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CMS Continues the Push for Medicare Drug Payment Reform

The Centers for Medicare & Medicaid Services ("CMS") has announced further proposed changes to the Medicare Program in an effort to decrease overall costs for beneficiaries. The latest changes focus on Medicare Part C and Part D plans, while other recent announcements have focused on drug costs under Part B (see our past article regarding these changes here). The Part C and Part D proposed changes were announced by Health and Human Services ("HHS") Secretary, Alex Azar, on November 26, 2018, and were said to be designed with the goal of increased affordability and access to medications for Medicare beneficiaries in mind. A copy of the proposed rule can be accessed here.

The proposed changes can be divided into four major categories. First, CMS seeks to provide Part D plans with greater power to negotiate discounts for medications in the six “protected” therapeutic classes. Part D sponsors are currently required to provide coverage for all medications that fall into these six classes (antidepressants; antipsychotics; anticonvulsants; immunosuppressants for treatment of transplant rejection; antiretrovirals; and antineoplastics). CMS proposes three new exceptions to the current rule. First, Part D sponsors would be allowed to implement greater use of prior authorizations and step therapy, particularly to determine use for protected class indications. Second, a drug may be excluded from protected status if the medication is merely a new formulation of an existing single-source drug or biologic. Last, a medication may be excluded if the price of the drug increased beyond a certain threshold during a specified look-back period. The proposed threshold policies for the years 2020 through 2023 are set out within the proposed rule published in the Federal Register cited above.

The second change would require Part D plans to provide beneficiaries’ and their physicians with the actual out-of-pocket costs for prescriptions at the time the prescription is written. This will be accomplished by requiring Part D providers to adopt real time benefit tools ("RTBT") by January 1, 2020. These tools would integrate with existing software tools to inform prescribers of lower cost alternatives to the medication being prescribed, benefitting patients as well as their physicians, by providing increased information regarding available treatment options and considering what the out-of-pocket cost is for the enrollee.

The next proposal is for the codification of a policy allowing “step therapy” in Medicare Advantage plans for Part B drugs (drugs typically administered in a clinical setting) through a utilization management program and prior authorization tools. If this rule is put into practice, Medicare Advantage plans may provide coverage for Part B drugs but require that lower cost medications be utilized before moving on to higher priced options. However, there would be certain protections and exclusions from the step therapy process, including exemptions for patients already taking more costly drugs or biologics, as the policy would only apply to drugs not currently active. Additionally, the proposed rule would contain specified time periods for utilization reviews and appeals, in order to decrease delays in access to medications. This may be seen as red tape for prescribers seeking to prescribe a particular medication, but it is believed that the utilization program may force pharmaceutical companies to lower drug costs in order to ensure that their products are accessed as early as possible in the step process.

Last, CMS has proposed codifying a recent statutory requirement prohibiting pharmacy gag clauses in Part D plans. The recent “Know the Lowest Price Act of 2018,” signed by the President in October, modified the Medicare Act to restrict Part D sponsors from prohibiting or penalizing participating pharmacies from disclosing lower available cash

prices for medications to plan enrollees. Several states have already adopted similar laws. According to CMS, the proposal seeks to harmonize the regulations with the statutory authority. By restricting these contractual provisions, pharmacists can freely inform patients of better cash prices for a particular medication, without fearing penalty from the patient's Part D plan. Further, CMS proposes requiring pharmaceutical companies to disclose the list price of drugs in direct-to-consumer television ads.

CMS will review comments from the public through January 25, 2019, with the goal of implementing the proposed changes as early as January of 2020.

As we noted in our prior article regarding the previously announced changes to the Part B program, CMS will continue making efforts to extend the life of the Medicare trust fund and seek out efficient ways to do so. However, one must keep in mind that these proposed changes impact Part C and Part D plans that are privately administered and the savings for the Medicare trust fund is indirect. Rather, the goals of these changes appear to be more beneficiary driven by offering increased transparency and hopefully lower costs for beneficiaries. However, it does seem likely that the changes will be met with criticisms, citing that the proposals create a more difficult process and restrict when and how a physician may prescribe a medication. That said, it is important to remember that these changes are only current proposals, and the stakeholder community will no doubt have its say before any final rules are implemented.

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