale acquisition cost of a brand-name or generic drug on the market in this state by more that an amount specified in the bill, or if it intends to introduce to market a brand-name or generic drug that has an annual wholesale acquisition cost of more than a specified amount. The manufacturer must include with the notice justification for and documentation regarding the price increase. The bill requires each manufacturer to provide OCI an annual description of each manufacturer-sponsored patient assistance program in effect during the previous year. Each manufacturer must also report to OCI the value of price concessions provided to each pharmacy benefit manager for each drug sold.

The bill requires pharmacy benefit managers to report to OCI the amount received from manufacturers as drug rebates and the value of price concessions provided by manufacturers for each drug. The bill also requires each hospital participating in the federal drug-pricing program, known as the 340B program, to report to OCI the per unit margin for each drug covered under the 340B program dispensed in the previous year, the total margin, and how the margin revenue was used. OCI is required under the bill to publicly post information submitted, analyze data collected, publish a report on emerging trends in prescription prices and price increases, and annually conduct a public hearing based on that analysis. OCI must also conduct a statistically-valid survey of pharmacies in this state regarding whether the pharmacy agreed to not disclose that customer drug benefit cost sharing exceeds the cost of the dispensed drug.

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

Insert analysis

Insurance Tag

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

SECTION 1. 632.796 of the statutes is created to read:

632.796 Drug cost report. (1) DEFINITION. In this section, "disability insurance policy" has the meaning given in s. 632.895 (1) (a).

(2) REPORT REQUIRED. Annually, at the time the insurer files its rate request with the commissioner, each insurer that offers a disability insurance policy that covers prescription drugs shall submit to the commissioner a report that identifies the 25 prescription drugs that are the highest cost to the insurer and the 25 prescription drugs that have the highest cost increases over the 12 months before the submission of the report.

SECTION 2. 632.865 (3) of the statutes is created to read:

632.865 **(3)** REGISTRATION REQUIRED. (a) No person may perform any activities of a pharmacy benefit manager in this state without first registering with the commissioner under this subsection.

(c) "Disability insurance policy" has the meaning given in s. 632.895(1)(a).

(b) The commissioner shall establish a registration procedure for pharmacy benefit managers. The commissioner may promulgate any rules necessary to implement the registration procedure under this paragraph.

SECTION 3. 632.866 of the statutes is created to read:

632.866 Prescription drug cost reporting. (1) DEFINITIONS. In this section:

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

(b) "Covered hospital" means an entity described in 42 USC 256b (a) (4) (L) to (N) that participates in the federal drug-pricing program under 42 USC 256b.

(d) → (c) "Generic drug" means a prescription drug approved under 21 USC 355 (j).

(e) → (d) "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.

(f) → (e) "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.

(g) → (f) "Margin" means, for a covered hospital, the difference between the net cost of a brand-name drug or generic drug covered under the federal drug-pricing program under 42 USC 256b and the net payment by the covered hospital for that brand-name drug or generic drug.

(h) → (g) "Net payment" means the amount paid for a brand-name drug or generic drug after all discounts and rebates have been applied.

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

(i) "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 commissioner if it is increasing the wholesale acquisition cost of a brand-name drug on the market in this state by more than 10 percent or by more than $10,000 during any 12-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 commissioner if it is increasing the wholesale acquisition cost 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 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 with a justification that includes all documents and research related to the manufacturer's selection of the cost increase or introduction price and a description of life cycle management, market competition and context, and estimated value or cost-effectiveness of the product.

(3) NET PRICES PAID BY PHARMACY BENEFIT MANAGERS. By March 1 annually, the manufacturer shall report to the commissioner 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.

(4) REBATES AND PRICE CONCESSIONS. By March 1 annually, each pharmacy benefit manager shall report to the commissioner the amount received from manufacturers as drug rebates and the value of price concessions, expressed as a percentage of the wholesale acquisition cost, provided by manufacturers for each drug.

(5) HOSPITAL MARGIN SPENDING. By March 1 annually, each covered hospital operating in this state shall report to the commissioner the per unit margin for each drug covered under the federal drug pricing program under 42 USC 256b dispensed in the previous year multiplied by the number of units dispensed at that margin and how the margin revenue was used.

(6) MANUFACTURER-SPONSORED ASSISTANCE PROGRAMS. By March 1 annually, each manufacturer shall provide the commissioner with a description of each manufacturer-sponsored patient assistance program in effect during the previous year that includes all of the following:

(a) The terms of the programs.

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

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

(7) CERTIFICATION AND PENALTIES FOR NONCOMPLIANCE. Each manufacturer and covered hospital that is required to report under this section shall certify each report as accurate under the penalty of perjury. A manufacturer or covered hospital that fails to submit a report required under this section is subject to a forfeiture of no more than $10,000 each day the report is overdue.

