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Drug manufacturers, pharmacy benefit managers (PBMs), pharmacist groups, and other healthcare industry players are all using the draft Medicare drug formulary suggested by the U.S. Pharmacopeia (USP) Convention for target practice. The USP issued its draft guidelines in mid-August 2004, then held a hearing on them in late August. The organization will publish final guidelines later this year. The Centers for Medicare & Medicaid Services (CMS) either will adopt the guidelines as is or will make some changes.

The final guidelines will have a major impact on the prescription drug plans (PDPs), which will offer the Medicare drug benefit after it becomes available on January 1, 2006. The PDPs will have two choices: (1) they can adopt the final guidelines, or (2) they can use an alternative formulary of their own choosing. If they pick the second option, the CMS will come in and conduct a thorough investigation of the formulary to ensure that it meets certain patient-access requirements and other standards.

That is not a prospect that any PDP welcomes. PDPs, and especially the PBMs they will work with, want the formulary guidelines to square with their needs. This happens to be the view of drug manufacturers, whose needs are structured currently in the commercial marketplace and could have the unintended consequence of increasing costs and jeopardizing a workable Medicare prescription drug benefit for seniors.

The debate boils down to whether the formulary should include more drug classes (backed by the drug companies, physicians, and patients) or fewer drug classes (supported by the PBMs and health insurers). The USP draft guidelines start out with 43 therapeutic categories, which are then broken down into 146 pharmacological classes. A PDP would have to offer at least two drugs in each pharmacological class. In some instances, those classes are broken down into subclasses. The PDP would not have to provide access to drugs in all subclasses.

From PhRMA’s viewpoint, this is where the problems begin. With the category of antidepressants, for example, the draft divides them into three pharmacological classes:

- monoamine oxidase inhibitors
- reuptake inhibitors and antidepressants
- others

The reuptake inhibitor class is divided into three subclasses:

- serotonin norepinephrine reuptake inhibitors (SNRIs)
- selective serotonin reuptake inhibitors (SSRIs)
- tricyclic agents

Thus, a PDP could square itself with the USP draft formulary by offering two tricyclic agents but not SNRIs or SSRIs.

“In the elderly, tricyclics often produce constipation, urinary retention, blurred vision, cognitive impairment, and other symptoms,” says Todd King, a spokesman for the American Society of Consultant Pharmacists. “Yet drug plans might choose to offer only two tricyclic antidepressants and restrict access to the newer antidepressants that are generally safer and better tolerated in the elderly, but are more costly.”

Pharmacy groups, PhRMA and others make that same argument for other pharmacological subclasses such as antihypertensive medications, statins, oral antidiabetic drugs, and treatments for osteoporosis. Many important drugs in these subclasses would not have to be available if the USP draft formulary were adopted wholesale.

On the other side of the fence, Judith A. Cahill, executive director of the Academy of Managed Care Pharmacy, opposes breaking down pharmacological classes into subclasses, which she refers to as recommended subdivisions.

“We are puzzled by the inclusion of the third designation of recommended subdivisions and fail to see its utility,” she says. “The process used by P&T committees in populating the categories and classes will naturally address the subcategorizations in the recommended subdivisions.”

Part of the problem is that the Medicare Modernization Act of 2003, which created the new outpatient drug benefit, provides few specifics on what a formulary should look like and how it should operate. Congress left a lot of details up to the USP and to the CMS.

Anyone with half an ounce of political instinct would have to expect the final formulary guidelines to come closer to the PhRMA position, not because the drug manufacturers have the upper hand here but because their position is backed by a weighty coalition of patient groups, senior citizens (including frequent PhRMA antagonists such as The Seniors Coalition), and physicians.