Cost Transparency – Prescription Drug (CTRx)
Workshop 2 – Data Submitters
4/11/2018
Outline and Summary

CTRx Workshop 2 Outline

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CTRx Workshop 2 Summary

OSHPD Background and Introduction to SB 17

The Office of Statewide Health Planning and Development (OSHPD) department has been collecting hospital and skill nursing annual financial data since 1975. Over the years, the department has included the collection of hospital quarterly financial and patient-level discharge data, nonprofit hospital community benefit reporting, coronary artery bypass graft information, patient-level emergency department and ambulatory surgery data, and more.

In October 2017, OSHPD was charged with the collection and reporting of prescription drug cost information resultant of the signing of California Senate Bill (SB) 17 (Chapter 603, Statutes of 2017) into law. SB 17 seeks to increase prescription drug cost transparency by requiring drug manufacturers to provide advance notification to public and private purchasers before a specified cost increase occurs.

Effective January 1, 2018, drug manufacturers must provide 60-day notice to specified public and private purchasers before a wholesale acquisition cost (WAC) increase takes effect where such increase would exceed 16 percent across the proposed increase and the cumulative increases that occurred with the previous two calendar years prior to the current year.

Beginning January 1, 2019, drug manufacturers must provide additional information to OSHPD related to cost increases that met the requirements of the 60-day notice, on a quarterly basis. Additionally, manufacturers must provide data regarding new prescription drugs with an initial WAC that exceeds the threshold set for a specialty drug under the Medicare Part D program (currently $670 per month) within three days after the release of the drug into the commercial market, and with further detail within 30 days after initial notification.

SB 17 allows drug manufactures to limit information to what is in the public domain or otherwise publicly available. Manufacturers that do not comply with SB 17 are subject to a $1,000 per day civil penalty. OSHPD will publish data received from manufacturers on its website beginning Spring 2019.

In conjunction with the information submitted by drug manufacturers relating to prescription drug cost increases, health plans and insurers must provide information to state health plan and insurer regulators for the 25 most frequently prescribed drugs, the 25 most costly drugs by total annual plan spending, the 25 drugs with the highest year-over-year increase in total plan spending, and any other aggregate data on the impact of drug costs to large group health care plans and health insurance policies by October 1, 2018 and annually thereafter.

CTRx Workshop 2 Synopsis

On April 11, 2018, OSHPD welcomed representatives from drug manufacturers, pharmaceutical representatives, research fellows, and advocacy groups to participate in a Prescription Drug Cost Transparency (CTRx) workshop and provide input and feedback related to the proposed process of data submission related to SB 17.

The public meeting was held at the OSHPD Conference Center and included a panel of invited guests from OSHPD, the California Department of Managed Health Care (DMHC), Boehringer Ingelheim, Bristol-Myers Squibb, Pharmaceutical Research and Manufacturers of America (PhRMA), and California Life Sciences Association (CLSA).

Scott Christman, Deputy Director and Chief Information Officer of the Information Services Division at OSHPD, opened the meeting with an overview of the OSHPD organization and a synopsis of SB 17. Pritika Dutt, Deputy Director of the Office of Financial Review at DMHC, spoke on the reporting requirements for the Health Insurer component of the bill. Bobbie Wunsch, workshop facilitator from Pacific Health Consulting Group, provided the overall workshop objectives and encouraged industry representatives to engage in robust conversation during the question and comment portions of the presentation.

Ty Christensen, Health Program Audit Manager at OSHPD, opened the definitions section noting the definitions proposed for regulations were recognized definitions from credible sources and that some definitions were adaptations to meet the requirements of SB 17. Jim Jones, a pharmaceutical industry subject matter expert and consultant for OSHPD, introduced 11 definitions of terms taken from or related to SB 17 that will be used in drafting regulations to support the Bill.

After reviewing definitions, Mr. Christensen and Mr. Jones outlined data elements specified in SB 17, including drug identifiers and cost, supporting information, marketing/pricing plan description, and cost change rationale. The speakers discussed drug manufacture and baseline data, Wholesale Acquisition Cost (WAC) history and acquisition data, WAC increase data, and new prescription drug data, as well as the ability for manufacturers to provide supporting documentation related to the structured data that is submitted. Further, it was conveyed that OSHPD is in the process of procuring the Medi-Span Electronic Drug MED-File v2. The file is an electronic drug dictionary of prescription drugs and over-the-counter products that will be used to strengthen reporting and compliance validation.

