Major Changes for Part D Drug Plans Scheduled for 2015

Health Plans and PBMs Would Be the Chief Beneficiaries

Stephen Barlas

Medicare is serving up a Big Gulp of proposed changes to its Medicare Part D drug program. The changes will go down easy for some health care providers and cause indigestion for others.

One anticipated major formulary change—to take effect in calendar 2015, as would all the proposed reforms—has shaken pharmaceutical manufacturers and some patient advocacy groups while pleasing Part D prescription drug plans (PDPs). But Part D plans will have to contend with other proposed changes they may not find so palatable.

One such change would target more beneficiaries for inclusion in medication therapy management (MTM) programs, an expansion pharmacists have long sought. In that case, the Centers for Medicare and Medicaid Services (CMS) is suggesting that PDPs work through pharmacies and meet a new “outreach” standard.

P&T committees at health plans and pharmacy benefit managers (PBMs) will have a lot of work to do in 2015 winnowing down the number of antidepressants and immunosuppressants on formularies, which would no longer have to include “all or substantially all” of the medications in those classes. The same would be true for antipsychotics in 2016. Brand-name drug manufacturers fear that on-patent medications will suddenly disappear from many formularies.

Patient advocacy groups for mental health, AIDS, transplant, and other groups have besieged Congress to pass legislation prohibiting the CMS from dropping the three protected classes. A February letter from both Republican and Democratic members of the Senate Finance Committee decrying the change showed that the patient groups have won sympathy on Capitol Hill. But it is not clear whether Congress will pass legislation blocking the CMS move.

If the CMS does eliminate the three classes, it is likely some if not many patented products will disappear from Part D formularies. “A vast number of branded products have gone generic between 2004 and 2014,” says Kim A. Caldwell, RPh, President of the Academy of Managed Care Pharmacy and Director of Pharmacy Professional Affairs for Humana Pharmacy Solutions. “So it is possible that after their P&T committees have reviewed drugs based on efficacy, safety, cost effectiveness, unmet need, and appropriateness, Part D formularies might possibly not include branded products.”

But P&T committees will not have to worry about the CMS shining a higher-wattage lamp on their operations. The agency essentially sloughed off recommendations that it tighten its regulations governing when the two P&T committee members required to be “independent” meet that standard.

These and other changes to Medicare Advantage (Part C) and Part D plans were announced on January 10, 2014, in a proposed rule from the CMS.1 In past years, the CMS has announced changes to Part D policies in annual “Call Letters” that are considered “subregulatory,” which is to say less enforceable. But any changes finalized in rule-making come with the imprimatur of federal law. Some of the other proposed changes relate to pricing concessions offered by pharmacies to drug manufacturers, making public some of the data that pharmacies generate, and deadlines that mail-order pharmacies must meet when shipping prescriptions.

The most significant change the CMS has proposed—reducing the number of “protected classes” on Part D formularies from six to four in 2015, and to three in 2016—has triggered a frenzied lobbying effort by patient advocacy groups to convince Congress to step in and block the proposal. The change could save Medicare $720 million between 2015 and 2019, by far the biggest chunk of the total $1.3 billion the agency would save from all of the changes it has proposed.

Antidepressants, antipsychotics, anticonvulsants, antineoplastics, antiretrovirals, and immunosuppressants are the six drug categories the CMS designated as protected classes in 2005, just before the Medicare Part D drug program was established. Part D plans must currently make available “all or substantially all” of the drugs in the six categories.

Health plans have pressed the CMS to reduce the number of protected classes. Caldwell says Part D plans can negotiate drug prices in the opened-up categories and do what they do best: Save money for beneficiaries and Medicare. He adds that plans will be able to employ utilization management to ensure products in the antidepressant and immunosuppressant categories are used properly. “Some of those products may have been used inappropriately,” he explains.

A policy executive for a major pharmaceutical manufacturer with numerous patented products says, “The evidence the CMS cites for reducing the protected classes—that they prevent plans from negotiating with drug companies—is weak, old, and anecdotal. The CMS does not explain how it came to its savings estimate. In fact, eliminating protected categories may increase costs for Medicare and patients because switching enrollees to a new drug could lead to hospitalization and additional physician visits.”

Andrew Sperling, Director of Legislative Advocacy at the National Alliance on Mental Illness, has been meeting with congressional offices in conjunction with other patient advocacy representatives with the intent of convincing the House and Senate to prohibit the CMS from ditching the three protected classes. “Not a single person in any of the 30-plus offices I have visited has defended this proposed rule,” he states.

In addition to dropping three of the six protected categories, the CMS wants to allow Part D sponsors such as

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Mr. Barlas, a freelance writer based in Washington, D.C., covers topics inside the Beltway.
UnitedHealthcare, Humana, and Cigna, which offer a number of different Part D plans, to use some new utilization management techniques for the remaining three protected categories.

**P&T Committees Escape Added Scrutiny**

Not only do the Part D plans appear to have won a five-year fight to slim down their formularies and expand utilization management, they also have warded off any new oversight of the P&T committees that help shape those formularies.

