C hanges to rules for P&T committees highlight new requirements for Medicare Part D drug and Part C Medicare Advantage plans for 2016. In addition, at about the same time the Centers for Medicare and Medicaid Services (CMS) was announcing those pharmacy changes, it disclosed additional changes it might make for calendar 2016.

First, the new P&T committee requirements. P&T committees in Medicare programs have always had to include at least one independent practicing physician and one independent practicing pharmacist, both of whom are “independent and free of conflict.” These physicians and pharmacists cannot have any financial arrangement with a pharmacy benefit manager (PBM), a drug company, or anyone else that might benefit from a formulary decision they participate in.

But Medicare regulations are being revised to require that the sponsor’s P&T committee clearly articulate and document processes to determine that members who are supposed to be independent are indeed independent, and committees must have a policy to manage recusals due to conflicts. Those processes must be enforced by “an objective party,” which may be a representative of the PBM—as long as that representative is not also a member of the sponsor’s P&T committee.

However, it appears that numerous gray areas could come up as P&T committees try to confirm that independent members are “free of conflict.” What about a pharmacist employed by the PBM who sits on the P&T committee and owns stock in the PBM or the Part C/D plan? How much stock would compromise his or her independence? What if that pharmacist owns no stock, but his or her spouse is the marketing vice president at a pharmaceutical company whose products are on the Part C/D plan’s formulary? It is not hard to imagine that different drug plans and different PBMs will define “independence” differently, and they are entitled to do so based on the terms of this new requirement.

Still, that P&T committee requirement is a done deal. The additional changes for 2016 were proposed in the CMS annual Call Letter for Part C and D plans. The Call Letter establishes guidance, as opposed to statutory provisions such as the P&T committee changes discussed above, which came via a “final rule.” The Call Letter proposed changes for 2016 that will likely be finalized this spring, as is, and will instruct Part D and C plans to implement procedures to guard against overutilization of opioids and possibly other categories of drugs. P&T committees will have to be involved.

The CMS established an Overutilization Monitoring System (OMS) for acetaminophen and opioids in 2013 and appears ready to expand that system in 2016 with regard to opioids. The OMS provides quarterly reports to sponsors on beneficiaries with potential opioid or acetaminophen overutilization issues identified through analyses of prescription drug event data from the previous 12 months and through CMS program integrity investigations. Sponsors are supposed to respond to the OMS within 30 days on the status of their review for each beneficiary’s case.

Although improved drug utilization review, case management, and beneficiary-level point-of-sale (POS) edits have reduced overutilization of opioids in the Part D program, CMS believes that Part D sponsors should implement soft formulary-level POS edits based on cumulative daily morphine equivalent dose (MED) to further limit opioid overutilization. The plan sponsor’s P&T committee will have to develop specifications for a cumulative MED soft POS edit—at the “200 mg MED and two or more prescriber” threshold—to prevent opioid overutilization while minimizing false positives. However, the CMS is open to alternative thresholds, such as higher MED levels or numbers of prescribers, if they can be justified.

One important issue for pharmacists hangs in the balance. The 2016 final rule requires that Medicare providers be enrolled in Medicare or submit a valid opt-out affidavit. Pharmacists are not recognized as “providers” under Medicare; they cannot “enroll.” So to continue prescribing for patients in states where that is legal—always under an agreement with a physician—a pharmacist would have to “opt out” of Medicare. That means a Medicare recipient who has been relying on a pharmacist for prescribing could no longer use the pharmacist, because that pharmacist will neither be enrolled in Medicare nor have the ability to opt out, according to Mary Jo Carden, Senior Director of Regulatory Affairs for the Academy of Managed Care Pharmacy (AMCP). A letter from the AMCP, the American Pharmacists Association, the American Society of Health-System Pharmacists, and other pharmacy groups to the CMS says, “Not only is this disruptive to the care process, it exacts a high human and financial toll, placing unnecessary stress on patients, other providers, and the health care system.” The pharmacist groups are hoping the CMS will clarify this when it publishes the final 2016 Call Letter.

REFERENCES