Talk of a “Default” Drug Formulary Rattles Industry

CMS Could Move in That Direction for Marketplace Plans After 2019, but the Discussion Has Already Started

Stephen Barlas

The Trump administration’s creep toward significant prescription drug policy changes across federal health programs has rattled drug industry sectors up and down the distribution pipeline. In its proposed regulatory initiatives for the federal health insurance exchanges in 2019, the Centers for Medicare and Medicaid Services (CMS) startled manufacturers, pharmacy benefit managers (PBMs), P&T committees, and pharmacies alike by promising to consider a federal default prescription drug benefit in years after 2019. The agency wants that discussion to begin now, and the chance that a national formulary will be dictated for the marketplace plans, along with drug price transparency changes that remain unspecified in the proposed rule, would amount to a small earthquake for the pharmaceutical industry.

Any federal standard might impinge on the current flexibility that marketplace insurers have to develop formularies. The CMS doesn’t provide data to explain why it is holding out the possibility of a federal default standard, which would ostensibly crimp state regulatory flexibility over the marketplace, except to cite an Institute of Medicine report from 2011 called Essential Health Benefits: Balancing Costs and Coverage. That report advocated a federal standard for the 10 essential health benefit (EHB) categories that each qualified health plan (QHP) must offer to “better align medical risk in insurance products by balancing costs to the scope of benefits.” Pharmaceuticals make up one of the 10 categories. Currently, QHPs in every state must at a minimum provide all the benefits in a state’s benchmark plan. The benchmark plans vary from state to state.

In its proposed rule for 2019 exchange policies, the CMS says it might establish a federal default standard for all 10 EHB categories. But the agency appears to single out the pharmaceutical category by implying that even if it doesn’t mandate a federal default standard for all 10, it may do so for drugs alone. The proposed rule states: “For now, we solicit initial comments on this longer-term approach, particularly with regards to setting a national prescription drug benefit standard under a Federal default EHB definition and the trade-offs in adjusting benefits from the current EHBs.” The use of the word “particularly” seems to single out prescription drugs compared with the other nine categories.

The prospect of a federal default standard for drugs has been taken to mean that the CMS would establish an arbitrary, restrictive drug count for each medication category and class, eliminating the flexibility QHPs have now. In doing so, the government might favor certain pharmaceuticals, perhaps using a “value-based” analysis to determine drug placement. The Pharmaceutical Research and Manufacturers of America (PhRMA) “was both surprised and dismayed that CMS stated it is considering adopting a ‘national prescription drug standard under a Federal default EHB definition’ for some benefit year after 2019,” Karyn Schwartz, PhRMA’s Vice President for Policy and Research, wrote in response to the proposed rule.

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they needed at an affordable price (that 13 million is almost certain to decrease in 2018 and beyond because Congress canceled the requirement to obtain coverage or pay a fine). Any analysis will examine trade-offs such as the relationship between formulary construction and consumer drug prices underlined by an examination of tiering, copayments, and premiums.

Under current law, states establish benchmark plans that contain benefits in 10 categories. Those benefits must meet federal minimum standards. One category is pharmaceuticals. There, the benchmark must have: 1) one drug in every United States Pharmacopeia (USP) category and class, or 2) the same number of prescription drugs in each category and class as the EHB benchmark plan. There are additional requirements, too, related to P&T committees, exceptions for drugs not on a formulary, appeals to plans, and other issues.

Are Drug Costs for Exchange Consumers a Problem?

There is nothing preventing a QHP from offering as many drugs in a category and class as it wants. Nor does the CMS have any data on how many QHPs offer only one drug in each USP category and class. With regard to cost, every exchange member has an annual out-of-pocket dollar limit. For the 2017 plan year, that limit was $7,150 for an individual plan and $14,300 for a family plan.4 How quickly someone reaches those caps depends on his or her plan’s deductibles and coinsurance.

Exchange plan deductibles cut more deeply into consumer pockets when it comes to drugs. Each QHP offers four levels of care based on cost, the so-called four metal categories: bronze, silver, gold, and platinum, with platinum having the highest premiums, lowest deductibles, and lowest coinsurance payments. But deductibles at all four levels have been increasing. Deductibles for individuals enrolled in the lowest-priced Patient Protection and Affordable Care Act (PPACA) health plans averaged more than $6,000 in 2017. Families enrolled in bronze plans had average deductibles of $12,393, according to a study by the consumer insurance comparison site HealthPocket.5

Those high deductibles take a bigger bite out of pocketbooks in the pharmaceutical category because consumers pay the list price for a drug prior to reaching their deductibles, when they start paying the discounted price the QHP’s PBM has negotiated with the manufacturer. In its comments, PhRMA pointed to an analysis from the actuarial firm Milliman that suggests this shift toward higher-deductible plans has had a disproportionate impact on cost-sharing for medicines. In its analysis, Milliman found that patients in a typical silver plan with a $2,000 deductible paid 46% of their total prescription drug costs while paying less than 30% of their costs for other medical care.6

The proposed rule the Department of Health and Human Services (HHS) issued in November is called the Patient Protection and Affordable Care Act: Benefit and Payment Parameters for 2019.1 Comments were accepted until the end of November and a final rule could come in late winter or early spring 2018, given that QHPs must typically present their initial 2019 plans for approval to HHS by mid-May.

