Medicare Spells Out Rules for P&T Committees and Part D Drug Plan Benefits

Stephen Barlas

Stephen Barlas is a freelance writer based in Washington, DC, who covers issues inside the Beltway. Send ideas for topics and your comments to sbarlas@verizon.net.

Many of the health plans that will be offering Medicare outpatient drug benefits, which are scheduled to begin on January 1, 2006, will decide to use a formulary, in order to control costs and for clinical common sense. Although these “Part D” drug plans will have flexibility in developing their own formularies, they will have to follow “bright lines” on how their pharmacy and therapeutics (P&T) committees are supposed to operate. The Centers for Medicare & Medicaid Services (CMS) printed its version of the instruction booklet in January, when it published a final ruling on how the new drug plans will work.

The majority of members comprising the P&T committee, which will be required to meet at least quarterly, are expected to be practicing physicians or practicing pharmacists. In addition, at least one practicing pharmacist and one practicing physician must be experts in the care of elderly and disabled individuals. Aside from these rules, there are no requirements for the clinical specialties that physicians and pharmacists must represent.

At least two members of the committee will have to be “independent and free of conflict.” However, Medicare doesn’t specify what this means. Obviously, these members may not be employees of the company offering the drug plan, of its suppliers, or of drug manufacturers. However, consultants to drug manufacturers may be considered “independent” as long as their relationship with the drug company does not constitute a significant source of income.

Two members of the committee will have to be truly independent, but all members of the committee must sign a conflict-of-interest statement that would reveal economic or other relationships with entities that could influence pharmaceutical decisions. These members would also have to disclose such conflicts to other committee members. If a P&T committee discussion focuses on a drug that presents a conflict of interest for any committee members, these members would have to excuse themselves from any deliberations or votes associated with that drug.

Medicare also has some fixed ideas about the ways in which the P&T committee can make decisions and how it can wield the most influence. When determining which drugs to include in a given drug category or class, the P&T committee would need to base its clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature. The whole process will be “black and white,” and it must be made available for review. But it is up to the P&T committee, not the drug plan, as to which drugs get covered.

At least two drugs will be included in each class, except when only one FDA-approved drug exists for that class; this requirement refers to two chemically distinct drugs. The alternatives cannot be two dosage forms or strengths of the same drug, and they cannot be a brand-name drug and its generic equivalent.

What happens if there are only two drugs for that class and one is clinically superior (or “vastly different,” according to the CMS)? Must the plan make both drugs available, even though one of them might be, clinically speaking, a “loser?” In the final ruling, the CMS says that drug plans can request exceptions in order to offer only the better of the two drugs.

As to decisions about which drugs to place in each formulary class, Medicare expects the plans to consider total health costs associated with the use of a particular drug (i.e., what that drug costs at the pharmacy) and its efficacy, along with factors such as hospital costs that can be avoided. Cost considerations must be balanced with clinical considerations.

Even though P&T committees will be calling the shots as to what goes on the formulary, they will have a much more limited say on the design of the benefits. For example, the committee can recommend the placement of a particular agent on a formulary cost-sharing tier, but the drug plan leader makes the final decision, based on both clinical and non-clinical factors.

P&T committees will also have a say in the drug utilization program established by each Part D plan. The CMS expects the P&T committee to review such items as formulary management practices and policies, including prior authorization, step therapy, generic substitution, quantity limits, and other drug utilization management activities that affect access to covered Part D drugs.

The final ruling from Medicare and its associated published guidelines hew closely to current industry practice for P&T committees. In the private sector, however, P&T committees that create formularies for private payers do not receive quite the level of scrutiny that they will receive from the federal CMS and its watchdog, the Office of the Inspector General. As a result, these P&T committees should ultimately expect a lot of latitude.