A March 2013 report from the Office of the Inspector General (OIG) at the Department of Health and Human Services recommended the CMS establish specific conflict-of-interest rules that would apply to the two committee members who are required by law to be “independent.” The OIG report criticized Medicare’s enforcement of its P&T committee conflict-of-interest rules and the way Part D plans have implemented those rules.

Sometimes Part D plans have their own P&T committees, and sometimes they use the P&T committee appointed by a PBM. UnitedHealthcare, Humana, and Cigna have multiple Part D plans, and each company’s multiple plans may use different P&T committees. Any Part D sponsor with a pharmacy benefit manager (PBM) is required to have a P&T committee. According to federal regulations, sponsors are required to follow the decisions that P&T committees make regarding which drugs to include on the formulary. However, sponsors can decide which formulary tier to place these drugs on, based on the recommendation of their P&T committees. Sponsors also must adhere to the P&T committees’ decisions regarding prescription drug utilization management practices.

A minimum of two members on each P&T committee must be independent from the sponsor and drug manufacturers, but not the PBM. One must be a physician, another a pharmacist. P&T committees can have anywhere from a handful of members to more than 100. Federal law and regulations and CMS guidance do not explicitly define what constitutes a conflict with sponsors, Part D plans, and pharmaceutical manufacturers. The OIG basically found that conflict-of-interest rules imposed by the Part D plans themselves were extremely limited, and that the CMS does not even review the sketchy P&T committee data Part D plans are required to submit—data the OIG called “unusable because of discrepancies.” The CMS makes no attempt to determine whether potential conflicts in P&T committees are resulting in biased formulary decisions.

The CMS basically ignored the OIG’s recommendations and instead simply wants to decree that Part D plans “establish processes” to guard against conflicts. Those processes “must be clearly articulated and documented, and enforced by an objective party,” the CMS adds. It is also considering applying its requirement that two P&T committee members be independent to PBMs as well as to Part D sponsors and pharmaceutical manufacturers.

**Expanded MTM Targeting Criteria**

For pharmacists, the proposed expansion of MTM targeting criteria would probably have the biggest impact of any of the proposed Part D changes. The pharmacy industry has long argued that MTM counseling saves big money via improved medication adherence and avoidance of adverse drug reactions, to name a few benefits. That argument has been backed by a number of credible studies. The CMS imposed enrollee targeting criteria for the first time in 2010, but the number of Part D beneficiaries actually receiving those services is tiny—about 6 percent, according to the CMS.

The current MTM targeting requirement allows Part D plans to select no more than three chronic diseases that a plan member must have in order to be eligible for the plan’s MTM program. Those are diseases such as diabetes, asthma, hypertension, hyperlipidemia, and congestive heart failure. Once members are targeted, the plan is supposed to provide services relevant to seven core diseases: hypertension, heart failure, diabetes, dyslipidemia, respiratory disease (such as asthma, chronic obstructive pulmonary disease, or chronic lung disorders), bone disease and arthritis (such as osteoporosis, osteoarthritis, or rheumatoid arthritis), and mental health (such as depression, schizophreni, bipolar disorder, or chronic and disabling disorders). Among the other criteria, the individual should be taking a minimum number of medications—the threshold has been up to eight—and should spend more than a certain amount of money annually on drugs.

Once a plan establishes its targets, it must “auto-enroll” all qualified members. They are able to opt out of the MTM program if they choose. But even a senior who is auto-enrolled may not necessarily receive MTM services, perhaps because he or she never keeps an appointment for a comprehensive medical review (CMR), which is supposed to lead to follow-up services. The plan may not be at fault: An enrollee may have changed his or her address or phone number without informing the plan, which then cannot reach the enrollee. But to prevent plans from giving up if targeted plan members simply do not respond to enrollment offers, the CMS wants to impose a new requirement that a Part D sponsor must “have an outreach strategy designed to effectively engage all at-risk beneficiaries enrolled in the plan.”

One of the suggested ways plan sponsors could accomplish this is by partnering with pharmacies that have a connection with a particular pool of beneficiaries. “Incorporating the pharmacies that targeted individuals utilize into the MTM program may be a particularly effective strategy for successful outreach that will lead to enrollment in MTM programs that is more broadly representative of the breadth of demographic segments in the targeted population,” the CMS says in the proposed rule.

The MTM programs have varied considerably among the 110-plus Part D plans. A recent study conducted in conjunction with the CMS, Medication Therapy Management in Chronically Ill Populations: Final Report, identified patients with equivalent MTM eligibility characteristics who were in different plans with different eligibility criteria. The enrollees were ineligible for MTM in their own plans, but would have been eligible for MTM if they had been enrolled in another plan that targets a particular chronic disease not targeted for MTM services by their own plan or that targets beneficiaries for MTM services based on a lower number of chronic diseases or Part D drugs. In the proposed rule, the CMS says:

But even those enrolled in MTM programs have sometimes gotten short shrift. There have been instances, apparently numerous ones, where a plan, for example, targeted beneficiaries with congestive heart failure and diabetes and designed interventions for those conditions. Beneficiaries who also had COPD qualified for MTM
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services, but the plan did not address their chronic obstructive pulmonary disease medication issues, a practice that is inconsistent with the intent of comprehensive MTM.