Following the discussion of data elements, OSHPD shared the proposed data submission process. Mr. Christensen noted an OSHPD web portal, currently used for healthcare data collection, would be updated to provide similar functionality for SB 17 data submitters. Mr. Christensen and Mr. Jones discussed and answered questions regarding the registration of manufacturers and user credential provisioning, as well as the collection, submission, validation, review, and publication of the submitted data.

Geoffrey Trautman, OSHPD Attorney, finished the presentation with a review of compliance requirements and non-compliance penalties prescribed by SB 17. Mr. Trautman, along with Mr. Christensen and Mr. Jones, responded to participant comments regarding registered users, penalties, and consistencies between First Databank, Medi-Span, and the data the manufacturers would be submitting.

In closing, Mr. Christman opened the floor for input from members of the general public with each speaker allotted one minute for comment. One public comment was made regarding perceived inconsistencies in OSHPD's implementation of the 60-day notification for purchasers and the quarterly data submission Sections of SB 17, as well as a recommendation for OSHPD to consider having all the registered purchasers re-register and certify under registry curation guidelines recently updated by OSHPD.

CTRx Workshop Definitions

OSHPD solicited questions and comments from panel guests as definitions were introduced. A summary of each definition along with participant questions and/or comments is provided in the table below:

Phrase	Definition	Public Question/Comment
Prescription Drug	A FDA-approved drug only available as prescribed by an authorized licensed health care professional, and intended to be used by one person. **SOURCE:** adapted from fda.gov	• No comments provided
Breakthrough Therapy Designation	Applies when a drug is: (1) intended alone or in combination with one or more drugs to treat a serious or life-threatening disease or condition and (2) preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies. **SOURCE:** fda.gov	• Consider the producer date or acceleration date in the definition. Those factors are considered benefits of being awarded a breakthrough designation, manufacturers get their drug approved at a faster rate. A minor modification made to a new product launch, like package size, can change but the product stays the same. Might help with the new drug and 11-digit NDC as well.
Drug Product	A finished dosage form, as in a tablet, capsule, or solution, that contains a drug substance, generally, but not necessarily,	• Some drugs are inhalers, but the definition does not call those out specifically. Consider adding inhalation medications to the definition.

	in association with one or more other ingredients. **SOURCE:** Code of Federal Regulations, Title 21, 314.3	
Single Source Drug	A covered outpatient drug that is produced or distributed under an original New Drug Application (NDA) approved by FDA. **SOURCE:** United States Code, Title 42, Section 1396r-8(k)(7)(A); Code of Federal Regulations, Title 42, 447.502	• No comments provided
Multiple Source Drug	For a rebate period, a covered outpatient drug for which there is at least one other drug product which meets the following criteria: (1) Is rated as therapeutically equivalent as reported in the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" (2) Is pharmaceutically equivalent and bioequivalent, as determined by the FDA (3) Is sold or marketed in the United States during the rebate period. **SOURCE:** United States Code, Title 42, Section 1396r-8(k)(7)(A); Code of Federal Regulations, Title 42, 447.502	• No comments provided
Innovator Multiple Source Drug	A multiple source drug that was originally marketed under an original new drug application (NDA) approved by FDA. **SOURCE:** United States Code, Title 42, Section 1396r-8(k)(7)(A); Code of Federal Regulations, Title 42, 447.502	• No comments provided
Noninnovator Multiple Source Drug	(1) a multiple source drug that is not an innovator multiple source drug or a single source drug; (2) A multiple source drug that is marketed under an abbreviated antibiotic drug application; (3) A drug that entered the market before 1962 that was not originally marketed under an NDA; (4) Any drug that has not gone through an FDA approval process, but otherwise meets the definition of covered outpatient drug.	• No comments provided

