Medicare Part D:

USP Draft Model Guidelines and Public Comment Session

August 2004

The U.S. Pharmacopeia ("USP") has issued draft Model Guidelines for Categories and Classes of Drugs ("Model Guidelines"). As provided by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), these Model Guidelines, when finalized, will provide a voluntary framework upon which prescription drug plan sponsors and Medicare Advantage organizations offering Part D drug benefits may structure drug formularies. Adherence to the Model Guidelines will be deemed to meet certain of the formulary requirements of the MMA, as described further below. Written comments on the draft Model Guidelines are due by September 17, and USP heard oral comments at a public meeting on August 27. USP will issue final Model Guidelines later this year.

The draft Model Guidelines establish 43 therapeutic categories, 8 of which are not further subdivided. 35 of the categories are subdivided into a total 138 pharmacologic classes. Some of the classes are further divided into recommended subdivisions. For instance, the category "antidepressants" includes three classes: "monoamine oxidase inhibitors," "reuptake inhibitors," and "antidepressants, other." The recommended subdivisions of "reuptake inhibitors" are "SNRI," "SSRI," and "tricyclics." Similarly, the category "anti-inflammatories" is divided into the classes "corticosteroids" and "nonsteroidals." Recommended subdivisions of "nonsteroidals" are "COX-2 inhibitors," "salicylates," and "nonsteroidals, other."

The MMA requires plans that implement formularies, whether or not based on the USP model, to cover at least two drugs in each formulary category and class. This two-drug requirement would not apply to the subdivisions in the USP model under the regulations proposed to implement the drug benefit. After finalizing the Model Guidelines, USP intends to populate the model with all FDA-approved drugs within each category, class, and recommended subdivision. USP will not attempt to influence any plan's drug selection.

A. CMS Response to Draft Model Guidelines

The Centers for Medicare and Medicaid Services ("CMS") issued a discussion paper in response to the draft Model Guidelines. CMS appears generally to endorse the structure of the draft Model Guidelines, noting that the draft gives providers

and beneficiaries detail about the types of drugs that will be covered while also providing plan sponsors flexibility in plan design.

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 Model Guidelines will be considered to have a formulary structure free from discrimination, but CMS's proposed rulemaking stated that these plans could still be found to discriminate through, for example, their tiering structure or the drugs chosen for inclusion on the formulary. It also appears that, since neither the MMA nor the proposed rule refers to subdivisions, CMS would consider a formulary structure to be free from discrimination even if the structure does not contain the recommended subdivisions contained in the Model Guidelines.

The discussion paper states that CMS "will evaluate formularies at a more granular level than described by the Model Guidelines to make sure they include sufficient choices of clinically significant drugs." CMS is likely to evaluate formularies at the sub-class, or recommended subdivision, level. CMS will issue more detailed formulary review guidelines this fall and welcomes comments on the factors to be included in these guidelines. CMS also could strengthen its language when issuing the final rule on the Part D benefit effectively to require coverage of drugs in certain recommended subdivisions. USP also might include certain recommended subdivisions as therapeutic classes in its final Model Guidelines in response to public comments and/or policy direction from CMS.

B. Comments at August 27 Public Meeting

USP's recommended subdivisions were the subject of a majority of the comments at the August 27 public meeting. Many of the commenters encouraged USP either to expand the proposed classes to include some or all of the subdivisions or to make the subdivisions mandatory. Others supported the proposed structure of the Model Guidelines, with some commenters even advocating the elimination of the subdivisions altogether.

Commenters advocating for greater weight for the subdivisions included the American Medical Association ("AMA"), the American Society of Health-System Pharmacists (publisher of the American Hospital Formulary Service Drug Information), the American Society of Consultant Pharmacists, the American Academy of Neurology, and members of the Pharmaceutical Manufacturers Advisory Forum (with which the USP consulted) including the Pharmaceutical Research and Manufacturers of America ("PhRMA"), the Biotechnology Industry Organization ("BIO"), and the National Pharmaceutical Council. These commenters were of the opinion that use of the categories and classes alone, without consideration of the recommended subdivisions, would discourage enrollment. For instance, the antidepressant category in the draft model includes the newer SSRIs in the same therapeutic class as older but cheaper tricyclics. Some commenters speculated that if plans are required to cover only two drugs in the pharmacologic class, without reference to the recommended subdivisions,

then the plans likely will cover only two tricyclics. Patients wishing to obtain coverage for the more widely-prescribed SSRIs would then be required to request a formulary exception. The AMA's commenter described this possibility as "unacceptable."

A number of commenters decried the cost of the exceptions process for physicians and for patients, in terms of both money and delay of treatment, arguing that the Medicare population is poorly situated to handle these costs. Commenters also noted that Medicare-Medicaid dual-eligibles, who are among the sickest and most vulnerable, will be at substantial risk of therapeutic noncompliance if the new formulary covers only a limited range of drugs.

Commenters arguing against strengthening the subdivision structure included America's Health Insurance Plans, the Academy of Managed Care Pharmacy, and the participants in the Drug Plan Advisory Forum (with which the USP consulted). These commenters noted that the MMA imposes only a minimum level of coverage and that plans can, and are likely to, cover more drugs than are required by the statute and the proposed rule. They described pharmacy and therapeutics committees as qualified and accustomed to populating categories and classes with the necessary and appropriate drugs. They also argued that potential plan sponsors must have flexibility in creating formularies. As the requirements and restrictions increase, they argued, the number of willing plan sponsors decreases.

Others pointed out in rebuttal that in the discount drug card program, sponsors have been able to negotiate substantial discounts under a formulary with substantially more categories and classes than the draft Model Guidelines. They also pointed out the variety of options for managing drug utilization, including tiering, prior authorization, and inclusion of generic products.

Comments on other topics included:

- Numerous statements from clinicians regarding particular types of products, including vaccines, phosphate-binding drugs, drugs for osteoporosis, ketolides, and anticonvulsants.

- Concern about the coverage of orphan drugs under the Model Guidelines. Two commenters advocated for a separate category and class for orphan drugs, instead of including them in categories and classes with dissimilar and often less expensive drugs.

- Requests for clarification or definition of some categories and classes. The draft dermatological and antifungal categories were described as particularly challenging.

- Criticism that classes within some therapeutic categories (*e.g.*, antivirals, antipsychotics) are very specific while others (*e.g.*, antidepressants, anti-

inflammatories) are general and leave the specific distinctions to the recommended subcategory level.

- Requests for a clear process for adding categories and classes as necessary. The MMA specifies that USP is to revise the Model Guidelines "from time to time," and commenters requested that USP define a more specific timeframe.

- Concern that some classes are primarily populated by over-the-counter products that will not be covered by the Part D benefit.

- Request for clarification regarding reimbursement for off-label drug use. Commenters inquired whether plans will cover formulary drugs for any prescribed use or will limit coverage to the specified category and class. CMS's proposed rule would permit plans to classify drugs in the formulary "based on an off[-]label use for that drug, provided the FDA has not made a determination that the drug is unsafe for that use." The proposed rule also does not prohibit off-label prescribing, although it appears to permit plans to limit coverage of off-label uses.

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We are continuing to analyze the Medicare Part D developments and their implications for industry clients.

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