2019 Medicare Advantage and Part D Advance Notice Part II and Draft Call Letter

By: Kate Woods and Jason Premus
Healthcare Alert
2.7.18

The Centers for Medicare & Medicaid Services (CMS) have released Part II of the 2019 Advance Notice of Methodological Changes for Medicare Advantage (MA) Capitation Rates and Part D Payment Polices (the Advanced Notice) and Draft Call Letter. Part I of the Advance Notice was previously released on December 27, 2017. CMS will publish final versions on April 2, 2018 and is accepting comments on all proposals up until March 5, 2018.

This Alert focuses on CMS's continued policy focus and proposals related to the Part D Program and ongoing efforts to eliminate and mitigate the effects of prescription opioid misuse and overuse. Plan sponsors, providers, pharmacies, and pharmacy benefit managers (PBM) are encouraged to view the 2019 Advanced Notices (Part I and II) and Draft Call Letter in its entirety and to submit any comments or suggestions on or before the March 5, 2018 date.

CMS continues to focus policy efforts and resources on combating the opioid epidemic and reducing effects of opioid misuse and chronic overuse among Part D beneficiaries. These focused efforts are intended to remain balanced with ensuring continued beneficiary access to legitimately prescribed and medically necessary drug regimens and do not include beneficiaries with cancer or on hospice.

Several proposed strategies will directly impact pharmacies, PBMs and providers as well as plan sponsors' policies, procedures and operational work processes, if or when finalized.

Proposals include:

- Implementation of hard formulary-level cumulative opioid safety edits at point-of-sale (POS) at the pharmacy, which only the sponsor can override and soft POS safety edits to serve as flags based on duplicative therapy of multiple long-acting opioids; these edits could be overridden by a pharmacist.
- Implementation of a hard safety edit in 2019 effective when a beneficiary is prescribed a high daily opioid dose as defined by a total cumulative daily dose exceeding 90 morphine milligram equivalents (MME). It is additionally proposed to allow for only one seven-day supply. That is, if a beneficiary attempts to fill multiple opioid prescriptions at one time or attempts to fill an opioid prescription subsequent to the initial seven-day supply after the MME threshold has been reached, the additional or subsequent opioid prescription fills will be denied. Patients and providers may continue to use the exception process when deemed medically necessary.
- Implementation of a hard safety edit for initial opioid prescription fills that exceed seven days for the treatment of acute pain. CMS requests comment on the effectiveness of a days supply limit, with or without a daily dose maximum (e.g. 50 MME per day), as well as information on recommended inclusions and exceptions for specific clinical situations and other parameters to ensure appropriate beneficiary access.
- Enhancing the Overutilization Management System (OMS) through the implementation of additional flags for high risk beneficiaries using "potentiator"[1] drugs in combination with prescription opioids. CMS also requests feedback on pharmacy related issues such as the potential overuse of gabapentin and pregabalin with opioids and other potentiator drugs that should be added to the OMS.

CMS will continue to closely scrutinize formulary and benefit submissions to ensure beneficiaries have appropriate access to medication-assisted treatment (MAT). Benefit designs that would substantially discourage in need beneficiaries from enrolling in MAT therapies will not be approved.

Other CMS recommendations or requests for comments related to the Part D program include Part D Over the Counter Program (OTC) enhancements and potential additional flexibilities such as adding dietary supplements and cough medicines without the need to offset the use of a Part D drug, enhancements to the 2019 Star Ratings measures, and improving access to Part D vaccines through $0 vaccine tier or formulary tiers with low cost-sharing. The 2018 Specialty tier formulary threshold will remain in effect for 2019; CMS will continue to monitor to determine if specialty tier threshold increases are necessary in future years.

If you have questions or need additional information, contact Kate Woods (215.864.6376; woodscj@whiteandwilliams.com) or Jason Premus (215.864.6399;premusj@whiteandwilliams.com).

---

1. Potentiator drugs are those that when taken with an opioid increase the risk of an adverse event. Examples of potentiator drugs include, but are not limited to benzodiazepines, barbiturates, antihistamines, certain classes of muscle relaxers, gabapentin, and pregabalin.