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Before the US Senate Special Committee on Aging

March 7, 2019

Chairman Collins, Ranking Member Casey and members of the Committee, thank you for the opportunity to speak to the Committee about state efforts to constrain the cost of prescription drugs. I appreciate the leadership of Senator Collins, Ranking Member Casey and this Committee in recent years to highlight the growing strain of prescription drug costs. Aging Committee leadership on drug costs goes back further -- to the late 1980's. Under then-Chairman Senator Pryor, an examination of drugs costs in Medicaid lead to the creation of the Medicaid Prescription Drug Rebate Program (MPDRP) in 1990.

I have worked with states and prescription drug costs for many years. In fact, in 1990, I represented the Medicaid Directors and ran the Association when the rebate program was created. Most recently, I have been working with states since 2016 on prescription drug policy, including Utah, Oregon, Massachusetts, Nevada, California, Vermont, Maryland, Illinois, Minnesota, and New Jersey among others. I work with community groups, legislators, and state agencies.

State Transparency Laws and Proposals

Requiring transparency of the prescription drug market and pharmacy benefits is an important first step. Transparency is one of the few policy areas where a legal challenge can be avoided, depending on how the transparency policy is structured. Drug companies have sued California and Nevada – two of the very first states to enact drug industry transparency laws back in 2017. The California lawsuit is ongoing; the industry dropped the Nevada lawsuit after agreement on how trade secrets data would be protected. Importantly, the Nevada law requires transparency of funding sources for organizations that work with the legislature.

Last year, five states enacted drug manufacturer transparency laws including Oregon and Connecticut. These laws build on the laws of California and Nevada to get more transparency from the drug supply chain and payors – notable pharmacy benefit managers. Increasingly, states are proposing and enacting transparency legislation that requires reporting from insurers and pharmacy benefit managers (PBMs) on net spending on high cost drugs, rebates received by PBMs and the percentage of rebates the PBM passes through to insurers. The information required in the new state laws complements the data on the CMS prescription drug dashboards which summarizes drug spending for Medicaid and Medicare B and D. These dashboards analyze the spending data in a variety of interesting ways, similar to what the states are requiring of commercial insurers.

The results of transparency legislation are available on state websites. Because of the number of states with transparency laws, I do not think that additional states need to enact transparency legislation. States with laws are setting up databases to capture reported information and share it with the public. States without transparency legislation can access the public data that will exist in the 11 states that have transparency laws and programs. States should also explore the use of Memoranda of Understanding to access proprietary data that some states will obtain.[1] I do not think every state should spend scarce resources setting up and maintaining similar databases, and federal initiatives could also obviate the need for more individual state transparency reporting systems. Drug launches and drug price increases are national. Insurer drug costs for a working age population are similar throughout the country – similar enough to see cost trends and identify the most expensive drug products.

Ideas for More Federal Drug Cost and Price Transparency

There are ways the federal government could improve transparency of drug costs, drug spending and manufacturer pricing behavior – improving the ability of policy makers to understand the prescription drug market more fully. The federal government could expand its current Medicare and Medicaid 'Dashboard' framework in the following ways:

- Office of Personnel Management (OPM) health plans and the Veterans Administration (VA) could report drug spending data. The OPM data – federal data on a working age population -- may obviate the need for state-level legislation that captures similar data. In addition to following the format of the CMS dashboards, the OPM data should also mirror the state data elements of drug spending such as breakdown of spend by generic and brand, manufacturer rebates as a percentage of pharmacy spend, and the top 25 most costly drugs.
- It is important to know which prescription drugs in the Medicaid program are rebated at only the flat minimum rebate (no deep discounts in the commercial sector that create a Medicaid best price).[2] This can tell us something about pricing behavior – if rebates increase when there is therapeutic competition, or if there any discounts for new first in class products for instance. Some of this data is proprietary but an oversight committee could request it and distill it.
- It would be helpful to know which drugs, by name, reach the cap on Medicaid rebate liability. The Medicaid rebate captures price increases that exceed growth in the CPI (in addition to the best price and minimum rebates). But manufacturer rebates are capped at 100% of the wholesale cost of a drug.[3] Drugs that hit the rebate cap are drugs that have had very high price increases or years of smaller price increases. The inflation calculation is a bit complex, but the cap on rebate liability means that exorbitant price

[1] Every state has trade secrets protection laws and there is a federal trade secrets protection law as well that prevent public disclosure of proprietary data.

[2] The actual dollar amount of the best price should remain confidential, simply knowing whether there is a best price -- that a manufacturer is offering price concessions to payers or purchasers is the important information.

[3] The Medicaid terminology is Average Manufacturer Price, which comes from a specific calculation, but the AMP is generally similar to the wholesale price for purposes of this testimony.

increases are not effectively recaptured in the rebates.[4] CMS should report which drugs have hit the cap of 100% of the wholesale price. Those drugs can be named since the fact of the price increase and the size of the increase are public information. This Medicaid data would help policy makings more easily see pricing behavior.

Federal Constraints on State Action Beyond Transparency

There are number of federal-level constraints on state action to constrain drug costs and drug spending.

Caselaw: In general state options are limited for taking the next step after transparency -- tackling prescription drug costs because of federal law and federal court rulings. Courts have ruled that states cannot set a price for a brand drug because it violates federal patent law and triggers the supremacy clause of the Constitution. Courts have also ruled that limiting a manufacturer's drug price violates the dormant commerce clause. Case law limits state ability to reference price (to limit the price or cost of a drug based on prices in Europe or Canada) because that has been ruled to violate the dormant commerce clause.

