

Shaping Public Health Policy

The role of the United States Pharmacopeia in Medicare Part D

by Amy K. Kennedy

MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003. SECTION 1860D-4(B)(3)(C)(II):

The Secretary shall request the United States Pharmacopeia to develop, in consultation with pharmaceutical benefit managers and other interested parties, a list of categories and classes that may be used by prescription drug plans under this paragraph and to revise such classification from time to time to reflect changes in therapeutic uses of covered part D drugs and additions of new covered part D drugs.¹

The enactment of Medicare Part D was the most significant change to the Medicare program since its inception in 1965. It stipulated the addition of a prescription drug plan for Medicare eligible seniors and dual eligibles. Development of that drug plan required input from various organizations. The following article details the involvement of the United States Pharmacopeia (USP) in developing the standards for Medicare Part D.

The United States Pharmacopeia (USP) was established by practitioners in 1820 to serve as a public standard setting organization to ensure safe and effective medication use within the United States. These standards encompass prescription medications and also extend to over-the-counter medications and dietary supplements. In 1980, this organization began publishing the USP drug information series, which provided information about off-label use and dosing beyond FDA-approved labeling and has aided health care professionals in furthering their practice. In 1985, the United States Veterans Administration sought out the USP to create, maintain, and publish categories and classes for their formulary.

Currently, the USP is comprised of more than 400 health care organizations whose mission is to promote public health.² Therefore, the USP was a logical choice for Congress to select to help implement Medicare Part D.

MODEL GUIDELINES FOR FORMULARIES

USP was charged with four objectives by the Centers for Medicare & Medicaid services (CMS): (1) develop the Model Guidelines consisting of drug categories and classes; (2) conduct an outreach program to evaluate said guidelines, including an environmental scan and public meeting; (3) provide a comprehensive listing of all drugs in each category; (4) develop a plan to provide revisions to the Model Guidelines. The Model Guidelines are used by CMS to evaluate proposed formularies submitted by insurance companies for approval. The guidelines are one of seven components that companies must comply with to provide services under the new benefit.³ Companies are not required under law to use the Model Guidelines. They are in place to ease administration of the benefit and to make the benefit clear, consistent and comprehensive for all constituencies.

It is important to note the Model Guidelines are not a formulary and are not intended to serve as treatment guidelines, but rather should be interpreted as a "safe harbor." That is, the companies that follow these guidelines will most likely not commit violations in developing their formularies. While companies are not required to use the Model Guidelines, they must provide justification to CMS if there are discrepancies in the level of care provided. Seventy-four percent of formularies used the Model Guidelines as a classification structure at the launch of the

program, indicating success in compiling a complete and useful guide for pharmacy benefit managers.³

The USP objectives for the Model Guidelines are succinct and comprehensive. The first is to assure beneficiary access to needed drugs while preventing substantial discouragement of certain patient groups from enrolling. The second objective is to produce formulary categories and classes that are clear, relevant, and will provide consistency to prescription drug plans. The final objective is to assist CMS in its evaluations of drug plan formularies.⁴

THE PROCESS OF DEVELOPMENT

How was the USP able to accomplish this project? The following is a project outline detailed by USP. The Model Guidelines Expert Committee (MGEC) was responsible for spearheading the project and making the final recommendations with input from several other groups. This group was drawn from the Council of Experts, which is comprised of experts from around the world whose nations use the USP-National Formulary as their national compendia. The MGEC contracted with Booz Allen Hamilton to conduct an environmental scan of the current health care system to examine other formulary classifications such as the Veterans Administration and the American Hospital Formulary Service (AHFS) to aid in the development of the guidelines. Four advisory forums assisted the MGEC in ensuring that viewpoints inherently involved in Medicare were considered. There were four advisory forums representing providers, manufacturers, beneficiaries, and pharmacy benefit managers. Thirty-one information committees staffed by USP employees supplied the MGEC with the most up-to-date and comprehensive data available on prescription medications. Lastly, the outreach program consisted of public meetings and 20 consultations from influential health groups from around the country to solicit opinions about the proposed guidelines.⁴

The revision process to update the Model Guidelines is very similar to the process used to create them initially. The MGEC meets four times per year to discuss recommendations from USP's information expert committees and new drug information that has been updated. From these meetings appropriate updates

are made to the Model Guidelines. The 15 expert committees are delineated by clinical specialty and are responsible for submitting recommendations to the MGEC based on their perusal of new information supplied by the USP staff. To supplement the expert committees work, five advisory panels in the following areas provide additional analysis. The five panels include comparative efficacy and safety, health maintenance and the pathophysiology of disease, mechanism of action, indication/molecular targeting, and clinical pharmacology.⁴ The last group to contribute to this process is the USP staff whose responsibility is to provide updated information related to medications and health which allow the committees to make the most informed recommendations possible.

