Secretary Azar Outlines Concerns With the Use of Step Therapy for Patients Who Are Stabilized on an Effective Treatment

In a February 12 speech before the American Medical Association (AMA), HHS Secretary Alex Azar acknowledged the dangers inherent in requiring step therapy for patients who are already stabilized on an effective regimen of medications. Interestingly, his remarks seemed to run counter to his agency’s current proposal to weaken Medicare’s successful “six protected classes” policy.

“I was very disturbed to hear that stable patients switching among insurance plans, like switching among Medicare Advantage plans, can often be required to start over again on a step therapy regimen. This is not just potentially injurious to their health; it’s also penny-wise and pound-foolish.”

“We know that getting a patient on the right drug, at the right time, is one of the best investments we can make in their health—and we do not want to impede physicians from making that happen.”

Background Details

Under current law, Medicare’s six protected classes policy ensures that patients with the most complex conditions (ex. mental health, cancer, HIV, organ transplants, epilepsy, etc.) will have access to a broad spectrum of medications. Patients who are so-called “new starts” — meaning they are not stable on a drug regimen already — may be subject to step therapy and prior authorization, requiring them to try alternative therapies or gain their insurer’s approval before filling a prescription for a certain drug. However, insurance plans currently cannot require these utilization management tools for patients who are already stabilized on a particular treatment within the protected classes. This is true both when a patient enrolls in Medicare for the first time and when a patient changes insurance plans.

In November 2018, the administration released a proposed rule that would allow Medicare drug plans to implement new utilization management tools on the six protected classes. Under the new policy, starting in 2020, plans may use step therapy and prior authorization and for protected class drugs, even if the patient is already stabilized on a particular treatment regimen.