FDA law: In addition to federal case law, federal FDA law currently limits state importation programs to Canada, which will limit how many states can try this approach. For example, Florida's governor just announced intent to get federal permission to import drugs from Canada. There are about 21 million Floridians and about 37 million Canadians. Vermont is working to implement their 2018 importation law. Seven other states have importation proposals before the legislature this year and several governors committed to importation in their election campaigns.

Medicaid law: Federal Medicaid law limits the effectiveness of programs such as the multi-agency drug bulk purchase initiative announced by California's Governor in January. Unlike federal agencies and federal programs whose drug discounts are exempt from the Medicaid Best Price calculation[5], the drug discounts of state agencies and programs are included in the Best Price calculation. While federal programs can get deep price concessions, state agencies cannot. State agencies will only get discounts that do not set a new, low Medicaid best price. Regardless how large a state's drug purchasing pool is and how much volume can be purchased, a state cannot do better than the basic Medicaid discount of roughly 23%. Importantly, state taxes support the pharmacy benefit of 25-30% of the residents of the states I've worked with.[6]

Interestingly, federal law limits state ability to drive deep discounts -- even though a state Medicaid program discount/rebate negotiation is exempt from the manufacturers' calculation of best price. Federal law prohibits state Medicaid programs from managing a drug benefit formulary in the same way that commercial insurers can. Private insurers can create a restrictive formulary -- the insurer can

[4] The cap on rebate amounts was included in the Medicare Part D law. It made sense at the time because small annual price increases could over ten years or so, cause the rebate to by more than the price of the drug. However, price increases today are bigger and more frequent than they were 15 years ago.

[5] Manufacturers report to CMS their best price in the US market to any purchaser or payor. That best price discount then has to be given for all Medicaid utilization of that product in all states. Medicaid covers about 71 million people, to creating a new best price for a drug is significant for a manufacturer. Generally speaking, a best price is created to the extent that the discount exceeds the base Medicaid rebate of 23% of the wholesale price.

[6] Of course the actual percentage is state-specific based on Medicaid, state, local employees, dependents and retirees, prisons, public health, higher education and public education employees and dependents.

choose one drug in a class rather than its competitors based on the price concession the manufacturer offers. Such formulary management can drive manufacturer discounts or rebates which allows health plans to better manage costs.

What States Can Do to Manage Drug Costs

Beyond transparency, state options to constrain prescription drug spending are quite limited because of decades old laws and court decisions. There are two ways I can think where a state could be successful in drug cost containment policy and avoid the range of legal limitations. Importation is one idea and creating statewide upper payment limits for certain high cost drugs is another. I wrote the model acts for these two approaches that states are using. These two approaches achieve what I believe is the single most important aspect of constraining drug spending and making drugs more affordable for patients – getting a lower cost product to the pharmacy counter.

For importation, the import is distributed to participating purchasers – hospitals, clinics, pharmacies. The imported price of the product is public. Insurers will only reimburse pharmacies and providers at the import price. Pharmacies can only charge patients the import price and the insurer pharmacy benefit is keyed to the import price. States administer the program to ensure compliance with global supply chain safety and to ensure that distributors and dispensers limit charges to the imported price. The FDA announced its desire to import certain generic drugs and biologics to create market competition in the U.S. State policymakers also view importation as a way to create price competition.

For a state all-payer upper payment limit (UPL) program, the law will do statewide and uniformly, what every insurer, Medicaid program, state employee program, and large hospital system do for every drug and every medical service – they set a payment rate. They do not pay charges. Health care payment rate setting has been the standard approach in US health care for decades. Payment rate setting drives providers and pharmacies to lower their costs. A statewide, obligatory UPL for certain high cost drugs will drive negotiations up the supply chain to the manufacturer – just as payment rates do today. Seven states have UPL bills in the legislature this year.

Manufacturers have never sued over patent law violations for the federal 340B program, Medicare payment rates or Medicaid drug payment rates. That is decades of acceptance of the idea of upper payment limits in the US healthcare system. Manufacturers never sued Maryland over its statewide, all payer hospital rate system when that required negotiation about the cost of new drugs that would cause a hospital to lose money under the statewide payment rate. No manufacturer has every sued on the basis of the dormant commerce clause when state-run facilities force negotiations on price up the drug supply chain because they can't afford an important drug product.

States would prefer to tackle drug costs more directly than importation or statewide upper payment limits, but there are few options that can really change the cost trajectory.

How Congress Can Help States Innovate on Drug Cost Policies

Congress can help states innovate and test new drug cost containment strategies with a few changes to federal law:

- In the Food Drug and Cosmetic Act, expand countries from which a state may import to the EU, in addition to Canada, for state-administered programs of importation. Allow these state programs to import biologics, which are safely imported today.
- Clarify that patent law does not limit states' ability to protect the health of residents in the regulation of the cost or price of patented products.
- Clarify that any state has authority to regulate in-state commerce even when that regulation causes a global, national or regional out of state company to take specific actions relative to the product that is sold in the particular state.
- Exempt state government drug cost control initiatives and programs from Medicaid best price calculations – extending the same privilege to states from which federal agencies and programs benefit.
- Allow Medicaid rebates to fully capture the impact of manufacturer pricing behavior by eliminating the cap on rebate amounts.

Thank you for the opportunity to share my thoughts on this very important public policy issue.