(8) HEARING AND PUBLIC REPORTING. (a) The commissioner shall publicly post manufacturer price justification documents and covered hospital documentation of

how each hospital spends the margin revenue. The commissioner shall keep any trade secret or proprietary information confidential.

(b) The commissioner shall analyze data collected under this section and publish annually a report on emerging trends in prescription prices and price increases, and shall annually conduct a public hearing based on the analysis under this paragraph. The report under this paragraph shall include analysis of manufacturer prices and price increases, analysis of hospital-specific margins and how that revenue is spent or allocated on a hospital-specific basis, and analysis of how pharmacy benefit manager discounts and net costs compare to retail prices paid by patients.

SECTION 9123. Nonstatutory provisions; Office of Commissioner of Insurance.

(1) PRESCRIPTION DRUG COST SURVEY. The commissioner of insurance shall conduct a statistically-valid survey of pharmacies in this state regarding whether the pharmacy agreed to not disclose that customer drug benefit cost sharing exceeds the cost of the dispensed drug.

(END)

Insert 6-11

INSERT ANALYSIS

The bill requires OCI to ensure that every health insurance policy that covers prescription drugs does not restrict a pharmacy or pharmacist from or penalize a pharmacy or pharmacist for informing an insured of a difference between the price of a drug or biological product under the policy and the price the insured would pay without using health insurance coverage.

END INSERT ANALYSIS

INSERT 6-11

(9) ALLOWING COST DISCLOSURE TO INSURED. The commissioner shall ensure that every disability insurance policy that covers prescription drugs or biological products does not restrict a pharmacy or pharmacist that dispenses a prescription drug or biological product from informing and does not penalize a pharmacy or pharmacist for informing an insured under a policy of a difference between the negotiated price of, or copayment or coinsurance for, the drug or biological product under the policy and the price the insured would pay for the drug or biological product if the insured obtained the drug or biological product without using any health insurance coverage.

END INSERT 6-11

State of Wisconsin
2019 - 2020 LEGISLATURE

LRB-1726/P3
TJD:cdc

DOA:.....Ames, BB0219 - Prescription drug transparency

FOR 2019-2021 BUDGET -- NOT READY FOR INTRODUCTION

AN ACT ...; **relating to:** the budget.

Analysis by the Legislative Reference Bureau

INSURANCE

1. Registration of pharmacy benefit managers; drug cost reporting

This bill generally requires certain prescription drug cost reporting by drug manufacturers, pharmacy benefit managers, insurers, and hospitals. The bill also requires pharmacy benefit managers to register with OCI in order to perform activities of a pharmacy benefit manager in Wisconsin.

Under the bill, each insurer that offers a health insurance policy that covers prescription drugs must submit to OCI an annual report that identifies the 25 prescription drugs that are the highest cost to the insurer and the 25 prescription drugs that have the highest cost increases over the 12 months before the submission of the report. Health insurance policies are referred to in the bill as disability insurance policies.

The bill requires a drug manufacturer to notify OCI if it increases the wholesale acquisition cost of a brand-name or generic drug on the market in this state by more that an amount specified in the bill, or if it intends to introduce to market a brand-name or generic drug that has an annual wholesale acquisition cost of more than a specified amount. The manufacturer must include with the notice justification for and documentation regarding the price increase. The bill requires each manufacturer to provide OCI an annual description of each manufacturer-sponsored patient assistance program in effect during the previous

year. Each manufacturer must also report to OCI the value of price concessions provided to each pharmacy benefit manager for each drug sold.

The bill requires pharmacy benefit managers to report to OCI the amount received from manufacturers as drug rebates and the value of price concessions provided by manufacturers for each drug. The bill also requires each hospital participating in the federal drug-pricing program, known as the 340B program, to report to OCI the per unit margin for each drug covered under the 340B program dispensed in the previous year, the total margin, and how the margin revenue was used. OCI is required under the bill to publicly post information submitted, analyze data collected, publish a report on emerging trends in prescription prices and price increases, and annually conduct a public hearing based on that analysis. OCI must also conduct a statistically-valid survey of pharmacies in this state regarding whether the pharmacy agreed to not disclose that customer drug benefit cost sharing exceeds the cost of the dispensed drug.

The bill requires OCI to ensure that every health insurance policy that covers prescription drugs does not restrict a pharmacy or pharmacist from or penalize a pharmacy or pharmacist for informing an insured of a difference between the price of a drug or biological product under the policy and the price the insured would pay without using health insurance coverage.

This proposal may contain a health insurance mandate requiring a social and financial impact report under s. 601.423, stats.

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. 632.796 of the statutes is created to read:

632.796 Drug cost report. (1) DEFINITION. In this section, "disability insurance policy" has the meaning given in s. 632.895 (1) (a).

