Differing Views on 'Essential Health Benefits' Extend to Drug Coverage

Composition of Formularies Is a Point of Contention

Stephen Barlas

With state health exchanges set to open their doors on January 1, 2014, administrators of qualified health plans that will be offering health insurance to individuals and small businesses under the Patient Protection and Affordable Care Act (PPACA, or ACA for short) still don't know which standards their pharmacy formularies will have to meet. In a reprise of some of the battles over formularies within the Part D Medicare drug program, insurance companies, drug manufacturers, and pharmacy benefit managers (PBMs) are now in hand-to-hand combat with drug manufacturers and patient-advocacy organizations over how the Department of Health and Human Services (DHHS) should define the pharmacy benefit, one of 10 categories of "essential health benefits" (EHBs) each qualified health plan will have to offer.

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Pharmaceutical companies are concerned that insurance companies and their PBMs will limit access to brand-name drugs, especially to vulnerable populations who have higher medication costs, such as patients with cancer, AIDS, and psychiatric problems. Insurance companies are worried that any requirements that pry open formularies will prevent them from offering premiums within ACA parameters.

The Obama administration is trying to broker compromises on numerous issues percolating beneath the cost-versus-access divide. The proposed rule issued by the DHHS last November describes the formulary structure that qualified health plans are expected to use. The rule also addresses P&T committee oversight, the use of U.S. Pharmacopeia (USP) classifications to determine the breath and depth of coverage (i.e., the number of drugs covered in each class), the use of tiers, when to add newly approved drugs to formularies, how each state should establish a benchmark formulary for qualified health plans in their state, where specialty pharmacy tiers can be used, and the appeals process for patients whose initial prescriptions are not on the formulary—which raises the question of prior authorization.

Although the requirements for pharmaceutical access clearly apply to outpatient pharmacies, there is considerable confusion over how they apply to inpatient hospital formularies and Part B drugs given in physicians' offices.

An industry source commented, "In the proposed rule, [DHHS] is silent on what the EHB minimum standards are for hospital inpatient formularies or for physician-administered drugs. Lack of standards on coverage of these treatments could lead to benefit designs that do not provide patients sufficient access to medically necessary care."

The DHHS may issue a final rule before the end of the year but ideally, from the standpoint of the qualified health plan, well before then. Companies such as UnitedHealth Group, Aetna, and Humana are currently deciding how many states they want to offer their health plans to. There will be separate markets for individual plans and small-business plans. Insurance companies will decide which states they wish to participate in based on the parameters set by the DHHS in all 10 EHB categories, including pharmaceuticals. In January 2013, UnitedHealth Group Chief Executive Officer Stephen Hemsley told analysts, "We will participate only in exchanges that we assess to be fair and commercially sustainable and that provide a reasonable return on the capital they will require."

Interested parties have criticized the proposed rule as much for what it includes as for what it excludes. Aside from omissions having to do with creating tiers, there is no requirement that qualified health plans with formularies (and most plans will have them) must have a P&T committee, as mandated under Part D. Drug manufacturers want every health plan with a formulary to have a P&T committee, one that is independent. The Pharmaceutical Care Management Association (PCMA) says this is fine in principle, but it wants to let the P&T committee decide which drugs should be available in which classes and on which tiers.

That is not the approach of the DHHS in its proposed rule that it published last November. Its core requirement is that plans subject to the EHB standard provide prescription drug coverage that is at least the *greater* of the following: one drug in every USP category and class, or the same number of prescription drugs in each category and class as the EHB–benchmark plan.

This is an expansion of the standard that the DHHS first endorsed in December 6, 2011, in its *Essential Health Benefits Bulletin*. That would have required health plans to cover at least one drug in each category and class in which the EHB–benchmark plan covered at least one drug. The *Bulletin* did not include a reference to the USP classification system. The specific drugs on each plan's drug list could vary under this approach as long as a drug in each category and class is covered.

