Ficek, Andrew - SClerk5 - SHMS - SWFD

From: Lee, Judy E.
Sent: Tuesday, April 22, 2025 12:23 PM
To: Ficek, Andrew - SClerk5 - SHMS - SWFD
Subject: FW: SB 2370 Background information

Please make copies for our conference committee tomorrow.

Senator Judy Lee
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From: Don Larson <Don@dakotastrategies.com>
Sent: Tuesday, April 22, 2025 10:12 AM
To: Lee, Judy E. <jlee@ndlegis.gov>
Subject: SB 2370 Background information

Senator Lee,

As I mentioned to you, PhRMA has some concerns with the reporting requirement that are currently in SB 2370. It is unclear to us what the intent is behind the requirements. When compounded by annual reporting requirements, the sheer amount of data that will have to be reviewed and summarized by the state is more than proves beneficial to public consumption.

- Information regarding clinical trials is vast and already public under clinicaltrials.gov. The amount of data on the government website is enormous and up to date. It is duplicative to have the state also collect such a vast amount of data. See below for more details:
  - The bill requires manufacturers provide "all trial data" for any program drug. Up to date information on clinical research studies and their results are available on clinicaltrials.gov which is a public website. In addition, Manufacturers are required to include information about clinical trials in their Prescribing Information as part of the drug approval process. The prescribing information is publicly available and contains a summary of the essential scientific information needed for the safe and effective use of human prescription drugs.
  - The current wording of the bill appears to require the actual trial data and not just information about studies which could not only significantly expand the amount of information that would be required to report but also potentially have confidentiality implications. There are federal requirements that protect the confidentiality of clinical trials data.
  - This is not only duplicative, it is unclear what a summary of the information even looks like. Will they just say "there are X number of studies" for a drug or will they be expected to interpret the trials information in some way which would require an extensive amount of work on the part of the Department.
  - Also, it is unclear how this relates to 340B.

- Information regarding tax incentives and grants could be extensive and intense in its reporting. Many times these types of incentives go down to the research and discovery of a single molecule or development mechanism that initiates the progress to the end product. It's not necessarily a 1 grant for 1 product ratio.

- Rebate information is confidential and would require an extreme amount of scrutiny to protect the confidentiality of this information. It is unclear what the intent is of sharing this information.

Below is list of data submitted by drug manufacturers to CMS. Data that CMS makes publicly available following manufacturer reporting, or that otherwise is generally publicly available, are noted in red.

Program	Data	Frequency
Medicare Part B	Manufacturers must submit product and financial data on a quarterly basis. For each NDC, the following *product* data must be submitted, per the Medicare Part B Average Sales Price Module – Submitter User Guide: • Manufacturer Name • Brand name vs. generic name • Volume Per Item • Unit for Volume Per Item • Number of Items Per NDC • Package Type • Strength • Unit for Strength • FDA Application Number • FDA Application Supplement Number (if applicable) • FDA Approval Date • First Marketing Date • Date of First Sale • Wholesale Acquisition Cost The following *financial* data must be submitted, per the same guide: • Manufacturer's ASP (*ASP is published and would directly reflect the manufacturer reporting for brand products; would be blended for multiple source innovator products) • Number of ASP Units • Wholesale Acquisition Cost • Average Wholesale Price (not required, but may be provided)	Quarterly. 42 C.F.R. § 414.804(a)(5)
Medicaid Drug Rebate Program	Each month, the following pricing information must be reported for each covered outpatient drug ("COD"): • AMP • AMP Units • 5i Drug • 5i Threshold Each quarter, the following pricing information must be reported for each COD:	Quarterly, except AMP also is reported monthly. 42 C.F.R. § 447.510

- AMP
- Best Price
- Initial Drug Available for LE (Note: cannot be entered or updated by labeler independently)
- Initial Drug (Note: cannot be entered or updated by labeler independently)
- Base AMP Used for URA
- Nominal Price
- Customary Prompt Pay Discount

The Medicaid Drug Programs system calculates URAs based on this pricing information.

In addition, each quarter, the following drug product data are reported under the Medicaid Drug Rebate Program, for each COD (this is publicly available here):

- Labeler Name
- NDC
- Package Size Code
- Drug Category
- Drug Type
- Termination Date
- Unit Type
- Units Per Package Size
- FDA Approval Date
- Market Date
- FDA Therapeutic Equivalence Code
- Clotting Factor Indicator (Note: cannot be entered or updated by labeler independently)
- Pediatric Indicator (Note: cannot be entered or updated by labeler independently)
- Package Size Intro Date
- Purchase Product Date
- COD Status
- FDA Application Number
- Reactivation Date
- Line Extension Drug Indicator (Note: a COD's status as a line extension is public, but the identity of the initial drug of the line extension and whether an initial drug is available for the line extension are not public; line extension indicator cannot be entered or updated by labeler independently)

The definitions for these drug product data are provided by CMS here.

Medicare Drug Price Negotiation (Part B and Part D)	Manufacturers must submit the following data elements:
	• Selected drug information
	  ○ Product name
	  ○ NDC-11
	  ○ Whether the drug is marketed and controlled solely by a manufacturer that is not the primary or secondary manufacturer
	  ○ Whether NDC is sample package
	  ○ Whether NDC is Inner Package
	  ○ Whether NDC is Outer package
	  ○ Whether NDC is Private Label
	  ○ NCPDP unit
	  ○ Total NCPDP units per package
	  ○ AMP unit
	  ○ Total AMP units per package
	• Non-FAMP data
	  ○ Non-FAMP for calendar year and calendar quarters
	  ○ Total non-FAMP package volume
	• R&D costs and recoupment
	  ○ Acquisition costs for selected drug
	  ○ Total acquisition costs
	  ○ Basic pre-clinical research costs for all FDA-approved indications of the selected drug
	  ○ Direct and indirect research expenses for selected drug
	  ○ Post-IND costs for approved indications of the selected drug
	  ○ FDA expedited program (often publicly available)
	  ○ Costs of allowable abandoned or failed products related to the selected drug
	  ○ Costs of other R&D for the selected drug not accounted for above
	  ○ Global and U.S. total lifetime net revenue for the selected drug
	• Current unit costs of production and distribution
	  ○ Average per-unit production costs
	  ○ Average per unit distribution costs
	  ○ NCPDP unit
	  ○ Total unit volume
	• Prior federal financial support
	  ○ Total federal financial support
	  ○ Agreements between manufacturer and federal government
	• Patents and exclusivity
	  ○ Patent number and date filed
	  ○ Expiry data
		Generally, once a drug is selected, but manufacturers may need to report restated pricing metrics. 42 U.S. Code § 1320f-2(a)(4)

	○ Patent type ○ Whether patented product is commercially available (while not listed in Orange book, this is generally available through other sources) ○ Whether previously/currently listed in orange/purple book ○ Type of exclusivity and expiration date ○ Application number, classification code, approval date ○ NDC-9s covered by exclusivity ○ Indication ○ Dosage form and strength ○ Sponsor ○ Application status of pre-approval applications • Market data and revenue and sales volume data ○ WAC ○ NCPDP Unit ○ Total unit volume ○ Best price ○ AMP unit ○ FSS price ○ Big Four price ○ US commercial average unit net price ○ US commercial average net unit price net of PAPs ○ US commercial average net unit price - best ○ Total unit volume for US commercial average net unit price - best ○ Manufacturer net Medicare Part D average unit price ○ Manufacturer net Medicare Part D average unit price – best ○ Total unit volume for net Medicare Part D unit price – best • Evidence of alternative treatments (optional)	

Thanks,

Don

DAKOTA STRATEGIES

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