P&T Committees May Want to Alter Some Formulary Policies Because of New Medicare Part D Standards

Stephen Barlas

Mr. Barlas is a freelance writer in Washington, D.C., who covers issues inside the Beltway. Send comments and ideas for topics to sbarlas@verizon.net.

Medicare’s proposed use of a new electronic prescribing (eRx) standard for prior authorization requests between physicians and Part D plans has been well received by the various players in the prescription drug delivery chain. That doesn’t mean, however, that it is problem free and without a number of concerns.

The new standard, which won’t be implemented prior to 2021, may force pharmacy and therapeutics committees to reconsider which tiers they put a couple of categories of drugs on. It may also prompt revision of step therapy policies.

The first thing to remember, though, is that there is no requirement that prescribers or plans implement eRx for seniors with Medicare outpatient drug coverage. But if they do, they must use standards sanctioned by the Centers for Medicare and Medicaid Services (CMS).

The current standard with regard to electronic prior authorization—the X12 278 standard designed to conduct batch transactions—was adopted mainly for durable medical equipment. So, understandably, the X12 standard is not really the right tool for the job. Important prescribing information can’t be inputted, and it doesn’t allow for “real-time” responses, or follow-up by physicians, health plans, or pharmacies.

For these and other reasons, CMS has proposed replacing the standards with National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard Version 2017071. CMS had already designated that SCRIPT standard for eRx prescriptions starting January 1, 2020. It would become mandatory for electronic prior authorization transactions one year later, if CMS finalizes its proposed rule.

Today under Medicare Part D, prior authorization requests and responses are transmitted mostly by fax and phone using the X12 standard. Prior authorization, both within and outside Medicare health plans, is a big deal these days as more plans use it for opioid prescriptions in response to overprescribing and the opioid epidemic.

Prior authorization requirements for oncology drugs are also an issue because the drugs are increasingly expensive. Howard Burris III, MD, the president of the American Society of Clinical Oncology, expressed reservations about streamlining prior authorization in his comments on the new standard. He urged the agency to “exercise caution in order to avoid unintended consequences of restricting or delaying care, resulting in harmful outcomes.”

CMS was required to designate a standard for electronic prior authorization by the 2018 SUPPORT for Patients and Communities Act. CMS had endorsed the SCRIPT standard for Medicare eRX standards prior to the SUPPORT Act, but it was constrained from extending the SCRIPT standard to electronic prior authorization transactions by the HIPAA issue. The SUPPORT Act eliminated that barrier by saying a new standard could be adopted “notwithstanding” any other provision of law, if such proposals were made in consultation with stakeholders and the NCPDP or other standard-setting organizations. As a result, HIPAA non-compliance is not a barrier to adoption of the SCRIPT standard by Medicare

Health plans and pharmacists appear to be generally happy with the application of the SCRIPT standard to prior authorization requests and decisions, even though some health plans with both Medicare and commercial plans currently use non-SCRIPT standards.

Joel White, the executive director of the Opioid Safety Alliance pointed out in his comments to CMS that in considering only two sets of electronic prior authorization transaction standards (X12 and SCRIPT) CMS “seemingly ignores current industry use of HL7 FHIR standards or APIs [application programming interfaces].” Leaving these additional standards out of consideration “unnecessarily and prematurely” limits the scope of public consideration and comments, wrote White. The agency’s proposed solution also runs “contrary to other agency efforts, such as increased interoperability and prohibiting information blocking,” he stated.

The American Association of Family Physicians has a different concern: the “significant administrative burden and/or access issues” that general practitioners face in introducing relevant software into their practices. The AAFP wants a “safe harbor” for primary care physicians and, like the Opioid Safety Alliance, the freedom to use standards other than SCRIPT if both a prescriber and a health plan agree to that. One of the concerns about imposing SCRIPT is that physicians might be faced with having to use different standards for e-prescribing within the state Prescription Drug Monitoring Programs and the Part D programs.

When all is said and done, CMS is likely to give physicians, pharmacies, and Part D plans some leeway in a final rule for eletronic prior authorization. Even so, P&T committees in and out of Medicare will have to consider new factors when putting together their prior authorization policies and programs.

Vol. 44 No. 11 - November 2019 - P&T® 651