	SOURCE: United States Code, Title 42, Section 1396r-8(k)(7)(A); Code of Federal Regulations, Title 42, 447.502	
Manufacturer	Any entity that holds the NDC for a drug or biological product and is engaged in the production, preparation, propagation, compounding, conversion, or processing of drug products; or is engaged in the packaging, repackaging, labeling, relabeling, or distribution of drug products and is not a wholesale distributor of drugs or a retail pharmacy licensed under State law. **SOURCE:** Code of Federal Regulations, Title 42, 447.502	• No comments provided
National Drug Code (NDC)	The numerical code maintained by the FDA that includes the labeler code, product code, and package code. A drug's NDC number is typically expressed using 11 digits in a 5-4-2 format (xxxxx-yyyy-zz) where the first five digits identify the manufacturer, the second four digits identify the product and strength, and the last two digits identify the package size and type. **SOURCE:** Code of Federal Regulations, Title 42, 447.502	• The note regarding the NDC numeric format will not be included in the regulations. • There was concern that use of the 11-digit NDC, rather than the 10-digit, could be an administrative burden. • Medi-Span uses the 11-digit NDC, which will help with the one-to-one comparisons for coding and prepopulating information. OSHPD wants to make it easier to track form, strength, size. OSHPD is not asking for descriptive information, but wants one-to-one codes that can be used to identify a drug by NDC.
Wholesale Acquisition Cost (WAC)	A published catalog or list price for a drug product to wholesalers as reported by the manufacturer. **SOURCE:** First Data Bank, Drug Pricing Policy (http://www.fdbhealth.com/policies/drug-pricing-policy)	• No comments provided
Medicare Part D Specialty Drug Threshold	An established dollar-per-month threshold above which drugs with sponsor-negotiated prices are eligible for specialty tier placement. The current threshold is set at $670. **SOURCE:** Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (PL 108-173, December 8, 2003, 117 Stat 2066); Code of Federal Regulations, Title 42, Section 423.578(a)(7)	• No comments provided

General Comments for Definitions

The following comments were made by workshop participants following the review of definitions:

- OSHPD may want to consider adding the definition of "New Prescription Drug" as the first drug to be defined/approved under an NDA. The definition should consider the intent of SB 17. The definition should be consistent with California law.
- There is a concern that new package sizes or strengths of a drug product could be considered a "new prescription drug." The definition of "new prescription drug" could alleviate the issue (speaking to 11-digit NDCs).
- Suggest adding definitions for "Data Recipient," including entities eligible to receive the data / entity acting on behalf of a state purchaser and what is considered permissible uses of the data. Might not be appropriate for definitions, but greater clarity to permissible use and eligible entity is desired.

Data Elements

OSHPD solicited questions and comments from panel guests as data elements were introduced. A summary of each data element and corresponding participant questions or comments is provided in the table below:

Category	Data Element	Public Question/Comment
Baseline Data	In addition to manufacturer submitted data, OSHPD has procured the Medi-Span Electronic Drug File v2. The file is an electronic drug dictionary of prescription drugs and over-the-counter products that will be used to strengthen reporting and compliance validation.	• There was a question regarding the baseline date for when the 16% price increase threshold would be calculated. This will be addressed in regulations. • OSHPD will use the Medi-Span Electronic Drug MED-File v2 for comprehensive price history file. Also looking at Medical conditions and medical indications.
WAC Cost Increases - Summary	For WAC cost increases, manufacturers will be required to provide OSHPD with a comprehensive summary of the item and include: • NDC Number • WAC Effective Date • WAC Amount • Item Description • Description of Decisioning Factors • Patent Expiration Date – as applicable • Drug Source Type • Change / Improvement Description – as applicable • US Sales Volume (Units) - Previous Calendar Year	• If drug identifier is by NDC, what about NDC switches for formulation change or package change? • In the mentioned fields, will there be a link to a portal to those documents? How would these documents be associated within the summary and displayed for the data users? • Documents will be available by link alongside the raw data elements. • OSHPD can link documents to individual NDCs so users could select an NDC and have access to the document. Or, users can download an Excel spreadsheet with all the NDCs and explanations in the text field.

