Special NCPA Advocacy Center Update- CMS Issues Final 2019 Medicare Part D Rule and Call Letter

On April 2, 2018 The Centers for Medicare & Medicaid Services released their final Part D Rule and final Call Letter for 2019 Medicare Part D and Medicare Advantage plans. NCPA is conducting a thorough analysis of each and will provide a more detailed member summary. NCPA issued a news release on these developments yesterday, and here is our initial top line assessment of the key provisions.

2019 Part D Final Rule

- **CMS is asserting its authority to propose a rule which would shift pharmacy price concessions (DIR) to point of sale in the future.** Although CMS did not make any final decisions related to pharmacy DIR fees, the agency did state that rulemaking on this issue is likely to occur in the future. CMS' recognition of the need to address the issue at all is largely the result of NCPA's forceful lobbying efforts and input.

- **CMS is clarifying that standard terms and conditions must be offered to "any willing pharmacy" for participation in Part D standard networks**. CMS further clarified that plan sponsors may not exclude pharmacies from their retail network solely on the basis that they, for example, maintain a traditional business while also specializing in certain drugs, diseases, or provide other services like home delivery. *CMS cited NCPA's efforts to bolster its clarification, stating that maintaining access to small businesses in rural areas may help maintain beneficiary access to specialty drugs from community pharmacies.*

- **CMS is requiring Part D plan sponsors to have standard terms and conditions for pharmacy network participation readily available by September 15th upon request by pharmacies**. A pharmacy must request the standard terms and conditions and the plan sponsor must provide these documents within 7 days of receipt of the request and no later than Sept. 15th of each year for the succeeding benefit year.

- **CMS is emphasizing that Part D plan sponsors cannot use additional accreditation standards to limit pharmacies in a network under certain circumstances.** Specifically, Part D sponsors cannot limit dispensing of certain drugs (such as "specialty" drugs) or drugs for certain disease states to a subset of network pharmacies if a pharmacy is capable of and appropriately licensed under applicable law(s) and agrees to meet the sponsor's standard terms and conditions.

- **CMS is finalizing the CARA drug management program that includes a prescriber/pharmacy "lock-in."** The drug management program could limit an at-risk beneficiary's access to coverage of frequently abused drugs beginning in 2019 through a beneficiary specific point-of-sale claim edit and/or by requiring the beneficiary to obtain frequently abused drugs from a selected pharmacy(ies) and/or prescriber(s) after case management and notice to the beneficiary. NCPA agrees with CMS' decision to ensure plan sponsors consider beneficiary preference. NCPA urges CMS to remain vigilant in ensuring appropriate patient access.

- **CMS is changing the Part D transition process.** The final transition fill supply policy effective for plan year 2019 is to require Part D sponsors to provide as a minimum (unless prescriptions are written for fewer days) an approved month's supply for enrollees in both the outpatient and LTC settings.

2019 Final Call Letter

- **CMS is improving drug utilization review controls in Medicare Part D for the 2019 contract year. The following are important changes for pharmacies:**
    - **There is a new hard safety edit for opioids.** All Part D sponsors must implement a hard safety edit to limit initial opioid prescription fills for the treatment of acute pain to no more than a 7-day supply.
    - **All Part D sponsors must implement a real-time safety edit at 90 MME (morphine milligram equivalent) per day at the time of dispensing.** This formulary-level safety edit would trigger when a beneficiary's cumulative MME per day across their opioid prescriptions reaches or exceeds 90 MME.
- **CMS continues to consider changing its current policy of beneficiary prior consent for mail order.** CMS asked for information on prior consent policies, signaling a potential change in its current policy which requires plans obtain consent from beneficiaries prior to shipping refills of mail-order prescriptions. NCPA provided survey information on the fraud, waste, and abuse of mail order and argued walking back prior consent policies would only exacerbate the issue. CMS is currently considering the information that NCPA provided on this issue.