Health Care Cabinet
Pharmacy Pricing Workgroup
Meeting Summary
Friday, September 15, 2017
10:00 a.m. – 11:30 a.m.
Office of the State Comptroller - 55 Elm St. Hartford CT
3rd Floor Conference Room F
and online via https://zoom.us/j/727249552

Members Present: *Chair* - Josh Wojcik, Policy Director, Office of the State Comptroller; Sarah Emond, Executive Vice President and Chief Operating Officer, Institute for Clinical and Economic Review (ICER);

Members Via Video Conference: Ellen Andrews, Executive Director, CT Health Policy Project; Robert Clark, Special Counsel, Office of the Attorney General

Other Participants: Tahar Thompson, Exec. Director, Govt Afffairs, Bristol-Myers Squibb; Audra Edele, Director, Contracts, Boehringer Ingelheim; Andrew Zebrak, Exec. Director, Govt. Affairs, Boehringer Ingelheim; Leslie Bennet, National Organization of Rare Diseases, Consumer Advocate; Tim Shea, Boehringer Ingelheim; Joe Oros, AbbVie Inc.; Anita Schepker, Schepker & Associates, LLC; BMS; Jessica Tyburski, Schepker & Associates, LLC; BMS; Paul Pescatello, CBIA; Sandra Czunas, Assoc. Health Care Analyst, Office of the State Comptroller; Sarah Emond, Executive Vice President and Chief Operating Officer of Institute for Clinical and Economic Review (ICER)

1. Welcome and Introductions

The Chair opened the meeting at 10:05 a.m. and participants introduced themselves.

2. Public Comment

No public comment

3. Presentation on Value Based Purchasing Arrangements & Discussion

Tahar Thompson, Exec. Director, Govt. Affairs, Bristol-Myers Squibb (BMS) read a prepared statement on the mission, vision and focus of BMS in value based contracting (VBC)

Josh Wojcik: recommend presenters take questions once they've finished their presentations.

Audra Edele, Director, Contracts, Boehringer Ingelheim (BI), read a prepared statement on BI's goals and focus on its VBC and highlighted the complexity of measuring outcomes. Data may be able to measure the outcomes of some drugs, but not all drugs. Stated medical claims data is not always available.

Sarah– Learned that patients are often paying full co-insurance on full price not price net of Sarah rebate and where there are outcomes based contracts, where a refund is realized later, the patient only gets their co-insurance back. Have you heard of this issue and thought about creative ways to get the PBMs to think more about the patient when where we are thinking of these innovative contracts?

Tamar: PBMs are customers as well so it's an interesting dynamic, pharma and bio have done a lot of work in outlining the structure of the supply chain and how the system works. In certain instances such as Medicare, PBMs are required to share savings, but in other environments that requirement is not there. We are supportive of the patient sharing in the value and cost savings when there.

Audra - Of course we have this issue. We do have programs, patient affordability programs such as copay cards, patient assistance programs, that help patients with co-insurance, but understanding the complex structures PBMs use to create the formularies and cost structures is complicated. The more that plans and employers demand more transparency, that will evolve over time.

Sarah: recently at a national business group on health meeting – employers focused on this on a panel with CVS Caremark. "He was" shocked at how few employers ask for the product they have where they can give point of sale rebate information so that the co-insurance is adjusted. Employers in the audience did not seem to be aware of this. Believes there are mechanisms available to reduce the burden on the patient.

Anita: CT last year started down the path on a PBM bill, anti-gag, anti-claw-back

Josh: one component of a bill last year would have required that co-insurance be based off the net price. PBMs could already administer, pharma wanted to see the discounts go to consumers, consumer groups supported, but insurance stated their systems currently were not built to administer this.

