Very quietly, the Centers for Medicare and Medicaid Services (CMS) has proposed some major changes to its Part D drug program that would affect formulary design and P&T committee members’ responsibilities. The prospective changes are a big victory for the Part D plans and would generally provide more flexibility for their formularies and more authority for P&T committees. But expect to hear yelps from both patient advocacy groups and drug manufacturers as they become aware of what the CMS is proposing.

The big change concerns the current six “protected” Part D drug classes: antipsychotic agents, antidepressants, anticonvulsants, immunosuppressants to prevent transplant rejection, antiretrovirals, and antineoplastics. Part D plans must carry “all or substantially all” of the chemically distinct drugs in these categories on their formularies. For other categories, the plans can typically carry one brand-name drug and one generic drug.

The CMS established these six classes when the Part D program was established in January 2006. The idea was to protect Medicaid recipients who were transferring into the Medicare Part D program and who were considered especially vulnerable (for example, those with AIDS or severe mental illness) so that they would be able to stay with the drugs they were taking under Medicaid, even if that drug was not on their Part D plan’s formulary.

Part D plans and pharmacy benefit managers (PBMs) have argued that the six protected classes have outlived their usefulness and that CMS’ policy is costing Medicare more than it should be paying for drugs in these six categories. One Part D plan sponsor in the Blue Cross Blue Shield system reports that 40% to 60% of the drug expenditures by its Medicare low-income and dually eligible clients (i.e., former Medicaid beneficiaries) stem from current use within these six classes.

Patient advocacy groups have a different view, of course. They would like to retain the six protected categories and perhaps even add extra ones. Mental Health America, for example, points to large-scale trials such as the National Institute of Mental Health (NIMH) Sequenced Treatment Alternatives to Relieve Depression (STAR*D) study. In that trial, only half of those individuals with depression experienced remission with the initial therapeutic agent used in the study. Four different strategies involving multiple medication regimens were needed to achieve maximal clinical results for these patients.

In August 2008, the tension between those two views led Congress to pass Section 176 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). Section 176 set two criteria for the CMS to use in determining whether to keep the six categories or to add new ones. One criterion was whether restricted access to all drugs in a category as a result of unique chemical actions and pharmacological effects of all the drugs in that disease category.

In January 2009, just before the Obama administration came to town, the CMS issued an interim “final” rule, which defined some of the key terms in Section 176. Based on those definitions, the CMS seemed to indicate that at least the six protected categories would be retained. As a result of its new Section 176 definitions, the final rule estimated that Part D costs would be $4.9 billion higher between fiscal years 2010 and 2019.

However, in the proposed rule of October 22, 2009, the Obama CMS did an about-face—it defined the two MIPPA criteria much more narrowly than the agency had done last January, calling the constricted definitions “a significant new Part D policy.” In an admission that is sure to shake up some patient advocacy groups, the CMS said:

While some commenters and a few outside parties have suggested that the Congress’ intention behind Section 176 of MIPPA was to codify our pre-existing ‘6 class’ policy, we do not believe that the plain reading of the statute supports such an interpretation because the six classes are not expressly identified in the MIPPA.

The CMS argued for interpreting the MIPPA criteria more narrowly to avoid duplicative protections and to preserve one key aspect of the Part D program—namely, that Part D sponsors have the ability to undertake cost-containment efforts through formulary design.

Elsewhere in the October 22 proposed rule (and having nothing to do with MIPPA in one instance), the CMS provides additional authority to Part D P&T committees. The CMS wants to allow P&T committees not only to review but also to approve all clinical previous authorizations—namely, that Part D sponsors have the ability to undertake cost-containment efforts through formulary design.

Overall, the breadth of the proposed changes to Part D is an important endorsement of P&T committee oversight and the right of formularies to control costs. It remains to be seen whether expected opposition to the changes from patient advocacy groups and their supporters in Congress will force the CMS to reconsider some of the modifications.