		• Will the templates be made publicly available to users? • Structured templates will be available. Users will have the option to upload via a report without keying everything in, or users can manually enter the data. Data may be prepopulated, if that is helpful to the data submitter.
WAC Cost Increases – History	For WAC cost increases, manufacturers will be required to provide OSHPD with a five-year history of the item and include: • NDC Number • WAC Effective Date • WAC Amount	• No comments provided
WAC Cost Increases – Drug Acquisition	For WAC cost increases for drugs acquired by another manufacturer, the current manufacturers will be required to provide OSHPD with drug acquisition information and include: • NDC Number • Acquisition Date • Company from Which Acquired • Acquisition Price • WAC at Acquisition • WAC Calendar Year Prior to Acquisition • Year of Market Introduction • WAC at Market Introduction	• What you paid for as an individual drug versus a suite of drug products and/or what other components go along with acquisitions that factor into cost. May be difficult to parse out the acquisition of what you paid for an individual drug versus what you paid for the entire company during a merger. • It is difficult to identify when one particular clinical asset begins and another ends with the acquisitions of NDCs. There may not be a one-to-one relationship between what was acquired versus what then becomes available on the market. • Would it be valuable for OSHPD to include an open descriptor field to include supplementary information on acquisitions? This would provide additional flexibility to manufacturers. • What about HCPCS (Healthcare Common Procedure Coding System) codes? Are they included in the Medi-Span data? • If two pharmaceutical companies merge is that considered an acquisition? • . • Information in acquisitions may be subject to non-disclosure clauses. It may be difficult to determine the purchase price of an individual drug.
New Prescription Drug – Initial Notice	For new specialty drugs introduced to market with a WAC exceeding the specialty drug threshold, manufacturers will be required to provide initial three-day notice to purchasers and include: • NDC Number • Product Launch Date	• What qualifies as a “new drug”? Is it a new molecule? • “New Specialty Drug” is not necessarily limited to specialty because any drug that fits within the Medicare threshold will need to be reported.

	• WAC Amount	• If a manufacturer was launching multiple NDCs for one molecule, will they need to report on each of those values? • Will a new dose of an existing drug count as a new drug?
New Prescription Drug – Item Summary	For new specialty drugs introduced to market with a WAC that exceeds the specialty drug threshold, manufacturers will be required to provide a follow-up 30-day summary to specified purchasers and include: • NDC Number • Marketing/Pricing Plan Description • Estimated Patient Volume Units • Breakthrough Therapy Indicator • Priority Review Indicator • Acquisition Date – as applicable • Acquisition Price – as applicable	• A new formulation may not have a separate marketing or pricing plan. Perhaps OSHPD can add an indicator or allow the ability to indicate the marketing plan applies to the entire family of items / NDCs related to a molecule. • OSHPD can make it so that the data elements include a “Not in the Public Domain” box that the user can check. This will indicate that the data element was left blank because the information is not in the public domain. • OSHPD will provide flexibility for the documents that are required to be submitted.
Document Management	In addition to the structured data requirements of the law, manufacturers will have the ability to attach supporting documentation for WAC cost changes and new prescription drugs. Documents collected will be associated with item summary records that have been provided.	• No comments provided

Data Submission Process

OSHPD solicited questions and comments from panel guests as data the data submission process was proposed. A summary of each data submission step and corresponding participant questions or comments is provided in the table below:

Category	Data Element	Public Question/Comment
Existing Data Submission Platform	OSHPD currently uses a web portal to collect, validate and collaborate about data required for submission by healthcare systems at a frequency prescribed by statute. This system will be updated to provide similar functionality for SB 17 data submitters.	• No comments provided
Registration	In the Fall of 2018 manufacturers will be invited to register for access to the data portal. As part of the registration process, organizations and representative system users will be vetted, and login credentials will be provided after OSHPD review. During Q4 2018, OSHPD will provide access to user guides and make available contact information for user support and technical assistance.	• The number of users a company may have will not be limited. Companies can self-maintain with a primary user who will be able to add/remove permissions for other users within a manufacturing company. There are cases where the last user added is no longer with the company. In those cases, the manufacturer can work directly with OSHPD to get the user removed and add a new designated user. • There was mention of a vetting process, what protections are being put in place to verify a manufacturer identity. We don't want someone impersonating a manufacturer and uploading price changes, for example. • OSHPD is working to develop a process to authorize users to submit data. The users will likely have to have a company email to register. • It would be helpful to manufacturers to be able to see who a company's vetted, registered users are.
Collection Timeline	Beginning January 1, 2019 and April 1, 2019, for new prescription drugs and WAC increases respectively, manufacturers will be able to access the data portal and provide item information online (one record at a time) or using structured data templates for offline completion and upload. • Notification of new drugs is due within three days of introduction to market.	• For January 1 through March 31, the time to report would be before the end of April; however, users don't have to wait until the end of the quarter to submit. • Price increases only need to be reported for the quarter in which they occur. • The onus is on the manufacturers to report decreases if they want the public to have access to that information.