That one-drug-per-class requirement provoked considerable consternation among many interested parties. Almost 11,000 comments flooded the DHHS. The "benchmark plan" alternative was then added when the November 26 proposed rule was published. By comparison, the Medicare Part D program requires plans to provide a minimum of two drugs per class.

Under the ACA, each state chooses one benchmark health plan from among four possibilities operating in that state:

- the largest plan by enrollment in any of the three largest small-group insurance products in the state's small-group market
- any of the largest three state employee health benefit plans by enrollment

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- any of the largest three national Federal Employees Health Benefits Program plan options by enrollment that are open to federal employees
- the largest insured commercial non-Medicaid health maintenance organization operating in the state

The addition of the benchmark formulary option did not satisfy a lot of people. Opposing sides want many more modifications. For example, drug manufacturers are unhappy that the DHHS has said that formularies operating in 2014 and 2015 would have to carry only drugs that were on the formulary of the state benchmark plan when that plan was originally selected by the state. Some states selected benchmark plans in 2011 and 2012.

"That would allow plans to exclude coverage for life-saving medical innovations and [would] result in coverage that lags far behind standards of care and typical coverage in the commercial marketplace," says Richard Smith, Executive Vice President of Policy & Research at the Pharmaceutical Research and Manufacturers of America (PhRMA).

He also argued that the USP drug classification system was developed for the senior population served by Part D and should not be used to guide EHB formularies. The American Hospital Formulary System would be a better classification yardstick.

"The combined effects of multiple policy choices in the proposed rule risk creating powerful incentives to narrow coverage of prescription drugs and limit patients' access to innovative therapies as compared to today's typical coverage," he claimed.

Daniel Durham, Executive Vice President of Policy and Regulatory Affairs at America's Health Insurance Plans, the insurance industry lobby, wants the DHHS to discard the USP option entirely and the larger option for formularies to provide one drug per class. He said, "Instead, DHHS should require plans to cover the same categories and classes covered under the EHB benchmark plan in a state," he said.

Greg Low, RPh, PhD, thinks that this is a bad idea. As Director of Massachusetts General Physicians Organization's Pharmacy Quality & Utilization Program, he is largely a disinterested observer but a highly informed one. He serves on two P&T committees: one supervises ambulatory coverage for employees of all Partners Healthcare hospitals in Massachusetts who are covered by its self-insured insurance program; the other determines the inpatient drug formulary at Massachusetts General Hospital.

He commented: "The proposed approach would motivate manufacturers to discount to the benchmark plan via generous rebates but to inflate costs for other plans. Unless the benchmark plan captured a majority of the population, the net effect would be an increase in overall health care costs without a corresponding benefit in quality of care or outcomes."

Although Dr. Low can speak only for the formularies he works on, he explained that most drug plans cover more than one drug per class, whether it's a USP class or anther class. There can be rare exceptions, such as weight-loss drugs. In its comments to the DHHS, PhRMA pointed out that some states chose benchmark plans before the DHHS published its proposed rule and that some plans did not offer drugs for obesity. Very few of those drugs are on the market. Two that are available—Qsymia (phentermine/topiramate, Vivus) and Belviq (lorcaserin, Eisai)—have been placed on Dr. Low's formularies but at Tier 3, the highest copay level.

"That is because they have substantial risk profiles," he says.

Given this fact, he explains that there is no reason why insurers can't offer several drugs in many classes, including entrants in Tier 1, the lowest copay category. His formularies offer 13 Tier 1 angiotensin-converting enzyme (ACE) inhibitors, for example. Tier 2 includes ramipril (Altace, Monarch/King), a more expensive generic drug with no clinical advantage. Tier 3 includes brand-name Zestril (lisinopril, AstraZeneca).

Dr. Low suggests: "There is no reason a formulary couldn't offer only six drugs in Tier 1 for ACE inhibitors. But four is as low as you would want to go, since we have two options that are combination products, including hydrochlorothiaizide."

