PRESCRIPTION DRUG AFFORDABILITY BOARD
VIRTUAL MEETING
Monday, May 24, 2021
Minutes

Chair Van Mitchell called the meeting to order at 2:01 p.m.

Board Members present: Van Mitchell, Joseph Levy, PhD, Eberechukwu Onukwugha, MS, PhD, Gerard Anderson, PhD, and George Malouf, MD. The Chair confirmed that a quorum was present.

AGENDA ITEM 1.

Approval of minutes

Chair Mitchell moved that the March minutes be approved as submitted. Dr. Malouf made a motion to approve the minutes, which was seconded by Dr. Onukwugha and unanimously approved.

AGENDA ITEM 2.

Policy Review, Presentation, and Discussion

Next, the Board received a series of presentations of different policy options regarding prescription drug prices and costs.

Delegate Bonnie L. Cullison – Review of Maryland's Reverse Auction System

Delegate Cullison opened the presentation with a review of the PDAB, noting it was created to provide the necessary information to address prescription drug affordability and rising costs. Next, Delegate Cullison provided the Board with a presentation of the Pharmacy Benefit Manager Marketplace, the reverse auction system discussed previously during the March Board Meeting. The intent of the PBM Marketplace was to optimize Maryland's drug spend. The inspiration for this entity comes from the State of New Jersey, whose reverse auction marketplace is predicted to save the state approximately $2.5 billion by 2022.

The PBM Marketplace will replace the current process through which DGS issues an RFP, through which PBMs make non-standardized bids. The new Marketplace will allow the State to set the terms of the pharmacy benefits contract, and provide for standardized comparisons across bidders based on certain financial and qualitative factors. DBM, DGS, and DoIT will procure a technology platform to complete analysis of certain needs, and establish a method for monitoring and comparing the bids. Delegate Cullison also noted the possibility of other public entities joining and benefitting from the Marketplace. Delegate Cullison explained that the PDAB can support the PBM Marketplace by providing assessments of the Marketplace's performance, and making additional recommendations to the General Assembly.

Sarah Emond – Institute for Clinical & Economic Review

Sarah Emond provided an overview of ICER's research, and recent work they've performed on drug pricing. Ms. Emond noted that the Department of Veterans Affairs has been using ICER's work for the past three years, and states have begun to engage ICER to help with drug pricing policies. For example, ICER worked with New York's Drug Utilization Review Board to provide support regarding clinical- and cost-effectiveness of certain drugs that exceed state-established caps or thresholds. ICER has also provided similar support to Massachusetts' Health Policy Commission. Ms. Emond noted that manufacturers have also used ICER's clinical- and cost-effectiveness work to proactively price their drugs, presumably to place pressure on payers.

Ms. Emond next explained ICER's work on unsupported price increases (UPI). This work was in response to states' frustration with annual price increases seemingly unsupported by any justification. ICER reviews these price increases and measures them against the clinical benefit the patient receives, finding a possible justification where a drug is demonstrating added benefits or fewer side-effects for patients. Through ICER's research of comparing price increases against existing evidence of efficacy, Ms. Emond explains, states can know whether certain price increases are justified.

Celia Segel & Sara Sadownik – Massachusetts Health Policy Commission

Sara Sadownik opened the presentation by discussing the roles and responsibilities of the HPC, and providing an overview of the research it has completed. Ms. Sadownik explained that the HPC was created in 2012, with the goal to reduce total health care spending growth across the commonwealth to meet certain benchmarking goals. In particular, the HPC has extensively studied drug spending trends, insulin price growth, specialty pharmacy use for physician-administered drugs, pricing practices by PBMs, and copay coupons.

Celia Segel continued the presentation, explaining the "MassHealth Process." This process may ultimately lead to a drug pricing review of certain drug products, if negotiations are unsuccessful. First, MassHealth negotiates with drug manufacturers for a supplemental rebate. Next, if negotiations are unsuccessful, MassHealth may propose a value for the drug in question, possibly soliciting public input regarding this value. If these negotiations fail to produce an agreement, the matter can be referred to the HPC for a drug price review. If referred, HPC notifies the manufacturer that it has been referred for review, and requests certain standardized information. After reviewing the information, HPC may propose a value or supplemental rebate for the drug, or determine whether the pricing is potentially unreasonable or excessive compared to the drug's value. If it reaches this determination, HPC conducts additional fact-finding and reviews to make a final determination of unreasonableness or excessiveness. Ultimately this review includes a review of the net benefits (*i.e.*, clinical benefits, societal benefit, unmet needs), information relating to pricing and costs (*i.e.*, comparative international pricing, alternative treatments, development and manufacturing costs), and other considerations. Ms. Segel also provided a comparison of two example cases, with supported reasoning, where the HPC might find a drug more or less likely reasonable.

No Action Needed

AGENDA ITEM 3.

Prescription Drug Affordability Fund – Update

Andrew York turned the Board's attention to the Prescription Drug Affordability Fund. Mr. York noted that the General Assembly overrode the Governor's veto of S.B 669 (2020), the Board's funding legislation, during the 2021 legislative session. Mr. York next provided an overview of the funding regulations necessary to carrying out the legislation, as well as a chapter focused on "General Provisions," which will grow over time. Mr. York also provided an overview of the regulatory promulgation process in Maryland before asking the Chair to take the vote.

Chair Mitchell asked for a motion to vote on whether to move forward with the regulatory process. Dr. Anderson made this motion, and Dr. Levy seconded. The Board voted unanimously in favor of moving forward with the regulatory process.

AGENDA ITEM 4.

Administrative Updates

Kris Vallecillo provided an overview of the 2021 legislative session, including the veto override and a bill that made the reporting dates for the Board's work more uniform with previously passed legislation (HB 1034). Mr. Vallecillo notified the Board that the Health and Government Operations Committee and Senate Finance Committee filed a joint letter requesting the Board to study the issue of copay coupons, out of pocket maximums, and copay accumulator programs, and include its findings in its December 2021 report.

Jim Johnson provided a synopsis of the Board's FY21 Budget, as well as projections for its FY22 Budget.

Mr. York then provided updates on the office space and the procurement contracts. Regarding the office space, the building is furnished and open for staff. Regarding the procurement contracts, Mr. York noted that there are two University Agreements (UA) that require Board review and approval, but these matters would be addressed at a brief future meeting, tentatively scheduled for June 8. Mr. York also provided a brief walkthrough of the UAs. The first UA would be with the Hilltop Institute for analytics capabilities, and the University of Maryland-Baltimore's School of Pharmacy for clinical support.

AGENDA ITEM 5.

Chair's Update, Van Mitchell

Chair Mitchell thanked the Board members and the public for joining today, and expressed hope that the next regularly scheduled meeting of the Board, July 26, 2021, will be in person in Annapolis. However, he also noted that PDAB staff would need to confirm with the Senate Office's staff to confirm. Chair Mitchell also thanked the PDAB staff for its work on the regulations and preparing for today's meeting.

Chair Mitchell closed his update by announcing Board Member Dr. Malouf's resignation from the Prescription Drug Affordability Board, and expressed his and the Board's gratitude to Dr. Malouf.

No Action Needed

Adjourned at 4:00 p.m.