The proposed rule was extremely wide-ranging and technical, covering administrative, financial, medical, and legal issues, from risk adjustment models to medical loss ratio calculations to premium setting to EHB requirements, where states would be able to substitute benefits from other states’ EHB categories into their own benchmark plans, except in the case of pharmaceuticals, or eliminate some offerings within categories—for example, for pregnancy coverage.

The Rationale for the Proposed Rule

The exchanges established by the PPACA and considered a major legacy of President Barack Obama have been under attack since President Donald Trump took office in 2017. The Republican Congress failed to take a sharp legislative ax to the marketplace exchanges, though the requirement that individuals not covered by an employer or Medicare buy policies or pay a tax was canceled by the tax bill Republicans passed at the end of 2017. In the absence of a Congressional blade, the HHS has used its annual responsibility to update the exchanges as the vehicle to suggest changes that, on their face, are pegged as efforts to reduce insurance costs for consumers by increasing flexibility offered to both the states and the insurers, whose numbers have been decreasing as premiums have been rising.

The Republicans have been walking a politically narrow path, not wanting to incur retribution at the polls in 2018 for totally blowing up the exchanges but at the same time wanting to satisfy their base by fulfilling a promise to cancel key aspects of the PPACA. That will not happen legislatively, so the GOP is in fallback mode, depending on the Trump HHS to inject free-market solutions into the exchanges in an effort to stop the bleeding of insurers, put a tighter lid on premium increases, and hopefully induce salutary modifications to insurance policies related to coinsurance and deductions, the latter being particularly troublesome in the area of pharmaceuticals.

The potential replacement of the two-option standard with a new federal prescription drug benchmark and the agency’s stated intention to consider proposals in future rulemaking that would help reduce drug costs and promote drug price transparency are a clear Trump administration effort to continue its recent initiatives aimed at lowering consumer drug prices. The proposed exchange rule’s assault on allegedly high drug prices aligns with the administration’s final rule reducing reimbursement for 340B outpatient drugs and its proposal to force PBMs and Medicare Part D drug plans to convert a significant percentage of manufacturer rebates into pharmacy-counter discounts for seniors.7

But critics believe any attempt to reduce exchange premiums via a federal default drug standard would be a net negative in terms of plan affordability because formularies would contract and coinsurance would increase across all tiers. “We are concerned that efforts to improve plan affordability may focus solely on reducing premiums at the expense of offering meaningful coverage to patients at accessible cost-sharing levels,” wrote Angela Wasunna, Vice President of Global Policy at Pfizer, Inc.

The proposed CMS rule does not answer two very important questions: “what is wrong with the current drug standard,” and “why would a federal drug benchmark be preferable.” As to the first question, there isn’t much substantiation. Take oncology drugs, for example. They are among the top cost drivers among pharmaceuticals. Jennifer Singleterry, Senior Analyst of Policy Analysis and Legislative Support at the American Cancer Society Cancer Action Network, says that studies by
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her organization show that almost all cancer patients reach the annual out-of-pocket limit. But those patients typically are paying first for expensive diagnostic tests and some medical expenditures before they start racking up drug costs. So by the time they reach expensive cancer infusion drugs, they are already close to or at their cap, and not because of drug costs.

The EHB Category for Drugs

While nearly no one greeted the possibility of a default standard for drugs with cheers, neither is there much love lost for the current federal two-option standard. Although it offers state plans some flexibility, that standard still uses a vilified “drug-count” mechanism, specifying adherence to the USP methodology or “at least” the number of drugs in the state benchmark plan, which is generally based on a typical employer plan. Each plan offered in the state has flexibility regarding the tier where it places each drug. Typically, each formulary has four tiers, with the top tier holding the most expensive drugs with the highest coinsurance. The Kaiser Family Foundation’s 2017 Employer Health Benefits Survey found that 83% of covered workers are in a plan with three, four, or more tiers of cost sharing for prescription drugs.8

“P&T committees consider category and class frameworks, such as USP’s, in addition to a myriad of other information and evidence, and we see no reason why CMS should continue to use a drug-count standard that, at best, is unnecessary, and at worst, undermines the role of the P&T committee and the ability of issuers and their PBMs to negotiate better discounts with manufacturers,” wrote Wendy Krasner, Vice President of Regulatory Affairs for the Pharmaceutical Care Management Association, which represents PBMs.

