

January 2005

Medicare Part D: USP Final Model Guidelines

The U.S. Pharmacopeia (USP) has issued final Model Guidelines for Drug Categories and Classes in Part D (Model Guidelines). As provided by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), these Model Guidelines will provide a voluntary framework upon which prescription drug plan sponsors and Medicare Advantage organizations offering Part D drug benefits may structure drug formularies.

The MMA prohibits plans from substantially discouraging enrollment by certain (e.g., higher-risk) beneficiaries. Plans using formulary categories and classes that are consistent with the USP Model Guidelines will be presumed to have a formulary structure free from such discrimination. Under CMS's proposed regulations, however, plans may still be found to discriminate through, for example, their tiering structure or the drugs chose for inclusion on the formulary.

This memorandum summarizes the differences between the draft Model Guidelines and the final Model Guidelines.¹

A. Category and Class Modifications

The MMA requires plans that implement formularies to cover at least two drugs in each therapeutic category and pharmacologic class. The final Model Guidelines establish 41 therapeutic categories, nine of which are not further subdivided. Thirty-two of the categories are subdivided into a total of 137 pharmacologic classes. The final Model Guidelines maintain the total number of categories and classes established in the draft Model Guidelines at 146.

Some categories and classes that existed in the draft Model Guidelines, however, have been eliminated or combined with others and some new categories have been added. For example, the new therapeutic category "inflammatory bowel disease agents" and three pharmacologic classes within that category have been added, the therapeutic category "anticonvulsants" has been divided into four pharmacologic classes, and the five pharmacologic classes that had existed within the therapeutic category "antifungals" have been eliminated.

B. Elimination of Proposed Subdivisions and USP's New Recommended Approach

The draft Model Guidelines had further divided some of the therapeutic categories and pharmacologic classes into "recommended subdivisions." These subdivisions were included as illustrations of drug groups that would assure beneficiary access to medications but, unlike categories and classes, would not be subject to the two-drug requirement. These subdivisions were the subject of a majority of the comments at a public meeting held on August 27. Many commenters encouraged USP to expand the

¹ A summary of the USP draft Model Guidelines and public comment session is available at <http://www.cov.com/publications/download/oid6075/487.pdf>.

proposed pharmacologic classes to include some or all of the subdivisions or to make the subdivisions mandatory. Other commenters advocated the elimination of the subdivisions altogether.

The final Model Guidelines do not contain any recommended subdivisions. Instead, in addition to the final Model Guidelines, USP created a separate listing of “formulary key drug types” within certain categories and classes. For example, the therapeutic category “blood glucose regulators” contains, among others, a pharmacologic class “insulins,” which includes four formulary key drug types – “insulin, intermediate-acting,” “insulin, long-acting,” “insulin, rapid-acting,” and “insulin, short-acting.” These four formulary key drug types had been included as recommended subdivisions in the draft Model Guidelines.

According to USP, the listing of formulary key drug types is designed to provide additional guidance to CMS with respect to drug types that should be included in formularies. Specifically, USP recommends that CMS require that a plan's formulary include at least one drug of each formulary key drug type or that the plan provide to CMS “substantial clinical, scientific or other rationale for excluding such drugs.”

In addition, some of the recommended subdivisions that existed in the draft Model Guidelines have been converted into pharmacologic classes in the final Model Guidelines. For example, in the draft Model Guidelines, the therapeutic category “respiratory tract agents” contained, among others, the pharmacologic class “antiasthma/bronchodilators,” which included four recommended subdivisions. In the final Model Guidelines, all four of those recommended subdivisions have been converted into pharmacologic classes. The same was done within the therapeutic category “gastrointestinal agents.”

We expect that CMS will address its policy concerning the final Model Guidelines and USP's recommended approach to the formulary key drug types in its final Part D regulation. CMS has indicated that it will publish the final Part D regulation during January 2005.

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This information is not intended as legal advice, which may often turn on specific facts. Readers should seek specific legal advice before acting with regard to the subjects mentioned herein.

If you have any questions concerning the material discussed in this client alert, please call the following members of our life sciences group:

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