CMS Changes to Medicare Advantage and Prescription Drug Benefit Programs for Contract Year 2015

On May 19, 2014, the Centers for Medicare & Medicaid Services ("CMS") issued a final rule, published in the Federal Register on May 23, 2014, that sets forth changes to requirements for Medicare Advantage ("MA") and prescription drug benefit ("Part D") programs for contract year 2015.

After receiving approximately 7,600 responses to the proposed rule, CMS intends to address at a later date certain provisions included in the proposed rule, including proposed changes to audit and inspection requirements (*see* Table 3 of the final rule). However, CMS also chose not to finalize certain other provisions introduced in the proposed rule, effectively withdrawing the proposals (*e.g.*, changes to drug categories or classes of clinical concern, the limitation on stand-alone PDP sponsors to no more than two plans per PDP region, and a formal interpretation of the non-interference provision).

The regulations are effective on July 22, 2014, with some exceptions. We summarize key provisions of the final rule below.

Direct Request of Information from First Tier, Downstream and Related Entities

- The final rule allows CMS and its designees, including antifraud contractors and other oversight agencies, to collect records directly from any first tier, downstream, or related entity ("FDRs," *e.g.*, pharmacy benefit managers and pharmacies). This authority is on top of existing authority to audit, evaluate and inspect such information, and stems from a 2013 OIG report finding that the current process, through which Medicare Drug Integrity Contractors ("MEDICs") request information from FDRs indirectly through requests to MA organizations and prescription drug plan ("PDP") sponsors, involves delays.
- Except in exceptional circumstances, CMS will notify MA organizations and PDP sponsors when it makes a direct request for information from one of their FDRs.
- CMS will publish sub-regulatory guidance explaining when direct requests of FDRs will be appropriate.

Enrollment Requirements for the Prescribers of Part D Covered Drugs

- Section 6405 of the Affordable Care Act requires physicians and eligible professionals who order durable medical equipment, prosthetics, orthotics and supplies ("DMEPOS") to be enrolled in Medicare. It also allows the Secretary to extend these Medicare enrollment requirements to physicians and eligible professionals who order or certify all other categories of Medicare items or services, including covered Part D drugs. The final rule provides closer oversight of Part D prescribers by requiring their enrollment in Medicare by June 1, 2015. This addresses CMS's concerns regarding payments for drugs ordered by prescribers who do not have authority to prescribe, which has implications for patient safety.

Required Experience in the Part D Program

- Given the availability of a large number of organizations performing key Part D functions, CMS intends to be "more discriminating" when selecting Part D plan sponsors. As such, under the final rule, any entity seeking to contract as a Part D plan sponsor (either as a stand-alone PDP or as an MA offering Part D benefits), on its own or with one of its contracted FDRs, must have served as a Part D plan sponsor for at least one full benefit year, or have performed key Part D functions (described

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below) for another Part D plan sponsor for at least one full benefit year. The applicant or contracted FDR must obtain this experience during the two years preceding submission of the Part D sponsor application.

- The key Part D functions in which a prospective sponsor must have experience include:
  i. Authorization, adjudication and processing of pharmacy claims at the point of sale;
  ii. Administration and tracking of enrollees' drug benefits in real time, including automated coordination of benefits with other payers; and
  iii. Operation of an enrollee appeals and grievance process.
- It is not, however, necessary for any one single entity to have prior experience in all three areas. The requirement applies to the Part D applicant in combination with its FDRs, if any, who have Part D experience covering these key functions. Thus, joint-ventured satisfaction of the requirements is possible.

Pharmacy Price Concessions in Negotiated Prices

- This provision changes the manner in which pharmacy price concessions are reported to CMS. Currently, certain price concessions (such as network access fees, administrative fees, technical fees and service fees) offset sponsor or PMB operating costs, but are not included in the "negotiated price" reported to CMS. The final rule redefines "negotiated price" such that all price concessions from pharmacies are reflected in negotiated prices, except contingent price concessions that cannot reasonably be determined at the point of sale. This provision will be effective in the 2016 contract year, to allow CMS to work with industry stakeholders to develop guidance as to when the exception for contingent price concessions should be applied.

Implementing Overpayment Provisions of the ACA

- The final rule implements Section 6402 of the Affordable Care Act ("ACA"), which, through Section 1128J(d) of the Social Security Act, requires MA organizations and Part D sponsors to report and return identified Medicare overpayments within 60 days of the date of identification. The rule states that an overpayment is "identified" when the MA organization or Part D sponsor "has determined, or should have determined through the exercise of reasonable diligence," that the MA organization or Part D sponsor has received an overpayment. The final rule also codifies a six-year look-back period for the reporting and returning of overpayments. CMS plans to release operational guidance as to when MA organizations and Part D sponsors will be deemed to have returned an overpayment.

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