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Revisions to the Medicare Part D 'Protected Class' Policy Engender Strong Pushback From Stakeholders

BY THOMAS R. BARKER

On Jan. 10, 2014, the Centers for Medicare & Medicaid Services (CMS) published a proposed rule in the Federal Register that proposes policy and technical changes to the Medicare Advantage and Part D programs.[1] Over the past month, stakeholders have identified several controversial proposals in the hundred-plus page rule that, some argue, would fundamentally damage both programs. One proposal identified very early on as controversial was CMS' proposal to alter its so-called ''six protected class'' policy for Part D drugs.

This article examines the history of the Part D program and the protected class policy, explains the CMS proposals, and describes the reaction by stakeholders so far.

CMS is expected to finalize the rule in early April, but it is anyone's guess whether the agency will adopt its proposed revisions to the protected class policy.

[1] CMS, ''Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Programs,'' 79 Fed. Reg. 1918 (Jan. 10, 2014).

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Medicare Part D: History

Prior to the enactment of Medicare Part D, Medicare coverage of outpatient prescription drugs was quite limited.[2] In general, Medicare had only covered outpatient drugs under Part B of the program if they were administered incident to a physician service; specifically named in the statute; or necessary for the effective use of durable medical equipment (DME).

The Part D program corrected a major gap in Medicare coverage that had existed since the program's enactment in 1965. Under Part D, a drug is covered under this Medicare benefit so long as it is approved by the Food and Drug Administration, dispensed pursuant to a prescription, dispensed for a medically accepted indication,[3] and not otherwise covered under another part of Medicare.

Unlike traditional Medicare, however, Medicare Part D is only available through private insurance plans; there is no ''government'' Part D program. Therefore, a beneficiary who chooses to obtain prescription drug coverage must enroll in a private plan once they become entitled to Medicare (or, if later, during an open enrollment period). In this sense, Medicare Part D is akin to the Medicare Advantage program; the benefit,

[2] Former President Bush signed Part D into law on December 8, 2003. *See* Medicare Prescription Drug, Improvement, and Modernization Act, Pub. L. No. 108-173, 117 Stat. 2066 (Dec. 8, 2003). The program became effective on January 1, 2006.

[3] A ''medically accepted indication'' is essentially a use of a drug for which there is compendia support.

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although subsidized by the government, is managed by private companies.

Because Part D is administered by private payers, the payers have significant discretion to design the benefit parameters.[4] This means that payers will typically utilize pharmacy management tools such as a formulary to control spending on prescription drugs. Indeed, the statute gives Part D plans express authority to institute a formulary.

Designing the Part D Benefit

Because imposition of a formulary necessarily implies that the plan sponsor will impose restrictions on access to non-preferred drugs, CMS took pains in its initial Part D regulations to ensure that beneficiaries had access to a broad range of drugs. CMS said that it intended to ''ensure[ ] sufficient drug choice for beneficiaries.''[5] CMS imposed a requirement in the regulations that a part D plan sponsor must offer at least two drugs in every category or class of drugs (unless, of course, there is only one drug in the particular category or class).[6]

Stakeholders, however, expressed concern that the CMS ''two drug'' policy would not protect vulnerable populations. Two principal arguments were advanced that called for CMS to strengthen its policy.

First, with respect to some individuals with chronic and severe medical conditions, advocates expressed concern that because each individual responded differently to different medications, an individual with a serious medical condition (HIV or cancer, for example) needed access to all drugs in a class.

Second, prior to Part D, individuals who were dually-eligible for Medicare and Medicaid had their outpatient prescription drugs covered by Medicaid. Medicaid typically did not utilize formulary management tools. Coverage for dual eligible individuals shifted to Part D on Jan. 1, 2006. CMS received comments that those individuals would not be accustomed to formulary restrictions and needed time to transition to a different means of receiving a prescription drug benefit.

In response to these concerns, CMS adopted new formulary restrictions when it finalized its Prescription Drug Manual in the fall of 2005. Under the new policy, for six specified ''classes of clinical concern,'' CMS required that Part D plan sponsors include ''all or substantially all'' drugs in the category or class of drug.[7] The ''six protected classes'' of drugs were the following:

- o Anti-neoplastics (cancer treatments),
- o Anti-retrovirals (HIV and AIDS),
- o Immunosuppressants (when used to treat organ rejection),
- o Anti-convulsants,
- o Anti-psychotics, and
- o Anti-depressants.

In adopting the six protected class policy, CMS recognized that it was attempting to balance two competing goals: first, ensuring that beneficiaries (especially vulnerable populations) had access to a broad class of drug treatments; and second, ensuring that Part D plan sponsors were able to have maximum flexibility in designing a Part D benefit.

And of course, there was a cost to CMS (and beneficiaries, through higher premiums) of the protected class policy as well: because manufacturers of the protected classes knew that Part D plan sponsors had to cover all drugs in the class, manufacturers felt no pressure to grant rebates to plan sponsors in exchange for favorable formulary placement, a typical practice in the industry.

Public and Congressional Response

Nevertheless, on Jan. 1, 2006, the Part D benefit began with the six protected class policy in place. Despite some initial enrollment hiccups, the benefit took effect with strong beneficiary satisfaction. Congress, moreover, seemed to approve of the policy; in 2008, in the Medicare Improvement for Patients and Providers Act (MIPPA), Congress effectively codified the policy.[8]

If anything, Congress seemed to encourage CMS to *expand* the protected class rule; the statute directed CMS to include on the protected class list any drug for which restricted access would have major or life-threatening consequences and for which there is a clinical need for patients to have access to multiple drugs in the category or class.[9] Congress also expanded the requirement that a plan cover ''all or substantially'' all drugs in the protected classes to ''all'' drugs in the classes.