(2) REPORT REQUIRED. Annually, at the time the insurer files its rate request with the commissioner, each insurer that offers a disability insurance policy that covers prescription drugs shall submit to the commissioner a report that identifies the 25 prescription drugs that are the highest cost to the insurer and the 25 prescription drugs that have the highest cost increases over the 12 months before the submission of the report.

SECTION 2. 632.865 (3) of the statutes is created to read:

632.865 **(3)** REGISTRATION REQUIRED. (a) No person may perform any activities of a pharmacy benefit manager in this state without first registering with the commissioner under this subsection.

(b) The commissioner shall establish a registration procedure for pharmacy benefit managers. The commissioner may promulgate any rules necessary to implement the registration procedure under this paragraph.

SECTION 3. 632.866 of the statutes is created to read:

632.866 Prescription drug cost reporting. (1) DEFINITIONS. In this section:

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

(b) "Covered hospital" means an entity described in 42 USC 256b (a) (4) (L) to (N) that participates in the federal drug-pricing program under 42 USC 256b.

(c) "Disability insurance policy" has the meaning given in s. 632.895 (1) (a).

(d) "Generic drug" means a prescription drug approved under 21 USC 355 (j).

(e) "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.

(f) "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.

(g) "Margin" means, for a covered hospital, the difference between the net cost of a brand-name drug or generic drug covered under the federal drug-pricing program under 42 USC 256b and the net payment by the covered hospital for that brand-name drug or generic drug.

(h) "Net payment" means the amount paid for a brand-name drug or generic drug after all discounts and rebates have been applied.

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

(j) "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 commissioner if it is increasing the wholesale acquisition cost of a brand-name drug on the market in this state by more than 10 percent or by more than $10,000 during any 12-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 commissioner if it is increasing the wholesale acquisition cost 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 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 with a justification that includes all documents and research related to the manufacturer's selection of the cost increase or introduction price and a description of life cycle management, market competition and context, and estimated value or cost-effectiveness of the product.

(3) NET PRICES PAID BY PHARMACY BENEFIT MANAGERS. By March 1 annually, the manufacturer shall report to the commissioner 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.

(4) REBATES AND PRICE CONCESSIONS. By March 1 annually, each pharmacy benefit manager shall report to the commissioner the amount received from manufacturers as drug rebates and the value of price concessions, expressed as a percentage of the wholesale acquisition cost, provided by manufacturers for each drug.

(5) HOSPITAL MARGIN SPENDING. By March 1 annually, each covered hospital operating in this state shall report to the commissioner the per unit margin for each drug covered under the federal drug pricing program under 42 USC 256b dispensed in the previous year multiplied by the number of units dispensed at that margin and how the margin revenue was used.

(6) MANUFACTURER-SPONSORED ASSISTANCE PROGRAMS. By March 1 annually, each manufacturer shall provide the commissioner with a description of each manufacturer-sponsored patient assistance program in effect during the previous year that includes all of the following:

(a) The terms of the programs.

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

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

(7) CERTIFICATION AND PENALTIES FOR NONCOMPLIANCE. Each manufacturer and covered hospital that is required to report under this section shall certify each report as accurate under the penalty of perjury. A manufacturer or covered hospital that fails to submit a report required under this section is subject to a forfeiture of no more than $10,000 each day the report is overdue.

(8) HEARING AND PUBLIC REPORTING. (a) The commissioner shall publicly post manufacturer price justification documents and covered hospital documentation of how each hospital spends the margin revenue. The commissioner shall keep any trade secret or proprietary information confidential.

(b) The commissioner shall analyze data collected under this section and publish annually a report on emerging trends in prescription prices and price increases, and shall annually conduct a public hearing based on the analysis under this paragraph. The report under this paragraph shall include analysis of manufacturer prices and price increases, analysis of hospital-specific margins and how that revenue is spent or allocated on a hospital-specific basis, and analysis of how pharmacy benefit manager discounts and net costs compare to retail prices paid by patients.

(9) ALLOWING COST DISCLOSURE TO INSURED. The commissioner shall ensure that every disability insurance policy that covers prescription drugs or biological products does not restrict a pharmacy or pharmacist that dispenses a prescription drug or biological product from informing and does not penalize a pharmacy or pharmacist for informing an insured under a policy of a difference between the negotiated price of, or copayment or coinsurance for, the drug or biological product under the policy and the price the insured would pay for the drug or biological product if the insured obtained the drug or biological product without using any health insurance coverage.

SECTION 9123. Nonstatutory provisions; Office of Commissioner of Insurance.

(1) PRESCRIPTION DRUG COST SURVEY. The commissioner of insurance shall conduct a statistically-valid survey of pharmacies in this state regarding whether

the pharmacy agreed to not disclose that customer drug benefit cost sharing exceeds the cost of the dispensed drug.

(END)