	• New drug information is due within 30 days of notification of introduction to market. • WAC increase information reported quarterly based on increases during that calendar quarter. • Due date for WAC increase information will be the end of the month following the calendar quarter.	
Data Submission Process	To the extent possible, the data portal will pre-populate existing data elements (item description, source type, etc.) and allow users to confirm accuracy or make applicable modifications. As information is entered, users will have the ability to upload supporting documents for association with one or more records. Information provided may be limited to what is in the public domain or otherwise publicly available; however, users will be asked to indicate that any data elements not provided are not currently in the public domain.	• For example, users will have the ability to attach SEC findings, annual reports, etc. • The data submission is by both report and by company. Users will be able to specify NDCs that they are uploading and submit all of the NDCs at one time. A report is a batch of NDC records. A company may submit multiple reports with various NDCs. • Indicating proprietary information is something to do only if you leave a field blank or receive a critical error when submitting. • OSHPD has the ability of associating NDCs and information one-to-one, one-to-many, or many-to-many within the system.
Data Validation	Once data has been entered and saved, the data portal will perform data validations to check that information is complete and meets formatting requirements. Records that do not pass validation constraints will be flagged for user remediation or explanation. Validation errors may be corrected or explained on a record-by-record basis, and users have the ability to log on and off intermittently during the correction process. Once all edits have been satisfied, users may officially submit records, certifying all information to be true and correct to the best of their knowledge.	• No comments provided
Submission Review	After records are submitted, they are reviewed by OSHPD staff to ensure that all validation issues have been sufficiently addressed. Where issues remain, OSHPD staff may apply additional validation notes and notify the submitter that records require additional attention. Submitters may then log into the	• OSHPD staff will review for completeness. OSHPD staff will not review and approve the justification for raising cost. If a manufacturer were to accidently upload the wrong file, OSHPD staff will provide the submitter the chance to correct it.

	data portal, provide adjustments or explanations, and resubmit.	• OSHPD will contact the person that submitted the information, not the main point of contact for the company.
Data Publication	Reports that satisfy all validation requirements are marked final and accepted by OSHPD staff, making report data available for publication as prescribed by the SB 17. Users may continue to access reports that have been marked final and accepted but cannot make additional changes. Data will be available in a structured, machine readable format at the level of data granularity provided. Unstructured data submitted in the form of documents will also be available for public retrieval. Additionally, reports that provide summary information or allow users to filter by item attributes may be made available. OSHPD continuously evaluates the value and effectiveness of all its reports and data products.	• No comments provided

General Comments for Data Submission Process

The following comments were made by workshop participants following review of the data submission process:

- OSHPD will make the system as user-friendly as possible. The system is flexible and OSHPD will be able to adapt quickly to add new “not publicly available” fields as necessary.
- OSHPD wants to work with some of the manufacturers that would be interested in testing the product and providing feedback when the development is complete. OSHPD wants to make sure the workflow makes sense to data submitters.

Compliance and Penalties

After the data submission process, OSHPD reviewed the compliance and penalty section of SB 17 from the Health and Safety Code Sections 127679(e)-(f), 127681(f)-(g). The following comments were made during the compliance and penalties section:

- Penalties begin accumulating after the last date that the submission is due. Late submissions will be assessed to the manufacturers via a letter. If an appeal is received, a hearing will be conducted by an OSHPD hearing officer. Appeals must be submitted in a timely manner or the penalty amount is final.
- An example of being penalized would be if a new drug to market is failed to be reported. Time starts at the day the report is overdue and stops at the time of reporting is submitted.
- OSHPD is working on how to identify individual points of contact within each company. OSHPD would like feedback to best create a contact individual or authorized official. Under the OSHPD facility data program, often there is a facilitator who helps with collecting the data but is not the same individual whom to contact about issues related to late submission and penalties.
- It can be helpful to have one authorized person per company who could approve additional users to submit data. It would be good to have a designated list of appropriate contacts per manufacturer.
- Most manufacturers have a chief compliance officer role who is responsible for responding to data requests. Trade associations can ask for their feedback specifically and provide for their members.
- The in-house appeal process makes OSHPD flexible in responding to and resolving compliance issues.
- OSHPD does not publish the penalties, but they are publicly available if someone were to submit a public records request for them.
- Medi-Span data will be updated monthly to start, but it could update it to be more frequently as needed.
- Medi-Span provides some basic labeler data, which provides a starting point to be able to reach out and see if the manufacturer is part of a larger company.
- What about NDC switches? Is there a drug history for NDCs? How would OSHPD manage records of obsolete products that have been replaced?
- There is item switch data in Medi-Span that OSHPD will use to track item switches.

