Final Formulary Rules for Health Exchanges
Nettle Drug Manufacturers

Health Plans and PBMs Block Broader Drug Access For Patients and Businesses

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Pharmaceutical companies failed to convince the Obama administration to force health plans to offer wider access to brand-name drugs for individuals and small businesses that will be buying policies on the state and federal health exchanges, which start in January 2014. The Patient Protection and Affordable Care Act (PPACA) dictates that all health plans offered on exchanges include “essential health benefits” (EHBs) in 10 categories. Pharmaceuticals is one of the categories. In the EHB final rule published by the Department of Health and Human Services (DHHS) in February, the pharmaceutical requirements are almost identical to those in the proposed rule that the agency issued in late November 2012.

The drug companies had pressed for numerous changes after the proposed rule was published, as described in last month’s issue of P&T.7 But the DHHS was either entirely unmoved by those pleas or had very little time (given the short interval it faced for setting the ground rules for the new exchanges) for considering the drug companies’ suggestions. Another possible reason why the DHHS might have refused to expand the requirements for brand-name drug access is its concern that broader formularies might put exchange plans out of reach of the individuals and small-business owners who are expected to purchase them.

For example, the DHHS chose not to expand the formulary requirements to include Medicare Part D’s standard, which states that health plans must offer “all or substantially all” of the drugs in each of six categories: antidepressants, antipsychotics, anticonvulsants, immunosuppressants, antiretrovirals, and antineoplastics. Drug companies and patient advocacy groups had pushed hard for this benefit. The Pharmaceutical Care Management Association, the lobbying group for the pharmaceutical benefit management (PBM) industry, says that the “protected class” requirement has cost Medicare $4.2 billion per year without any improvement in quality of care or drug access.

The only saving grace in the final rule, from the standpoint of the pharmaceutical manufacturers, was the DHHS’s refusal to discard, per the suggestion of the health plans, one of the two options for constructing formularies. The final rule adopts the DHHS proposal’s general requirement that the health plans’ formularies provide prescription drug coverage that is at least the greater of the following: (1) one drug in every U.S. Pharmacopeia (USP) category and class, or (2) the same number of prescription drugs in each category and class as the EHB—benchmark plan. America’s Health Insurance Plans (AHIP), the health insurance industry’s lobbying group, asked the DHHS to eliminate the USP option.

One pharmaceutical industry source says that her company is glad the DHHS kept the USP option alive. She explained:

We think there are still significant gaps in patient access protections. We are hopeful that some of the shortcomings in the prescription drug category rules will be addressed by DHHS via subregulatory guidance over the next 2 years as the agency gets experience with how plans are providing drug access.

Also cushioning the drug industry’s concern is the fact that about 7 million people are expected to purchase medical insurance coverage as individuals and as employees of small businesses starting in 2014. That is a small market compared with commercial and Medicare Part D markets.

Another issue that was decided in favor of health plans and PBMs, at least for now, concerns access to nonformulary drugs. Drug companies wanted the DHHS to spell out requirements such as more specific rights of appeal for EHB pharmacy benefits, which should include shorter timelines for determinations of the appeals. The DHHS did not include any additional safeguards in the final rule, and it did not alter its proposed rule language at all. Instead, the DHHS said that “additional guidance regarding our expectations for the required exceptions process is forthcoming in subregulatory guidance.” The agency claimed that its research showed that many plans today already offer access to nonformulary drugs in the market.

“It is expected that plans that currently have such a process in place will not be expected to modify their existing process,” the agency said.

Besides the DHHS requirements for formulary coverage within the “pharmaceuticals” category under the EHB rule, insurance plans must also meet “anti-discriminatory” standards, which apply to all 10 statutory EHB categories—ambulatory patient services; emergency care; hospitalization; maternity and newborn care; mental health, substance use, and behavioral health treatment; prescription drugs; rehabilitation; laboratory services; preventive and wellness services and chronic disease management; and pediatric services, including oral and vision care, for those younger than age 19. However, these requirements are uniquely relevant when applied to pharmaceutical access. The issue is whether the health plans can adopt utilization management techniques to decrease the cost of unnecessary and overly expensive drugs.

The final rule simply states the
PPACA’s prohibition against discrimination in formulary design and drug access, but it then goes on to approve the use of “reasonable medical management techniques.” The rule explicitly endorses the use of prior authorization; however, a health plan would not be able to implement this if it discriminates on the basis of membership in a particular group according to certain factors (e.g., age, disability, quality of life, or expected life span) that are not based on nationally recognized, clinically appropriate standards of medical practice evidence or that are not medically indicated. For example, as stated in the final rule, a reasonable medical management technique would be to require preauthorization for coverage of the zoster (shingles) vaccine in persons younger than 60 years of age; this requirement would be consistent with the current recommendation of the Advisory Committee on Immunization Practices.

As the state and federal exchanges move through their infancy, the DHHS will have more to say about what constitutes reasonable medical management techniques. The agency will also be addressing some of the other formulary items, just as it has modified some Part D requirements in its annual Call Letters.

REFERENCE