However, drug companies and some patient advocacy groups want the DHHS to import this requirement into the EHB pharmaceutical standard in Part D: that formularies offer "all or substantially all" of the drugs in six "protected classes:" antidepressant, antipsychotic, anticonvulsant, immunosuppressant, antiretroviral, and antineoplastic agents. Drug companies, physicians, and patient groups say failure to do so poses disadvantages to cancer and psychiatric patients in particular.

Derek L. Asay, Senior Director of Government Strategy, Federal Accounts, and Quality at Eli Lilly, says: "Incorporating the same policy within the EHB benefits standards can help ensure that these benefits are implemented in a way that does not discriminate against certain patient populations, as is also required by the Affordable Care Act."

PBMs and insurance firms claim that including this language would launch premiums into the stratosphere. Kristin A. Bass, Senior Vice President of Policy and Federal Government Affairs at the PCMA, argues: "The Medicare protected classes effectively eliminate the ability of health plans and their PBMs to negotiate rebates for drugs in those classes, thereby causing drugs in those six classes to be considerably more expensive than they would be if competitive forces were allowed to come into play."

Dr. Low does not support the "all or substantially all" formulary requirement, although he acknowledges the need for health plans to offer at least a couple of choices in the lowest copay tiers for second-generation ("atypical") antipsychotic and anticonvulsant medications. His formularies offer six antipsychotic agents on Tier 1; they are all generics and a mix of first-generation ("typical") and second-generation antipsychotic agents. Tier 2 offers Abilify (aripiprazole, Bristol-Myers Squibb/Otsuka). Abilify, a brand-name drug, is on Tier 2 because it is labeled for patients with apathy, giving it a unique clinical profile. Tier 3 includes only brand-name drugs, some of which have generic competitors on Tier 1.

But even for antipsychotic or anticonvulsant agents, Dr. Low does not support a hard-and-fast requirement that formularies cover X number of drugs.

"I think P&T committees will get there on their own," he adds.

Though the DHHS proposed rule does address the number of classes on a formulary as well as the number of drugs in each class, it does not discuss tiers, which enable P&T committees to manage pharmaceutical costs. The Obama administration hopes to keep premiums within the reach of those who purchase drugs. For example, all plans sold or renewed in 2014 must limit consumers' out-of-pocket costs to approximately $6,000 for individuals and $12,000 for families. For small group

plans, the deductible would be limited to $2,000 for individuals and $4,000 for families in 2014, also indexed to average premium growth in future years. All plans must also design their cost-sharing (deductibles, copays, coinsurance) to fit into specific levels of coverage. Plan levels must cover the following costs:

- bronze—60% of expected costs for the average individual
- silver —70% of expected costs for the average individual
- gold—80% of expected costs for the average individual
- platinum—90% of expected costs for the average individual

The four levels of coverage are supposed to guarantee that all individuals without health insurance by 2014 will be able to afford it, because they or their family will have to pay a penalty—which will be small compared with the cost of the insurance if they do not obtain coverage. The point of this requirement, beyond keeping people out of the emergency department and preventing "cross-subsidization" (charging higher prices to one group of consumers in order to subsidize lower prices for another group) is to ensure that these newly covered individuals have access to equivalent policies, in terms of breadth and depth (the number of drugs covered in each class), as those offered by employers to employees.

In addition to requirements in each of the 10 EHB categories, two broad "antidiscrimination" standards are imposed by the ACA that will determine access in each category, including pharmaceuticals. One standard prohibits discrimination based on a person's age, expected life expectancy, present or predicted disability, degree of medical dependency, quality of life, or other health conditions. The other standard dictates that benefits not be "unduly weighted." However, the DHHS proposed rule does not apply either to the prescription drug category except for a glancing reference that ... "we will use information on complaints and appeals and data on drug lists to refine our prescription drug benefit review policy for future years."