CVS Health, which has 2.3 million lives under PBM management in the exchanges (18% of the total exchange population), says the current drug-count standard increases costs for plans and patients. CVS’s influence on exchange patients will grow if its acquisition of Aetna is completed, not to mention its influence over Anthem once that insurer gets its IngenioRx PBM up and running in 2019 with the help of CVS Health, which is required to develop and maintain at least 50 formularies for exchange plans in 50 states. This is in stark contrast to the typical employer plan serving workers in different states, which generally adopts a single national formulary. “Not only does the current approach pose operational difficulties and significantly increase administrative costs for issuers, but it also hampers their ability to harness the full power of their enrolled population in negotiating drug discounts with pharmaceutical manufacturers,” wrote Don Dempsey, Vice President of Policy and Regulatory Affairs for CVS Health.

Manufacturers, of course, generally want to see as many branded products as possible in each category, although companies vie with one another within categories to win favorable placement on tiers through higher rebates. But the two-option standard has significant hypothetical limitations in certain categories—oncology, for example. In its comments to the CMS, PhRMA used tyrosine kinase inhibitors (TKIs) as an example. First approved as a treatment for a rare form of blood cancer called chronic myelogenous leukemia (CML), TKIs represented a tremendous, targeted advance over traditional chemotherapy treatments that destroy healthy and cancerous cells indiscriminately. However, despite TKIs’ effectiveness, cancer often develops resistance to an individual TKI over time. Other options have become available. Dasatinib (Sprycel, Bristol-Myers Squibb) is a TKI specifically approved by the FDA for treatment of CML that is resistant or intolerant to prior therapy, including imatinib (Gleevec, Novartis), another TKI that may be considered to fall into the same class. Everolimus (Afinitor, Novarisa) is approved for treatment of advanced renal cell cancer after treatment failure of sunitinib (Sutent, Pfizer) or sorafenib (Nexavar, Bayer Healthcare). If only a single drug were available in each class, patients whose cancer had progressed on or proven resistant to that initial treatment would not have access to appropriate care.

However, not everyone agrees that the current two-option benchmark floor presents a problem for patient access. Asked about PhRMA’s example, Mary Gleason Rappaport, Director of Policy Communications for the American Society of Clinical Oncology, replied, “At this point, we’re not seeing treatment access a problem for cancer patients on the exchanges.”

Measures to Improve Drug Price Transparency?

The proposed rule laying out exchange policy modifications also opens the door to drug price transparency measures. CMS seeks comments on ideas to “foster market-driven programs that can improve the management and costs of care and that provide consumers with quality, person-centered coverage,” particularly in relation to value-based insurance design.

Value-based drug contracts are a touchy subject. While drug manufacturers have been partly open to the notion, there has been little uptake, and the methodology used by the Institute for Clinical and Economic Review (ICER) has put it in the cross-hairs of the National Pharmaceutical Council. On November 21, 2017, the ICER issued an evidence report for the first two drugs approved for tardive dyskinesia (TD), a repetitive, involuntary movement disorder caused by prolonged use of medications, most commonly antipsychotic drugs, that block the dopamine receptor. Until recently there were no FDA-approved therapies for TD. Valbenazine (Ingrezza, Neurocrine Biosciences, Inc.) became the first FDA-approved drug for TD in April 2017, and deutetebenazine (Austedo, Teva) was approved for TD in August 2017. The ICER judges the cost-effectiveness of a drug based on gains in quality-adjusted life expectancy. At current pricing levels, however, the estimated lifetime cost-effectiveness of these agents fails by a large margin to meet common cost-effectiveness thresholds.9 That ICER has in effect undermined the appeal of some new drugs (and older ones, too) has encouraged groups such as the Academy of Managed Care Pharmacy (AMCP) to come up with a more amenable measuring stick for the value of drugs. In June 2017, AMCP held a multistakeholder Partnership Forum, “Advancing Value-Based Contracting,” where representatives from health plans and integrated delivery systems, PBMs, data and analytics experts, and biopharmaceutical companies agreed on areas to strengthen and improve value-based contracting (VBC), including: 1) a definition of VBC for facilitating discussion with key policy-makers, regulators, and other stakeholders; 2) strategies for advancing development and utilization of performance benchmarks; 3) best practices in evaluating, implementing, and monitoring VBCs; and 4)
action plans to mitigate legal and regulatory barriers to VBC. But any move by the CMS to encourage VBC by insurers offering policies on the exchange (or under Medicare, for that matter) would have to involve parallel regulatory action outside the exchanges because federal antikickback and Medicaid pricing rules stand in the way of broader use of VBC.

Rather than focusing on VBC, PhRMA emphasized the cost-minimizing effect of PBMs, generics, and reduced hospitalizations. PhRMA suggested that the CMS somehow incentivize first-dollar coverage of drugs, meaning that they would not be subject to a deductible.

PhRMA makes some reasonable suggestions. And although drug price increases inside the exchanges and outside have moderated, some patient populations are paying eye-popping amounts for prescription drugs—amounts that are untenable for certain economic groups, even with annual caps on spending. A more aggressive cost-limiting approach in some categories is warranted. Whether a federal benchmark standard for drugs would accomplish that remains to be seen. But perhaps it is at least worth discussing.

REFERENCES