

# USP Issues Final Model Formulary Guidelines

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The standard-setting group U.S. Pharmacopeia has established 146 unique therapeutic categories and pharmacologic classes to guide the establishment of formularies under the new Medicare Part D prescription drug benefit.

The model guidelines created by USP will serve as a voluntary framework for health plans and prescription drug plans as they create drug plan formularies for Medicare, as established by the Medicare Modernization Act of 2003.

"The model guidelines are not a formulary," Roger L. Williams, M.D., USP executive vice president and CEO and chair of the group's Model Guidelines Expert Committee, said in a press teleconference.

In addition to the categories and classes created by USP, the group also created

formulary key drug types. ACR officials want to see drug plans cover the medications in this third category and make them available at affordable prices, Ms. Ferraro said.

The National Mental Health Association (NMHA) warned that the USP guidelines ignore recommendations from the mental health field not to group older medications with newer therapies. The association said that because these different medications are lumped together, health plans

could choose to cover only the older, less expensive drugs. But NMHA president and CEO Michael M. Faenza said in a statement that his group is encouraged that CMS plans to consider widely accepted treatment guidelines for mental health when reviewing formularies.

But America's Health Insurance Plans (AHIP) praised the USP's final document.

"The final model continues to provide needed flexibility by not expanding the number of categories and classes previ-

ously proposed," said Karen Ignagni, AHIP president and CEO. "The direction that CMS is clearly taking supports the building of effective private plan strategies to make the Part D benefit clinically appropriate and affordable for Medicare beneficiaries."

Officials at the Pharmaceutical Research and Manufacturers of America, which has supported access to a broad array of treatments, were still reviewing the document at press time. ■



The NMHA is encouraged by CMS plans to take a broad approach when reviewing formularies.

DR. FAENZA

a separate listing of formulary key drug types to help the Centers for Medicare and Medicaid Services assess the comprehensiveness of proposed formularies.

Under proposed Medicare regulations, plans that follow the model guidelines would need to offer at least two drugs in each therapeutic category and pharmacologic class. USP has also recommended that CMS require plans to offer at least one drug from the list of formulary key drug types or have a clinical or scientific rationale for excluding the drugs.

CMS officials will use the guidelines to help evaluate proposed formularies.

The USP issued draft guidelines last August that were criticized by physician groups and patient advocates as leaving too many critical drugs in a third category, where they would not be required to be covered.

The final guidelines include a new therapeutic category for inflammatory bowel disease agents and a new pharmacologic class for proton pump inhibitors. Other changes to the model guidelines include additional antimentia drugs and expanded dermatologic agents.

Dr. Williams said that he hopes all parties will see the final guidelines as "workable compromise."

The American College of Rheumatology (ACR) applauded USP's efforts in putting together the model guidelines and called it a good place to start. But much will depend upon how CMS decides to use the guidelines, said Pam Ferraro, a regulatory analyst for ACR.

Many of the drugs of interest to rheumatologists, such as tumor necrosis factor inhibitors, were not included as either therapeutic categories or pharmacologic classes but were part of USP's list of

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