That is not good enough for Lilly's Derek Asay. He says, "Stronger standards are needed in the proposed regulation's sections on antidiscrimination and prohibitions on discrimination, together with more guidance for state and/or federal level enforcement of such standards."

The antidiscrimination standards also come into play with regard to specialty drugs, which, again, are traditionally used to treat cancer, AIDS, and psychiatric problems. These medications are generally associated with higher cost-sharing and, according to PhRMA, raise some discrimination issues. Although the proposed rule does not discuss specialty tiers directly, the actuarial value calculator that plans will use to determine coverage limits in each of the four color-coded options appears to allow the plans to include a specialty tier. Specialty tiers are discriminatory because they lead to benefit designs that aggressively differentiate out-of-pocket costs based on the need for more costly services. That would violate the EHB's antidiscrimination dictate that benefits not be "unduly weighted."

PhRMA's Richard Smith explains: "Patients with higher-cost hospitalizations are not charged a dramatically higher specialty tier coinsurance percentage than patients needing less expensive hospital care."

Another hot-button issue related to the application of antidiscrimination standards is the drug utilization review (DUR). PhRMA wants the DHHS to adopt the full panoply of DUR prohibitions that are part of the Part D program in which Medicare checks a health plan's formulary for tier placement to ensure that high-cost beneficiaries are not being discriminated against, to determine whether there is appropriate access in the major drug classes, and to ensure that a broad range of drugs is available to vulnerable beneficiaries. Mr. Smith wants the DHHS to explore the possibility of designing an automated formulary review that would guarantee unbiased DURs.

However, PCMA's Kristin A. Bass believes that some drug management and utilization controls could be adversely affected by an overly restrictive reading of an EHB antidiscrimination requirement. For example, some skin medications are usually subject to age-related restrictions to ensure that their use is for medical purposes (e.g., acne) rather than for cosmetic improvement (e.g., wrinkle reduction). Vaccines may also be restricted to certain age groups by specifying which patients may receive an initial dose or a booster dose. These age-related controls ensure appropriate clinical use of certain medications, and clinical edits of this nature should not be prohibited under the antidiscrimination ban stated in this rule's provision.

Another category in which utilization management could be impeded or even prohibited includes the so-called lifestyle drugs, such as those for erectile dysfunction. Most health plans, both governmental and commercial, impose restrictions on access to these drugs, typically by limiting quantity. To the extent that the use of such drugs is higher among older enrollees, claims of age discrimination could be made in this regard.

The topic of DURs and lifestyle drugs suggests another question: What flexibility will patients have to request and obtain nonformulary drugs and to appeal negative decisions?

The proposed rule added the protection that an enrollee can request *clinically appropriate* drugs; however, Eli Lilly's Derek Asay is concerned that the EHB standards do not include sufficient safeguards to ensure that this and other important ACA patient protections will be enforced. The ACA and its regulations, some of which have already been implemented, provide internal appeals and the right to an external review when a plan denies a covered benefit as well as when a formulary exception is denied. Mr. Asay thinks that the DHHS needs to establish more specific rights of appeal for EHB pharmacy benefits, which should include shorter timelines for final verdicts of the appeals. Moreover, there seems to be some wiggle room between the proposed rule's application to "clinically appropriate" and "medically necessary" drugs. Patients need a meaningful process for exceptions that allows access to medically necessary drugs that goes beyond the standard in the proposed rule, which merely assures patients of their right to request a nonformulary drug, he emphasizes.

The differences between the drug manufacturers and insurance companies, in terms of the conflict between access versus cost, bring to mind the difference between congressional Republicans and the President on taxing versus spending. In the case of EHBs, however, the Obama administration, not one of the pleaders, is the final arbiter. That is probably a relief of sorts for the administration, but it might not be much of one. Instead of being in a foxhole exchanging political fire with Republicans, the White House is caught in the crossfire between insurers on one side and drug manufacturers on the other. ■