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Prescription drug affordability boards: Another quick fix with unintended consequences?

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Making medications more accessible to those who need them is the focus of attention in the media and in all levels of government. For a drug to be accessible, it must be affordable and available. Something may be affordable, but if it isn't available, no one will have access to it. Think of toilet paper in the first year of the COVID pandemic. The opposite is also true. An item may be available, but if it isn't affordable, access is lost. While medication affordability is viewed as the major problem for patients, lack of availability has begun to creep into our drug supply chain. We are now experiencing drug shortages for medications that are very affordable. The perverse incentives, inherent in formulary construction, favor higher-priced medications, which decreases the availability of lower-priced – yet still expensive – drugs, thus increasing patient cost share. Formulary placement and patient cost share, important determinants of accessibility, are controlled by health plans and differ considerably even from the same payer. And yet, the price of drugs remains the target of most approaches to increasing patients' access. And now price negotiations and drug affordability boards enter into the picture.

What are prescription drug affordability boards?

Both state and federal legislatures have placed the affordability of medications front and center on their agendas. However, neither are considering how formulary construction

affects patient's access to medications. The Inflation Reduction Act is Congress's foray into price setting/negotiation of expensive drugs. Over the last few years, states are also attempting to make drugs more affordable by creating prescription drug affordability boards (PDABs). Governors (or other state leaders) appoint PDAB members who are charged with the task of evaluating the affordability of certain drugs for both the state and its residents. How to do it, and what the limitations are, vary from state to state. In 2019, <u>Maryland was first state</u> to establish a PDAB, charging its members to study commercial insurance and drug pricing and make recommendations on how to make drugs more affordable for Maryland residents. Other states that have passed PDAB legislation are Colorado, Maine, Minnesota, New Hampshire, Ohio, Oregon, and Washington.

Colorado, Minnesota, and Washington – and soon Maryland and Oregon – hope to make drugs more affordable for patients by allowing their PDABs to set an upper payment limit (UPL). A UPL serves as a cap on the sales price and reimbursement for a drug. The Michigan legislature is actively debating legislation that would establish a PDAB and allow it to set UPLs. On the surface, this may appear to be a potential solution to the affordability issue. However, as always, there are many questions as to how this will work and what are the unintended consequences of price setting and establishing UPLs for medications. UPLs have the potential to harm access to provider-administered drugs. With the help of advocacy from the Coalition of State Rheumatology Organizations (CSRO), Washington's PDAB statute potentially has a carve-out for provider-administered drugs.

Possible unintended consequences for provider-administered drugs

CSRO asked for a meeting with the Colorado PDAB after they announced their list of drugs for which UPLs would be set. We spoke with the PDAB in October, hoping to point out some of the unintended consequences that needed to be considered. One of the big questions we have revolves around the "buy and bill" provider-administered drugs. According to the language of the Colorado statute, providers would not be paid any more than the UPL for a drug administered in their office. CSRO is concerned that this would leave providers uncompensated for the service of administering the drug and associated overhead. This is not to mention that providers may not be able to find a group purchasing organization that would even sell the drug at the UPL, much less a lower price than the UPL. And even if a provider could buy it at the UPL, that would mean there would be no margin to cover the overhead for their infusion suite. Interestingly, while Colorado's rules for the UPL state that pharmacies can be paid an additional reasonable dispensing fee beyond the UPL, no such allowance is made for providers administering one of these medications. In fact, the Colorado PDAB specifically indicated that the goal of the state's UPL methodology was to ensure that there was no "delta" between what is paid for the drug by the provider and what is reimbursed to a provider for the drug by the payer. This may cause some providers to be unable to "afford" to administer those drugs with UPLs, which ultimately reduces access for residents of Colorado to that particular medication. This is the exact opposite of what the PDAB is supposed to accomplish.

There are still many questions. What impact will UPLs have on a medication's placement on a formulary? As we know, preferred formulary placement is often given to drugs with the highest price concession from the manufacturers. Will setting a UPL on payment for specialty pharmacy drugs to pharmacy benefit manager-owned specialty pharmacies affect that drug's ability to be on the formulary? And again, how will the PDAB resolve the issue of compensating the provider for overhead costs associated with administering the medication?

Even more confusing questions remain. How will the UPL be enforced when a "purchase" or "sale" of the drug is made by an out-of-state entity somewhere along the supply chain? When ultimately the drug is purchased and delivered to a Colorado consumer by a Colorado provider/pharmacy, there are multiple points of the supply chain that may be outside of the jurisdiction of Colorado to enforce the UPL. This would create a misalignment in pricing among various supply chain entities.

While the sentiment behind creating PDABs is noble, it may end up having the unintended consequence of patients losing access to these drugs because of the perverse incentives involved in formulary construction or providers' inability to afford to offer provider-administered drugs with UPLs.

Remember, expensive specialty pharmacy medications are already discounted greatly by manufacturers, often more than 50% to pharmacy benefit managers; and yet those cost savings are not passed on to the patients. Also, there is no oversight of 340B hospital contracted pharmacies to make sure that they pass those savings on to needy patients. Perhaps PDABs should address those issues, as well, if patient access to expensive medications is the goal.

Clearly, there are no easy answers. But with so many variables in the drug supply chain affecting patient access, concentrating only on one aspect may end up causing more harm than good. If your state is thinking of passing a PDAB, please let your legislators know that there are issues with this type of legislation that perhaps should be worked out before the bill is passed.

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