In its proposed rule of January 10, 2014, the CMS says it intends to drop the initial targeting cap from three to two dis
cases. The agency estimates that approximately 55 percent of Part D beneficiaries will be eligible for MTM based on that proposed criterion and a second revision: targeting anyone whose out-of-pocket gross drug costs exceed $620 annually. The dollar threshold was $3,144 in 2013. The CMS believes that generics are not only keeping seniors from reaching the dollar threshold, but that they are also responsible for racial disparities among the 6 percent currently enrolled. A third revision would drop from eight to two the number of medications an enrollee can be required to be taking before he or she is targeted.

Part D MTM plans are not required to use pharmacists, but many do, if not most. The baseline service Part D plans must offer is an annual CMR, typically performed by a pharmacist. There is also a quarterly medication review. Part D sponsors must assess the findings of these reviews to determine if a follow-up intervention is necessary and if the intervention is warranted for the beneficiary, the prescriber, or both. Although the MTM service requirements have been upgraded since 2010 in some of the CMS Call Letters, those services are far from comprehensive. For example, Part D plans are not required to chart whether their MTM programs are achieving desired results, such as preventing adverse drug events, improving clinical outcomes, or heightening customer satisfaction.

Three Drug Classes To Be Protected No More

There is no question that eliminating three of the six Part D protected drug classes will cause major customer dissatisfaction. The six were protected when Part D was established because about six million Medicaid recipients were being transferred into the Medicare Part D pool of eligibles. They were called “dual eligibles.”

Medicare has a broad nondiscrimination statute. It was determined that any formularies that did not have all or sub
tehly all drugs in the six protected categories would have been discriminatory because state Medicaid program formlaries were generally open. So there was a concern that the Medicaid-to-Medicare transfers—a vulnerable group, medically speaking—would be disadvantaged by the drug utilization techniques that the Part D plans would be using across all drug categories, such as restricted formularies and step therapy. In other words, interruption of their established therapy could cause them harm, at least in the short term. “However, the circumstances that existed when this policy was originally implemented have changed dramatically in the more than seven years the program has been in operation,” the CMS acknowledges in its proposed rule.

Part D plans—generally combinations of health plans and pharmacy benefit managers—hated the protected classes policy from the beginning. They have repeatedly argued that the policy leads to higher drug costs for Medicare. The principal disadvantage of the policy, they say, is that it substantially limits Part D sponsors’ ability to negotiate price concessions or rebates with drug manufacturers who have products in the six categories in exchange for formulary placement of drugs.

A number of independent studies have supported that conten
tion. A 2008 study by the actuarial and consulting firm Milliman estimated that affected drug costs were on average 10 percent higher than they would be in the absence of the protected class policy and that this represented $311 million per year in excess costs to beneficiaries and the Part D program. A March 2011 report from the Department of Health and Human Services OIG focused on the drug-rebate issue. But drug manufacturers and patient groups fought to keep the policy intact.

The protected classes policy almost crumbled as a result of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). The Act instructed the CMS to redefine protected classes based on two specifications that probably would have led to the expansion of protected classes. The CMS started a rule-making process but cut it short because MIPPA was wiped away by a provision in the Patient Protection and Affordable Care Act (PPACA). It directed the CMS to “identify drug categories or classes of clinical concern” and protect those categories. The CMS has generally been more convinced of the arguments made by the Part D plans. Those arguments combined with political pressure to cut Medicare spending were on the minds of the CMS officials who developed the “classes of clinical concern” criteria demanded by the PPACA. They are:

- Hospitalization, persistent or significant disability or incapacity, or death likely will result if initial administration (including self-administration) of a drug in the category or class does not occur within seven days of the date the prescription for the drug was presented to the pharmacy to be filled; and
- More specific CMS formulary requirements will not suffice to meet the universe of clinical drug-and-disease-specific applications due to the diversity of disease or condition manifestations and associated specificity or variability of drug therapies necessary to treat such manifestations.

Using these criteria, a consensus panel of CMS pharmacists and the CMS chief medical officer reviewed all Part D drugs with utilization in 2012 using the American Hospital Formulary Service’s AHFS-6 classification system. The consensus panel determined that of the current six drug categories or classes of clinical concern, three (anticonvulsants, antineoplastics, and antiretrovirals) meet both of the proposed criteria, and three do not (antidepressants, antipsychotics, and immunosuppressants). The panel also determined that while other drug categories and classes met one of the criteria, no other drug categories or classes met both criteria. Even in the three chosen protected classes, there would be new exceptions allowing formularies to restrict the products offered. One allows for point-of-sale utilization management safety edits that are based on maximum daily doses and black-box warnings specified on the Food and Drug Administration-approved label, potential drug interactions, or duplication of therapy. Another allows plans to restrict access when the pre

scribed drug is not for a “medically accepted indication.”

The CMS’ proposed changes to Part D should make health
plans and their PBMs happy, although they won’t be crazy about the MTM expansion. But even these changes fall far short of what could have been a much more muscular reform, paying pharmacists for performing MTM services and forcing Part D plans to analyze their effectiveness.

REFERENCES