The USP devised a two-pronged attack to achieve the aims of CMS: the development of the Model Guidelines, and the development of the Formulary Key Drug Types (FKDT). The Model Guidelines are based on the conceptual framework that the most effective way to ensure coverage for all diseases is to link diagnosis to treatment to Part D prescription drug. The selection of ICD-9 codes for the basis of this link relates to the fact that ICD-9 codes are routinely used in the United States for billing purposes and for their practicality.

Drug classification was based on a three-tiered classification. The three tiers refer to general treatment category, general drug class, and pharmacologic effect. For example, in the general treatment category of antihypertensives, diuretics would be a general drug class and loop diuretics would be a specific pharmacologic action for a subset of diuretics. At times it may not be appropriate for the third tier to be classified by pharmacologic effect. When this occurs, it is often classified by chemical structure or time of introduction.

The requirement under the law was that each category and class was required to contain two drugs, while formulary key drug types (FKDT) were required to have one drug in each. The USP approach has been referred to as the “floor” since it is often the bare minimum required for formularies.

Many formularies offer many more choices for therapy than the Model Guidelines stipulate. There are six “ceil-

ings” within the Medicare Modernization Act. Ceilings are requirements where providers must cover all drugs within the specified class. These classes include antipsychotics, antiretrovirals, antineoplastics, anticonvulsants, antidepressants and immunosuppressants.² The USP had to find the balance between an open formulary which ensures beneficiaries adequate access to therapy, but discourages management of the plan through competitive bidding and one which facilitates competitive bidding, but raises questions about beneficiary access to needed medications. The compromise the USP reached was to

The USP had to find a balance between an open formulary and one which facilitates competitive bidding, but raises questions about beneficiary access to needed medications.

add the FKDT to its recommendations.

The FKDT allows plans more flexibility than with the Model Guidelines alone. Blood glucose regulators are a key example. Within this category is the pharmacologic class of oral hypoglycemics. The Formulary Key Drug types are alpha-glucosidase inhibitors, biguanides, meglitinides, sulfonylureas and thiazolidinediones. If the FKDT was not included in the guidelines, each formulary would need two agents each from the preceding types to comply with the regulations. With the compromise of the FKDT, a formulary that included metformin (biguanide) and glipizide (sulfonylurea) could satisfy both the Model Guidelines and the CMS guidelines.²

It should be noted that the FKDT is not limited to those formularies that choose to use the Model Guidelines, but

is applied to all submitted Part D formularies to ensure quality standards.³

GETTING INVOLVED

How can a single pharmacist impact the Model Guidelines? There are several ways for an individual practitioner to contribute. One way is to attend public meetings held about the Guidelines to voice opinions about the proposed changes and revisions. The second is to attend topic-specific seminars that educate practitioners about the ins and outs of Medicare Part D. These seminars will allow practitioners to better grasp the offered benefit and foster thoughtful discussion on the direction of Medicare Part D. Lastly, pharmacists and others can provide public comments on the proposed updates every year.

Comments can be submitted by email to drugclasses@usp.org. The time period where comments are solicited about the proposed revisions is November to February. In November 2007, Medicare Model Guidelines 4.0 will be available for public viewing and comment. Please visit [HTTP://WWW.USP.ORG](http://WWW.USP.ORG) to submit comments.

The USP has been and continues to be an important organization in shaping public health policy in the United States. With the ever-growing complexity of the health care system and the ever-expanding knowledge that is gained about health, it is imperative that organizations such as USP are consulted about major health care policies such as the Medicare Modernization Act. In this way, the future of health care likely will grow in a desirable direction. ●

Amy Kennedy is a third-year PharmD student at the University of Wisconsin. This article was completed in partial fulfillment of an independent study project.

REFERENCES

1. United States Pharmacopeia. Cooperative Agreement: “Secretary’s Request to USP”. Available at <http://www.usp.org/pdf/EN/mmg/uspCMSCorpAgreement.pdf>. Accessed February 15, 2007.
2. United States Pharmacopeia Model Guidelines Expert Committee. Narrative Review: The U.S. Pharmacopeia and Model Guidelines for Medicare Part D Formularies. *Ann Intern Med* 2006; 145:448-453.
3. Centers for Medicare and Medicaid Services. Medicare Modernization Act Final Guidelines-Formularies. Available at <http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/FormularyGuidance.pdf>. Accessed February 15, 2007.
4. United States Pharmacopeia. Summary of USP approach and methodology to the Model Guidelines. Available at <http://www.usp.org/pdf/EN/mmg/finalApproachAndMethodology2004-12-31.pdf>. Accessed February 15, 2007.
5. United States Pharmacopeia. For Public Comment: Draft Medicare Model Guidelines 3.0. Available at <http://www.usp.org/healthcareInfo/mmg/forPublicComment.html>. Accessed March 13, 2007.