

CMS Regulation Addresses Protected Drug Categories and Classes

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Some pharmaceutical manufacturers will be affected by a rule just issued by the Centers for Medicare & Medicaid Services (CMS) regarding how the Medicare program determines which drug categories and classes will receive favorable, “protected” status. If a drug is in one of these protected classes or categories, then Medicare Part D prescription drug plans must include in their formulary **all** of the drugs in that category or class. For manufacturers that have found it difficult to get favorable placement for one of their products on Part D plan formularies, CMS’s conferral on that product of protected status could help ensure patient access to it.

Legislative Background

CMS’s new rule is the result of recent legislation. In the Medicare Improvements for Patients and Providers Act (MIPPA), enacted July 15, 2008, Congress required that CMS identify categories and classes that require protected status. By statute, these categories and classes must have the following characteristics:

- (1) If treatment with products in the category or class is withheld, there could be major or life-threatening consequences to the beneficiary, and
- (2) Due to the unique chemical actions or pharmacological effects of the products in the category or class, there is a significant clinical need for access to multiple products within the category or class.

Part D plans must cover all the drugs included in any category or class identified by CMS as possessing these characteristics, unless an exception applies. CMS is allowed to create exceptions, provided that the exceptions (a) are in accordance with scientific evidence and standards of medical practice and (b) are vetted through notice and comment. CMS is mandated by statute to implement this process starting with Plan Year 2010.

This congressional action essentially codified what had already been agency practice. CMS already requires that Part D plans include in their formulary all or substantially all drugs that are (1) antidepressants, (2) antipsychotics, (3) anticonvulsants, (4) immunosuppressants, (5) antiretrovirals, and (6) antineoplastics. It is believed that Congress nevertheless enacted the MIPPA provision to

preclude CMS from changing its position regarding the protected status of these different categories and classes.

Regulatory Implementation

CMS published an interim final rule on January 16, implementing this statutory mandate. CMS's rule is quite short, with the bulk of the discussion of its implementation of the MIPPA provision spanning only three pages of the *Federal Register*. CMS does not proffer any suggestions for defining what is a "major" or "life-threatening" consequence that could result from limitations on access to a particular product. Nor does CMS explain how a product's chemical action or pharmacological effect could qualify as "unique." Rather, the only real regulatory expansion upon the statutory requirements furnished by CMS relates to its description of the general process by which protected categories and classes will be identified.

Though this process is not laid out in detail, CMS makes clear that its goal is to rely on outside sources to make determinations for the agency regarding the categories and classes to be protected. First, CMS intends to hire a contractor to review "widely used treatment guidelines" to determine which classes or categories contain multiple drugs that are each typically used to treat a specific disorder. In other words, CMS's instruction to its contractor will be to determine protected categories and classes based on the contractor's judgment of medical "best practices." If these "best practices" indicate that different drugs in a category or class are recommended for different situations, then presumably that category or class would be deemed to require protected status.

Second, CMS intends to "validate" the contractor's findings with an expert panel of physicians and pharmacists. CMS will make publicly available information regarding the independence, potential conflicts of interest, expertise, and balance of individuals participating in the panel. This panel will also help determine which products should be considered exceptions within a protected category or class. Finally, CMS will publish the results of this panel's findings in the *Federal Register* and will accept comments on them.

Timing of Regulatory Implementation

Notwithstanding the express dictates in the statute, CMS has stated that it will not implement this process for Plan Year 2010. Rather, it expects to begin implementation in Plan Year 2011, and, as mentioned above, it will do so through notice and comment rulemaking.

Significance to Manufacturers

Pharmaceutical manufacturers seeking to understand how their products will fare under the new regulatory framework may find CMS's guidance insufficient. Key terms such as "major," "life-threatening," and "unique" are not defined in regulation or regulatory guidance. Apparently by design, and in contravention of the statute, CMS is seeking to minimize its role altogether in setting forth the framework under which protected status determinations are to be made. Rather than setting forth explicit rules using concrete definitions for making these determinations, CMS is relegating its authority to an outside contractor and a supposedly "expert" panel. This lack of transparency and clear rules will leave many manufacturers unable to predict how their own products will be treated.

Not only does the system put forth by CMS lack transparency, but it also is not likely to produce ideal results. CMS's grant of discretion to a single contractor can lead to too much bias controlling the outcome. Further, no panel of experts is likely going to have sufficient experience with the panoply of disease states treatable by all the numerous drugs available in the marketplace to effectively understand each category and class. Thus, some important considerations will inevitably be overlooked. While there is the safeguard of notice and comment rulemaking, the wealth of new information that will likely be received by the agency during the comment period may mean that the agency will have to start from scratch in some years. Since truly significant changes to a proposed rule require an additional comment period, the whole process could become protracted, which works to the detriment of the Part D beneficiaries, whose interests the rule seeks to protect.

Importantly, the rule also does not appear to adhere to the statute. The statute requires that the "Secretary" identify protected categories and classes, not its contractor or expert panel. Further, the process CMS has laid out likely will not result in the protection of classes and categories that are meant to be protected by statute. If CMS's contractor is to rely on "widely used treatment guidelines" to make its determination regarding particular categories or classes, then categories and classes with newer drugs will be seriously disadvantaged under the system. A category or class could have multiple drugs, each of which has a unique chemical action and pharmacological effect, and yet, due to the relative newness of the drugs, there may be no pertinent treatment guidelines. Such categories and classes would be inequitably removed from consideration for protected status, in violation of the statute.

Solicitation of Comments

Manufacturers, however, do have an opportunity to affect this process. CMS has expressly sought comments on this procedure for choosing protected categories and classes. Any such comments must be submitted prior to **March 17, 2009**.

If you have any questions regarding any of the issues discussed in this LawFlash, please contact any of the following Morgan Lewis attorneys:

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