Two years later, as part of the federal health care reform law, Congress gave the Secretary more discretion to revise the protected class policy. As part of the Patient Protection and Affordable Care Act (sometimes referred to as the Affordable Care Act or ACA), Congress replaced the MIPPA test with a much simpler directive to CMS: the agency is simply required to identify categories and classes of drugs that are of clinical concern in the Part D program.[10]

Until the Secretary develops standards, the existing six protected classes remain in effect.[11] CMS is also authorized to develop exceptions to the ''all drugs'' requirement.[12]

The January 2014 Proposed Rule

With all of this by way of background, and considering the fact that Congress seemed interested in strengthening, rather than weakening, the protected class rule, the CMS January 2014 Notice of Proposed

[4] There is a ''standard'' Part D benefit consisting of a deductible; coinsurance after the beneficiary reaches the deductible; a coverage gap (which is being phased out over time pursuant to a provision of the federal health care reform law enacted in 2010); and catastrophic coverage once the beneficiary is through the coverage gap. Social Security Act § 1860D-2(b). According to the Medicare Payment Advisory Commission, however, only 8% of Medicare Part D enrollees actually choose the standard benefit design.

[5] 70 Fed. Reg. at 4260 (Jan. 28, 2005).

[6] 42 C.F.R. § 423.120(b)(2)(i).

[7] Medicare Prescription Drug Manual Ch. 6 § 30.2.5.

[8] Pub. L. No. 110-275 § 176 (122 Stat. 2494, 2581 - 82) (July 15, 2008).

[9] *See* 42 U.S.C. § 1395w-104(b)(3)(G)(i) (setting forth test) (West 2010).

[10] 42 U.S.C. § 1395w-104(b)(3)(G)(ii)(I) (West 2012).

[11] *Id.* at § 1395w-104(b)(3)(G)(iv).

[12] *Id.* at § 1395w-104(b)(3)(G)(i)(II).

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Rulemaking took several observers by surprise. In the proposed rule, CMS suggested that the rule had served its function but that now, after eight years of operation of the Part D benefit, it could be modified.

Thus, CMS announced that it would use authority granted in the ACA to ''identify . . . categories and classes of drugs for which [CMS] determines are of clinical concern.'' CMS cited two reasons for doing so: first, the six protected class policy had driven up the cost of Part D. The second concern related to patient protection.

As indicated previously, it seems obvious that if a Part D plan sponsor is required to cover a drug on formulary, it 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 noted that studies by the HHS Office of 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 over-utilization. The lack of formulary management tools under the protected class policy makes it difficult for Part D plan sponsors to guard against this over-utilization. Accordingly, CMS believes that a change in the policy is necessary.

CMS noted, in the proposed rule, that there are ample beneficiary protections that will protect Part D enrollees from the effects of the proposed change. It notes, for example, that Part D plan sponsors are required to adopt formulary transparency policies; follow rigid CMS requirements in developing formularies; offer beneficiary appeal rights and transition supply requirements.

Accordingly, CMS set forth a two-prong test for inclusion of drugs on the protected class lists. The CMS test appears similar to the test set forth in MIPPA that was subsequently re-written by the ACA. Under the new CMS proposal, a drug will be included on the list only if it meets *both* of the following two criteria:

- o First, unrestricted access to all drugs in a category or class is necessary when a beneficiary initiating access to the therapy would need to receive the drug within seven days; and if they did not, their failure to receive the drug would be expected to result in the patient's death, hospitalization, incapacity or disability.
- o Second, unrestricted access is necessary because 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 other words, access to multiple drugs in the category or class is necessary for the relevant clinical condition.

Applying the two-prong test to the existing six protected class list, CMS announced in the proposed rule that anti-depressants, anti-psychotics and immunosuppressants (when used for organ transplants) do not meet either one or both prongs of the new two-part test. Although CMS intends for the policy to be effective for the 2015 plan year, the agency said that it would delay deletion of anti-psychotics from protected class status for one year.[13]

Public Reaction

To date, the public reaction to the CMS proposed rule has been substantially negative. It is likely that Part D plans support the protected class policy change because it will increase their leverage in negotiations with manufacturers. Other than that, however, CMS has drawn widespread criticism for the rule. Patient advocate groups immediately expressed opposition. A broad group of stakeholders sent a nearly-unprecedented letter to the CMS Administrator asking that the rule be revoked in its entirety. All members of the Senate Finance Committee— Democrat and Republican— have signed a letter to CMS opposing this aspect of the proposed rule. And at a congressional hearing on Feb. 26 before the House Energy and Commerce Committee, members of the Committee and witnesses criticized the proposal.

The comment period on the rule closes on March 7. As noted, CMS will likely move quickly to finalize the overall policy and technical rule so that stakeholders will be able to adapt their plans for the 2015 plan year.

Given the pushback that the agency has received regarding the revisions to the protected class policy, it's anyone's guess whether the agency finalizes this aspect of the proposed rule. It is certainly within the realm of possibility that CMS may choose to abandon this battle for the year ahead.

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[13] Initiating the policy for the 2015 plan year is challenging in any event given the compressed calendar for the Part D benefit. Assuming that the rule is finalized by early April (which is, in and of itself, an aggressive schedule), Part D plan sponsors will have less than two months to submit plan bids and formularies to CMS for review. *See* CMS, 2015 Advance Notice at 67 (Feb. 22, 2014).