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Opinion: Why Pharmaceutical Market Reform Is So Hard and What to Do About It

By Guest Commentary
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The pharmaceutical market has become complex and dysfunctional.

In the absence of federal action on the costs of prescription drugs, state legislatures continue to debate and enact policies that help policymakers understand the market problems. More recently, states have begun to take action to manage the costs of drug products through creation of prescription drug affordability boards.

Two of these boards — in Maryland and Colorado — are specifically considering statewide rate setting for certain high-cost products. Statewide rate setting can address most of the market dysfunction, improve patient access and manufacturer market access, and complement Federal drug cost policies when enacted.

Why is it so difficult to lower the costs, if not the prices, of prescription drugs?

Legislative hearings across the country and on Capitol Hill highlight how dysfunctional the pharmaceutical marketplace has become. We have all seen at least one byzantine, inscrutable, schemata of how the prescription drug market operates.

What is not always clear is who profits from prescription drugs and how they profit, but this is information that gets to the heart of the issue – and the solution.

While almost all segments of the pharmaceutical supply and financing chain can create new schemes or workarounds to preserve their various business models and profits, patients cannot. These workarounds cause net costs to decrease for some players, revenue to increase for others, and patient out of pocket spending to increase in almost all corporate workarounds.

The persistent rise in patient spending is why pharmaceutical pricing and costs remain consistently high on the public's "to-do" list.

The level of market dysfunction

Key participants in the pharmaceutical marketplace are manufacturers, pharmacy benefit managers (PBMs, which operate on behalf of employer health plans and commercial insurers), large hospital systems and large pharmacy chains.

These are the entities that can manage/manipulate prescription drug prices, costs and profits, and work to create advantages for themselves at the expense of the other players (when they are not corporately aligned). Wholesalers are not in the mix because they operate between manufacturers and drug purchasers (hospitals, pharmacies, etc.) and have no relationship with PBMs.

In many cases, large pharmacy chains are corporately related to national pharmacy benefit managers and national insurance companies.

Large national pharmacy chains have a distinctly different market position than small independent pharmacies.

Recently, PBMs have portrayed independent pharmacies as a cost problem presumably because independents cannot buy drugs at vast volumes like other players and thus their product acquisition costs are higher than say, CVS. But independent pharmacies operate in communities where large chains will not always locate and serve a variety of community needs.

These entities are key players because they each can adjust their drug prices, drug costs and drug profits with a variety of strategies that push costs elsewhere to maintain or increase profits. Patients cannot manage like the corporate behemoths, and neither can small independent retail pharmacies.

The entities which profit off of drug prices, and profit more handsomely as prices rise, are more than you might think. For instance, a drug that came through the 340B deep discount channel may be dispensed to an employee whose employer's PBM may also get a manufacturer rebate on that product. The employer's PBM cannot know if the hospital's cost was deeply discounted so the hospital can bill market rate for the drug and is paid based on market. The manufacturer cannot know that the same drug was discounted to the hospital before it pays a rebate to the PBM.

Transparency would both benefit and harm different market participants which is why we have so little transparency.

The system is opaque even to employers and commercial market health plans that do not own their own PBMs.

Employers may know the total amount of rebates received through their PBM (and in general, PBMs say they are passing along 100% of those rebates), but employers and commercial market insurers may not know the net cost after rebates for any one drug because their PBM contracts may prohibit sharing this detailed information.

An employer may believe they are getting the best deals in the market, but there is no way to actually validate this because all the PBM and manufacturer price concession information is confidential. It also seems that national PBMs arrive at a national price concession agreement with a manufacturer but provide differing levels of price concessions for that drug to different employers.

Patient cost sharing at the point of service is typically based on the market price (something akin to a list price). Pharmacies or providers bill employer plans based on market price because actual pharmacy or provider acquisition costs are not known to the employer health plan or its PBM although pharmacies and providers generally get discounts based on volume.

All the major players in the market received some level of price concession for a product – except the patient. Even though all the different players get some level of price concession for a drug, it likely was not the same price concession even though it was the same drug.

Employers and commercial insurers want to know that despite rising costs, their PBMs will keep pharmacy spending in check. To this end, there can be PBM contract provisions that guarantee x percent reduction in an employer's total pharmacy spend.

This simple provision is also a source of (unwitting) market dysfunction.

