Centers for Medicare & Medicaid Services Proposes Changes to Six Protected Class Rule under Medicare Part D

Written by Thomas Barker, Ross Margulies

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On December 8, 2003, the Medicare Prescription Drug, Improvement, and Modernization Act (the "MMA") was signed into law by former President George W. Bush[1]. Prior to the enactment of the MMA, Medicare prescription drug coverage was very limited, and was generally only available for physician-administered drugs, drugs necessary for the effective use of durable medical equipment such as inhalers, and a handful of drugs listed specifically in the statute. The MMA corrected a major gap in Medicare coverage. It added a new Part D to the program and provided coverage for FDA-approved drugs that had not previously been covered.

Unlike the traditional Medicare program, Part D coverage is only available through private insurers. A Medicare beneficiary who wants prescription drug coverage must select a private plan. Each plan will typically design a formulary (that is, a list of the drugs that the plan will cover). A "plan finder" tool on the Medicare website will help beneficiaries select a plan whose formulary best matches their prescription drug needs.

The law tasked the Centers for Medicare & Medicaid Services (CMS) with implementing the Part D benefit. In designing the benefit to take effect in 2006, CMS took several steps to ensure that Part D plans offered a robust formulary design. For example, a Part D plan must offer at least two drugs in every category or class of drugs (unless, of course, there is only one drug in the therapeutic category or class).[2] In designing the two-drug policy, CMS wanted to "ensure[ ] sufficient drug choice for beneficiaries."[3]

The "Balancing Act"

During the development of the final Part D regulation, several outside commenters expressed concern to CMS that its two-drug policy was not sufficient for certain vulnerable populations. Commenters were concerned about the potential for "discriminatory practices" in Part D plan designs, at least for "certain classes of enrollees."[4] At the same time, other commenters urged CMS to ensure that plans had sufficient flexibility in plan benefit design. These commenters urged CMS "not to be overly prescriptive in [its] formulary review criteria."[5]

As a result, CMS walked a fine line in the final Part D rule. It recognized the needs of vulnerable populations, but hesitated to lock any particular formulary review policy into regulation that would hinder the ability of Part D plans to develop innovative benefit designs and appropriately negotiate with pharmaceutical manufacturers regarding formulary placement. Thus, the agency conducted a balancing act in the final rule. At the same time, the agency did commit to providing guidelines that the agency would use when reviewing plan formularies.

The Six Protected Class Rule

As noted above, CMS did not want to be locked into a particular policy toward formulary review in its regulations. At the same time, CMS had several concerns about prescription drug access. For one, approximately 6 million Part D enrollees were dually eligible for Medicare and Medicaid. Prior to the enactment of Part D, these individuals' drug coverage was provided by Medicaid, and they had little experience with formulary management tools that were more common in private insurance coverage. CMS was concerned that a restrictive formulary would limit access to drugs to this population, especially because many Part D enrollees had been auto-enrolled into their prescription drug plan.

To address these concerns, when the Medicare Prescription Drug Benefit Manual was released in 2005, CMS developed a policy affecting

drug classes that it entitled "Classes of Clinical Concern." Under this policy, CMS announced that it had "instituted this policy because it was necessary to ensure that Medicare beneficiaries reliant upon these drugs would not be substantially discouraged from enrolling in Part D plans."[6] In creating this policy, CMS relied on a provision of the MMA that prohibited the agency from approving a Part D plan contract if it found that "the design of the plan and its benefits … are [not] likely to substantially discourage enrollment by … part D eligible individuals under the plan."[7]

Under the policy, a part D plan is required to cover all or substantially all drugs in the following six therapeutic classes: anti-retrovirals; immunosuppressants when used for organ rejection; anti-depressants; anti-psychotics; anti-convulsant agents; and anti-neoplastics. Moreover, Part D plans may not impose step therapy or prior authorization requirements for these drugs for beneficiaries who are currently taking the drug: both beneficiaries who are currently enrolled in the plan, as well as beneficiaries taking a protected class drug that are newly enrolled in the plan.[8] The CMS policy first applied to formulary review for the first year of the program: in 2006.

Congress Steps In

In July 2008, Congress, overcoming a Presidential veto, passed the Medicare Improvements for Patients and Providers Act (MIPPA) into law.[9] In enacting Section 176 of MIPPA, Congress sought to statutorily recognize the approach taken by CMS in the Medicare Prescription Drug Benefit Manual recognizing certain protected classes of drugs. MIPPA amended section 1860D-4 of the Social Security Act (detailing beneficiary protections for Part D enrollees), authorizing CMS to establish a new regulatory review process for the purpose of identifying those drug classes for which a Part D plan would be required to include all drugs on its formulary. In particular, the MIPPA language directed the Secretary to identify those categories and classes of drugs which meet two criteria: (1) where restrictions on that class would have major or life threatening consequences; and (2) where there is a significant need for individuals which a disease or disorder treated by the drugs in the class to have access to multiple drugs within that class.