Talking through some of the challenges raised – having the data available. PBMs don't always have the data but they are a primary negotiating partner. They must show they are holding trend down, and they also have shareholder concerns but direct payers - Self-insureds, have this information. At the state, we have a long term interest – there is low turnover in our population. We realize savings generated long-term and the Medicaid program is in a similar position. Looking at the state employee plan, negotiating smaller contracts may be burdensome on the manufacturer, but negotiating with the two or three largest PBMs, you are providing assistance to

Where do you see the most opportunity. Is it negotiating standardized contracts with the PBMs that their customers can sign onto having standardized data structures that they can feed up thorough the PBM, or are there opportunities for direct contracting (for example in large populations such as the state) where they may have a mutual interest

Audra: tricky to marry up all the interests. BI contracts directly with the PBMs, it is easier and the PBMs hold the buying power. When looking at contracts, it needs to be clear who is

getting the benefit. Need to also be clear about legal constraints. When going outside PBM framework, it's going outside the contract. Have explored using a template. When developing VBC concept, they buy data from a third party source, analyze results based on demographics, and develop a concept for a risk-sharing agreement. Using a template allows the PBM to pass it down to its customers. Data is an issue. Data they purchase may be very different from the state employee data, for example. The state may want to analyze data on its side. There may be a mistrust between payer and manufacturer that needs to be bridged. These are the complications around building a collaborative VBC. When both parties have the same interests and goals, it works better.

Tamar – transparency is a need. Having mechanisms – through legislation or policy requirements, stipulations or incentive for PBM, to share in having a transparent approach is something to add to the conversation. Examples – Medicare quality metrics – PBMs are often not penalized or sharing risk in meeting these metrics. Have found that a measure can be put in place and have a health plan, but the PBM may not be focused on this but are looking at the bottom line and cost and bringing savings to the immediate moment of the system and not looking at the long term duration, for a stable population for example like state employees and Medicaid. Recent federal regulations have allowed for having more data sharing, but in the past it has bene unclear about risks around sharing information and being penalized for doing so. More onus should be put on PBM as a stakeholder in the HC system to look at the broader spectrum the way the state or manufacturer does.

Josh: identified limitations around federal regulations on sharing clinical data and other things, are there other additional changes that you see as necessary to foster VBP?

Tamar: Yes – the manufacturer is being held to anti-trust, anti-kickback provisions at the federal level, unlike other stakeholders. There are government price reporting requirements having broad-based implications when putting together VBC. Until recently, being able to ask for extensions or unique circumstances was off the table. These challenges have prohibited the broadening of VBC arrangements into the broader population.

Sarah: Amgen appears to be able to work around best price requirements - giving full refunds which means best price is zero. There must be some work around.

Tamar: It depends on the population, how much is Medicare, Medicaid, indications drive this as well, recently, manufacturer entered into an arrangement with CMS for a Medicaid population, piloted arrangement. There are areas of opportunity for exceptions but when looking at larger spaces of chronic disease, cardiovascular or diabetes, and smaller disease states that are targeted population that are purely Medicare or Medicaid centric that are met with roadblocks. With a larger broader, largely commercial population – not Medicare, then different opportunities become available.

Sarah: also difficult when you have a second indication for an already use product, you may want two different prices but the mechanisms are not there.

Tamar: may not get FDA approval to do this.

Andrew: Changes with 21st century cures did expand definitions, giving more flexibility to share data with payers, but even with these improvements, still have legal and compliance departments wanting to do what is appropriate need more clear carve-outs and safe harbors that explicitly say these arrangements are ok. Further clarity would better enable this.

Josh: Does it simplify negotiations if PBM you're working with has a . . . relationship with their payers instead of traditional PBM model. Does this have any impact?

Tamar: answers are variable. There are PBMs owned by a larger entity that don't talk to one another and I've gone into meetings where they are meeting for the first time. Don't know if it's a parent-company relationship or a closeness by contract relationship that defines the ability to be transparent or more nimble and collaborative. It's more the incentives and how the relationships are put together when coming to the table.

Audra: Agrees. Business shifts over time and what we see is there's a need and desire for more transparency and for PBMs to become more flexible with their offerings and working with manufacturers to make sure providers are seeing the best outcomes for their patients.