In order to get to goal, PBMs will "prefer" high-priced drugs with large rebates instead of lower-cost products with little or no rebates. A large rebate can provide the PBM more certainty on meeting its obligation to reduce total employer spend by x percent without having to be overly concerned that total spend may be increasing because drug prices are increasing.

That is why high-priced insulins are on formulary and their biosimilars are not, or why a drug company may market its own "generic" at much lower cost to the uninsured but that lower cost (identical) product is not available through an employer plan. PBM success is measured in cash back rather than on utilization of lower-cost drug products.

Manufacturers have been rebuffed by PBMs when offering to bring a product to market at a lower price point than existing competitors. The PBM metric is rebate dollars which can grow as prices of individual drug products rise. It is not clear that employer plans and commercial insurers understand this dynamic, and it is not clear they would support this approach if it were more transparent.

The system was not always like this.

Complexity started as more people utilized more drugs and prices of those drugs started to rise. At one time, managing the pharmacy benefit was administratively straightforward and low cost, but this did not meet the growing need to control rising costs. Because of complexity and volume of utilization, employer health plans needed help – pharmacy benefit managers.

In another part of the market, rising drug costs caused more hospitals to participate in the federal so-called 340B program – a program of federally required, deep, manufacturer discounts for

hospitals and clinics that served the indigent. The once sleepy program has grown into a $30 billion program of discounted drugs and most of the volume is in hospital purchases.

Using those discounts to relieve patient drug cost burdens is the exception rather than the rule.

What to do?

The system is not working for consumers and does not really work for employer plans and commercial insurers. Arguably, it no longer works even for manufacturers who created the system.

Addressing just one part of the market (say PBMs, manufacturers or hospitals) is likely to lead to even more dysfunction than we have today — and we can hardly coherently describe the market today.

At the state level, our dysfunction can only be addressed by managing the cost of a product as it travels through the supply chain – aka rate setting. Rate setting is already ubiquitous and familiar in the health care market. State-level rate setting could either be accomplished by importation of certain drugs and/or establishing statewide upper payment limits on U.S. licensed drugs.

States are debating and enacting prescription drug affordability boards with authority to manage the costs of drugs that challenge health care financing systems and patient access. Several of the boards are charged with reducing prescription drug costs for all residents and the idea on the table is rate setting, or upper payment limits, for certain drugs. The rate/upper payment limit applies to all state licensed entities that buy, sell, or bill for drugs such as wholesalers, clinics, hospitals and pharmacies.

The transparent, public, upper payment limit travels through the supply chain to the point of service. The upper payment limit is the basis of the consumer cost sharing. The upper payment is basis for pharmacy or hospital billing. The upper payment limit is the basis of employer health plan provider reimbursements.

Statewide all-payer, all-purchaser rate setting will force alignment of incentives such that consumers benefit *along* with the rest of the system.

Upper payment limits will benefit pharmaceutical manufacturers because rebates should not be needed when an upper payment limit is in place. Employers and their PBMs will set patient cost sharing based on the upper payment limit. Employer plan pharmacy spending will be lower for the drugs with upper payment limits. Hospitals will be able to bill up to the upper payment limit which will benefit patients, without limiting hospital 340B participation.

Community oncology practices could be more competitive with 340B hospital cancer clinics. Independent pharmacies will have a more level playing field relative to high volume/high discount chain pharmacies.

Some entities in the pharmaceutical market will pay less than the upper payment limit, but no one can pay more. Rate setting can do what no other policy approach can do to simplify the system and reduce the monumental amount of administrative time and money spent managing high-cost drugs in our current system – a system that does not benefit patients.

Interaction with Medicare negotiation policies

State affordability boards and statewide rate setting would be complimentary to a federal drug price negotiation in one or more ways.

Affordability boards could extend the federal negotiated price to all residents of the state by making the federal negotiated price the statewide upper payment limit which would amplify the impact of the Medicare process. An affordability board could establish rate setting for drugs excluded from the federal Medicare negotiation process which would fill in gaps of the Medicare process.

State affordability boards have the flexibility to ensure that they do not duplicate federal activity.

Expected Results

Statewide upper payment limits on costly drugs would unwind the misaligned incentives that plague the market as far as the rate-set drugs. There would be ancillary effects on costs of other drugs in the same class as well as follow-on therapeutic competitors.

Over time, statewide rate setting could have a substantial impact on market behavior. The end goal is to facilitate patient access to important products and facilitate market up-take of important drugs.

Tags: Jane HorvathPrescription Drug Affordability Board