Notably, the MIPPA language did not reference the existing six protected classes. As a result of the MIPPA provision, on January 16, 2009 CMS announced publication of an interim final rule (IFR) stating CMS' intent to review the existing six protected classes to examine if any modifications are required.[10] In the IFR, CMS also stated its intention, consistent with MIPPA, to examine whether or not an exceptions process to the protected class rule was necessary. Finally, the IFR stated that for 2010, the existing six protected classes would remain intact.

Before CMS was able to further develop its regulatory scheme for a more refined protected class rule, in 2010 Congress once again modified its treatment of the protected classes, essentially putting into statute what CMS had proposed in the IFR.[11] In the Affordable Care Act (ACA) Congress restated its reliance on the two part test established under MIPPA and stated that until the Secretary has established formal criteria to identify classes of clinical concern, the existing six protected classes would remain intact. Since the modifications made to the protected class policy in the ACA, there has been no further updates from Congress or CMS.

The January 6, 2014 Proposed Rule

With all of this background, and the fact that Congress seemed to be strengthening, rather than weakening, the protected class rule, the CMS announcement on January 6 of a change in policy took many observers by surprise. In the January 6 proposed rule, CMS said that the six protected class rule had addressed a "learning curve" for beneficiaries taking drugs in the protected classes, but that circumstances had changed and the policy could be revised. Accordingly, CMS says in the rule that the agency is prepared to implement the ACA revisions to the policy. The CMS explanation for the change is significantly detailed. The agency articulates two principal reasons for the change. First, according to CMS, the six protected class policy has driven up the cost of Medicare Part D. Second, CMS notes patient protection concerns.

With regard to program costs, it seems fairly obvious that if a Part D plan is required to cover a drug on formulary, the plan has little room for negotiation with the manufacturer on formulary placement. Accordingly, rebates for these drugs (which, under Part D, ultimately serve to reduce the cost of the program for both beneficiaries and CMS) are lower. Indeed, CMS notes that studies by the HHS Inspector General and independent researchers have concluded that the policy may contribute as much as $500 million to program costs.

With regard to beneficiary protection, CMS says that many drugs on the protected class list are prone to overutilization. The lack of formulary management tools under the protected class policy makes it difficult for Part D plans to guard against this overutilization. Accordingly, CMS believes that a change in the policy is necessary.

CMS then explains that there are five beneficiary protection provisions in Part D and that only where these patient protections do not

adequately protect beneficiaries should the protected class policy apply. CMS identifies the beneficiary protections: formulary transparency; formulary requirements; reassignment formulary coverage notices; the transition supply policy; and the beneficiary appeals process.

According to the agency, this then leads to two criteria that will implement the ACA requirements. First, unrestricted access to all drugs in a category or class of a drug is necessary where a beneficiary initiating access to a drug class would need to receive that access within seven days and, if they did not receive access within seven days, the lack of access would be expected to result in the patient's death, hospitalization, incapacity, or disability. Second, unrestricted access is necessary where CMS is unable to establish that a formulary that includes less than all drugs in a category or class has sufficient drugs to treat the diseases or conditions treated by those drugs.

In addition, CMS proposes to create several exceptions to the revised protected class policy. For example, where there are two or more chemically identical or therapeutically equivalent drugs in a category or class, the requirement to cover all drugs in the category or class would be waived. In addition, the exceptions policy permits a plan to conduct prior authorization to ensure that a drug is being dispensed for a medically-accepted indication.

Applying the new two-prong test to the universe of Part D drugs, then, CMS identifies three categories or classes of drugs for which unrestricted access remains appropriate: anti-retrovirals; anti-neoplastic; and anti-convulsants. The other three classes (anti-depressants, immunosuppressants used for organ rejection and anti-psychotics) would be removed from the list.[12]

The new policy would apply to the 2015 plan year. Because formularies for the succeeding plan year are usually due in May, this would mean that if CMS were to finalize the rule, formulary submissions due in May 2014 would reflect the new policy. Interested parties have 60 days to comment on the proposed rule and comments will be due on March 6, 2014.

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1. Pub. L. No. 108-173, 117 Stat. 2066 (Dec. 8, 2003).↩
2. 42 C.F.R. § 423.120(b)(2)(i).↩
3. 70 Fed. Reg. at 4260 (Jan. 28, 2005).↩
4. Id. at 4262 - 63.↩
5. Id.↩
6. Medicare Prescription Drug Benefit Manual (the "Manual") Ch. 6 § 30.2.5.↩
7. 42 U.S.C. § 1395w-111(e)(2)(D)(i).↩
8. Manual at § 30.2.5.↩
9. Pub. L. No 11-275, 122 Stat. 2494 (July 15, 2008).↩
10. 74 Fed. Reg. 2,881 (January 16, 2009).↩
11. Pub. L. 111-148, 124 Stat. 119 (March 23, 2010).↩
12. CMS would delay removal of anti-psychotics for one year.↩

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