- NDCs are tied to a company so if a product was moved to another company that would be considered a new NDC. If a component changed in the compound of the drug, the drug could change NDCs. These would be identified as switches that Medi-Span tracks. SB 17 requires facility-specific five-year history. OSHPD has a mapping of changes that go across NDCs. This data will most commonly be used in pre-population.
- How does the process work now with hospitals and penalties? For other penalties that OSHPD enforces, penalties were more prevalent earlier on in the process, but decreased over time as users became more adept to the process.
- Reporting is at the item level. The report is the container for records or items. Each NDC would have its own triggering information. Each submission may have the same data elements and submission. OSHPD will try to make this as least onerous as possible, but it appears via the statute that the triggering event is at the item level.
- Through the appeal process, OSHPD does have the appeal process and can take into account during the appeal the circumstances of the suspected violation.
- Does the manufacturer need to have a match between an NDC and a WAC price? In the case of samples, they may have an NDC, but there is no WAC price, are they subject to penalties?
- If items have no WAC value, then those items are not subject to penalties. If there is no WAC, there is nothing to report on.

Public Comment

At the end of the presentations, OSHPD opened the floor for public comment and allowed workshop participants to share additional remarks. The following comment was captured during the public comment period:

- Sidley Austin - Thanks for allowing manufacturers to make a public comment. There is some asymmetry between the 60-day notification to purchasers versus how the quarterly data submission is being implemented by OSHPD. The law empowers OSHPD to provide guidance for anything under Chapter 9. Also wanted to note that the vetting process for eligible entities to receive the 60-day notice has been updated for new registrants, but OSHPD should consider having the people who registered before the change reregister and recertify under the new process now that all the fields listed are mandatory.

Closing

In closing the meeting, OSHPD reviewed next steps for the CTRx project team, which included reviewing feedback provided during the workshop and the public comment period. OSHPD also noted that an informal open public comment period would be available until April 20, 2018 for consideration if workshop participants wanted to submit any other feedback.

Additionally, OSHPD will continue drafting regulations and will provide formal notice in July 2018. There will be a public comment period during Summer 2018.

Additional Feedback Provided via Email

At the close of the workshop, we requested any additional feedback that attendees would like to provide be sent to OSHPD via email. Below is a summary of the email comments received as of April 20, 2018.

- Recommend definition of new prescription drug: “the first drug product to be approved under an original New Drug Application (NDA), Biologic License Application (BLA) or Abbreviated New Drug Application (ANDA).
- Suggest reporting be required by drug family rather than NDC; this would be easier for data submitters and for data users.
- NDC numbers may be reassigned after five years. This may be confusing for users and be a technical barrier to maintain data accuracy with NDC history.
- There is a concern about relying on Medi-Span’s historical mapping process for obsolete drug codes.here is a concern that an overly-broad interpretation of “state purchaser” related to entities acting on behalf of a state purchaser could make the 60-day notification unduly burdensome.
- Suggest that OSHPD provide guidelines for purchaser registration eligibility and the use by registered purchasers of advance notice information.
- Suggest that OSHPD apply 10-digit NDC standard for applying penalties. This suggestion is based on the concern regarding the diversity of product packaging that results in 11-digit NDCs for a similar prescription drug product.
- Suggest OSHPD clarify the WAC increase period subject to reporting.
- There is a concern that some reporting elements that require narrative responses may be ambiguous, such as Item Description, Cost Change Reason Description, and Marketing/Pricing Plan Description.
- Suggest the reporting system provide prescription drug manufacturers the ability to explain the pricing methodology used.
- Flexibility in timing for quarterly reporting is important.
- There is a concern regarding how Medi-Span will be used to validate WAC increases in accordance with the law.