Role of P&T Committees in Medicare: How Much Authority, Accountability?

Stephen Barlas

W hile formulary guidelines for the new Medicare outpatient drug benefit are being hotly contested, as described last month in P&T, there are also considerable differences of opinion about the composition and authority of the P&T committees that will be appointed by each prescription drug plan (PDP) to ride herd over their formularies.

The shape and role of the P&T committees drew much attention during hearings in the Senate Finance Committee in September, about one month after the Centers for Medicare and Medicaid Services (CMS) proposed a rule outlining its initial thinking on many issues related to the new prescription drug benefit, which kicks in on January 1, 2006. The Medicare Modernization Act of 2003 (MMA), which authorized the drug benefit, left quite a bit to the imagination in terms of the role of P&T committees, as it did with formulary construction and many other items. But the CMS is now trying to fill in the blanks. That was the purpose of the proposed rule.

For example, the MMA says that a PDP’s formulary must be “developed and reviewed” by a P&T committee. In its proposed rule, the CMS said it interpreted that language, at least on its first reading, to mean that the PDP has to do exactly what the P&T committee tells it to do. Now, the law doesn’t exactly say that, so the CMS asked for comments on that issue.

Regarding the composition of the P&T committee, again, the MMA is not very specific. The majority of members who make up the P&T committee would be required to be practicing physicians and/or practicing pharmacists. In addition, at least one practicing pharmacist and one practicing physician member would have to be experts in the care of elderly and disabled individuals. None of that is too controversial.

However, things get stickier when it comes to determining how many members of the committee must be independent and how that term is defined. The law says that at least one physician and one pharmacist must be independent. The CMS says that it interprets the statutory language in the bill—which refers to P&T committee members as being “independent and free of conflict with respect to the sponsor and plan”—to mean that such committee members must have no stake, financial or otherwise, in formulary determinations. This means that a pharmacist on the committee could not have any ties to the PDP or to any of its suppliers.

At the Senate hearings, Michael J. Fitzpatrick, executive director of the National Alliance for the Mentally Ill (NAMI), testified on behalf of a number of patients’ groups. He suggested that the CMS go way beyond its proposed rule with regard to independence. He said that P&T committees should consist of a majority of independent members—not just two—who are practicing clinicians.

Moreover, he urged the CMS to adopt a series of “sunshine” provisions, which have no origin in the MMA. For example, he recommended that P&T committees provide the PDP’s members with advanced notice of their meeting agendas and that the committees accept public input on drug coverage decisions.

“Considering [that] most P&T committees are independent from the PBM or drug plan, it would not be appropriate for them to be given authority for making decisions that affect a plan sponsor when they have no accountability for those decisions,” he adds.

So the question is not whether P&T committees will help direct PDPs but whether they will be just traffic cops or more like police commissioners.