Leslie: how much in e-scripts are controlled by (the PBMs) CVS, Medco

Audra: Cannot quote numbers . . .

Andrew: 80% managed by the top three largest

Leslie: hits us consumers at home when paying co-insurance based on list. I represent rare disease patients . . . young families being hit with $40-50K charges and can't manage them.

Josh: When considering candidates for VBP, what criteria are used to determine whether to engage?

Tamar: Disease state and population size play an important part in the ability to engage in a VBC solution**.** More limited in the scope for introducing this concept for a 1,300 patient population in rare disease versus a chronic, larger based population.

Sarah: VBC has a roll, but it's not for every drug. Nu alone, it's not the solution to the problem and will not put all the concerns about access and price to bed.
Audra: The issue also is the level of risk everyone on the continuum is willing to accept. Comorbidity also an issue - patients are not just diabetic or hypertensive and it's difficult to parse out performance.

Sandra: How is this done when looking at the claims data. What could be done to make the connection cleaner? There is no diagnosis code in Rx data.

Audra: Not easy to do – we have a department called HEOR . . . Health Economics Outcomes doing this work.

Sandra: What can we add to our data on the Rx side to make that connection cleaner?

Audra coding the data cleaner, standardize coding methodologies among EMR companies. The more we can match the data

Sandra: We don't have diagnosis info in Rx data

Tamar: Echos Audra's feedback. We need the ability to gather more information and share this across platforms and systems. Must have a better ability to capture the data, not just coding, but also data capture and quality metrics. This allows for better extraction by HEOR when looking at clinical data. When doing a data registry for clinical trials there are so many work arounds that have to be put in place to capture data using unlisted codes. Even with ICD 10, still don't have the deep level of complexity in the diagnosis coding to match up well with indications on drugs.
We could do a whole other day on this topic.

Josh: For participants on the phone – any other questions or comments?

Ellen: How long do you think it will take before these have an impact on spending or outcomes? If it's going to be longer than that, do you have other ideas on other tools, things happening in other states?

Tamar: Believes VBC are meaningful and are today making real impacts on health care costs. The challenge is that it's not a one-size-fits all. It will not do a sales flip and lower HC spending by 12% over a period of time. But it is one of many viable solutions to reshaping and reforming our health care system. This is one solution that should not be discarded due to the challenges and complexities. These complexities are due to part to antiquated policies, regulations or laws put in place that have not kept up with reform through ACA and other laws to reform healthcare. We should continue to fight to create that flexibility and updated solutions to move forward with VBC.

Andrew: These are two companies doing VBC and they are having an impact. It's an innovative solution. It's getting better with improved definitions from the federal government. With more experience, it may get easier over time. It's not a silver bullet but it's a good solution toward working on affordability and access.

Ellen: It would be great to get that in writing.

Tamar: Happy to share testimony

Josh: For clarification, were you thinking regulatory challenges to move forward?

Ellen: The issues around contracting challenges, trust, contract timing, the different populations, what it's appropriate for and not. What are challenges at the federal level – we cannot do much that, and at the state level, what those might be, it would help me as a committee member what piece of the puzzle this would work for.

Tamar: You say the federal level, that there's not much you can do – but as a state, to ask for flexibility under provisions of CMMI, or offering comments as a state, that is help that could be provided. We would support that as well.

Josh: Thanked the presenters – this was informative . . . asked the group if there was anything else. Asked the presenters if they could follow-up with some detail that will be used when considering recommendations on the place that VBC fits in.

5. Next Steps

The chair requested any additional comments and information be sent to him and he would disseminate to the group. These would be used to help with formulating recommendations. Presenters to provide their presentations.

The following entities will be asked to present in future meetings, specifically focusing on the list of questions the workgroup developed in their charge:
- State Medicaid Alternative Reimbursement and Purchasing Test for High-Cost Drugs (SMART-D)
- Harvard Pilgrim

The Chair will follow up with members to schedule the next meeting date.

6. Adjournment

The Chair adjourned the meeting at 11:00am