CMS Scaled Back Changes to the Medicare Part D Prescription Drug and Medicare Advantage Programs, but Some Important Revisions Remain

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On May 19, 2014, the Centers for Medicare & Medicaid Services ("CMS") released a final rule ("Final Rule") completing changes to the Medicare Program's outpatient prescription drug benefit ("Part D") program and the Medicare Advantage ("MA") program.

The Final Rule follows and responds to public and stakeholder comments on the January 6, 2014, proposed rule ("Proposed Rule"), which contained significant implications for a wide variety of health care stakeholders, including managed care organizations, prescription drug plan sponsors, pharmacy benefit managers ("PBMs"), pharmacies, drug manufacturers, and the vendors that provide them with services and products. See the previous Epstein Becker Green Client Alert on the Proposed Rule.

As expected, the Final Rule does not include a variety of proposals that had received significant comment, including proposals to remove protected status from three drug classes, revise preferred network pharmacy policies, reduce the number of Part D plans that a sponsor may offer, and change CMS's interpretation of the scope of the noninterference provision.[1] However, it is important to note that CMS states that some of the proposals not included at this time may still be finalized in future years. Further, CMS has moved forward with some changes that will have bid implications for Part D and MA sponsors (though more significantly in 2016 rather than 2015) and could have business impacts for some stakeholder (such as providers). This Client Alert highlights several of those provisions. If you would like to discuss how the Final Rule may impact your organization in 2014, 2015, or beyond, please contact the authors of this Client Alert or the Epstein Becker Green attorney who regularly handles your legal matters.

[1] CMS Administrator Marilyn Tavenner informed Congress on March 10, 2014, that these provisions would be put on hold in the Final Rule.

New Requirements for 2016 to Include Pharmacy Price Concessions in Point-of-Sale Prices

Currently, Part D sponsors generally have the option to apply pharmacy price concessions to reduce point-of-sale prices or treat the concessions as direct and indirect remuneration ("DIR") and report the DIR to CMS. CMS had proposed changing the regulatory definition of "negotiated price" to effectively require that all price concessions be incorporated into point-of-sale prices. The Final Rule generally follows the proposal by requiring that pharmacy price concessions be incorporated into point-of-sale prices but adds a "narrow exception" for contingent price concessions that "cannot reasonably be determined at point-of-sale." CMS will provide additional DIR reporting guidance after consultation with industry stakeholders on the scope of this exception. Until such guidance is issued, the full impact of this change will not be known, but the change will certainly have a direct impact on pricing and contract negotiations between Part D plans and pharmacies. Importantly, CMS has delayed the implementation of this provision to 2016. Accordingly, this provision should have no impact on 2015 contracting and bids.

New Requirements for 2016 on Maximum Allowable Cost Updates and Disclosure

Current law provides that if a Part D plan uses a standard pricing methodology based on cost for reimbursing pharmacies, the pricing standard must be updated at least every seven days. The Final Rule includes a provision from the Proposed Rule that specifies that the update requirement applies to methodologies based on maximum allowable cost ("MAC") or other costs that are not publicly available. In addition, the Final Rule adopts the new MAC price disclosure requirement from the Proposed Rule, under which all individual drug prices must be disclosed to pharmacies in advance of reimbursement if the source for the pricing standard is not otherwise publicly available.

The Final Rule does not specify a particular method or timing for the advance notice. In the Final Rule's preamble, CMS states that the prices could be made available through a secure Internet site that allowed network pharmacies to look up their drug prices—"so long as the site . . . enables pharmacies to connect a claim to the correct drug price at the appropriate point in time in order to validate the price." CMS also clarifies in the preamble that the new rule does not require the disclosure of MAC methodology, the proprietary data source or basis used to develop reimbursement rates, or the specific National Drug Codes used to compute MAC prices. Lastly, CMS has delayed the implementation of this provision to 2016. Accordingly, this provision should also have no impact on 2015 contracting and bids and is intended to give sponsors and PBMs time to develop their strategies for operationalizing the requirements.

Implementation of the 60-Day Overpayment Rules

MA plans and Part D sponsors are obligated, under the Affordable Care Act, to report and return any overpayments within 60 days after an overpayment is identified. The Final Rule generally adopts the provisions from the Proposed Rule implementing this requirement, including the provision that typically will allow plans to be treated as returning an overpayment when they submit corrected data that is the source of the overpayment through operational guidance to be released by CMS. (CMS would then recover the overpayment through routine operational processing.) However, the Final Rule modifies the

policy to clearly specify that an overpayment has been "identified" (and, thus, the 60-day clock begins) when the plan has determined or should have determined through the exercise of "reasonable diligence" that the plan received an overpayment. In addition, CMS indicates that the 60-day clock begins when a plan realizes that it has submitted any erroneous data to CMS that caused an overpayment. The plan then has 60 days to identify and submit to CMS the specific data that needs to be corrected (or deleted).

CMS also modified the Proposed Rule to provide that overpayments from fraud will be subject to the standard look-back period of the six previous plan years. This provision will be effective 60 days from the May 23, 2014, publication of the regulation in the *Federal Register*. Accordingly, sponsors will have to consider implementation of processes to address these requirements before the 2015 plan year begins.

New Obligations Related to Prescribing Physician Enrollment Starting June 2015

As proposed in January 2014, CMS will implement a new requirement that, in order for a prescription to be eligible for Part D coverage, a prescriber must be enrolled in the Medicare program. This provision creates corresponding obligations for plans and PBMs. Specifically, a Part D sponsor must deny or must require its PBM to deny pharmacy reimbursement for a Part D drug if the claim lacks a valid National Provider Identifier or if the prescriber is not enrolled in the Medicare program in an approved status and does not have a valid opt-out affidavit on file with a Part A/Part B Medicare Administrative Contractor. In response to concerns by providers over the time needed to operationalize these changes, CMS has delayed implementation of this provision to June 1, 2015, and will issue operational guidance for plan sponsors and pharmacies.

The Final Rule also allows CMS to revoke Medicare enrollment for a physician or eligible professional who has been found to have engaged in abusive prescribing practices. CMS declines in the Final Rule to define "abusive" but will instead evaluate the prescribing practices based on a set of criteria to determine whether they warrant a revocation.

Modifications to Requirements for Independent Agents and Brokers

Current regulations on agent and broker compensation limit initial compensation to a level at or below fair market value ("FMV") (as determined annually by CMS), with renewal amounts limited to 50 percent of the amount paid for the initial compensation. This approach has proved problematic due to the complexity of needing to track the initial compensation amount paid for each enrollment in order to determine the amount to be paid for renewal years. CMS finalized the proposed changes to the compensation structure for agents and brokers selling MA and Part D plans, maintaining the initial compensation at a level that is at or below fair FMV, while allowing for renewal compensation at a rate of up to 50 percent of FMV, rather than 50 percent of the initial compensation. The Final Rule differs from the Proposed Rule, which set the renewal at up to 35 percent of FMV.

Status of Other Major Provisions

In our prior Client Alert on the Proposed Rule, we described a number of other major provisions in the Proposed Rule. In light of CMS's decision to not include a significant

number of provisions in the Final Rule, the following chart identifies which provisions are included in the Final Rule.

Jan. 6, 2014, Proposed Rule Policy	In Final Rule?
Non-interference reinterpretation	No
Requirement that plans and sponsors hire and pay for independent auditors	No
Appeals process to challenge RAC findings of overpayments	Yes
CMS collection of records directly from plans or FDR entities	Yes
Requirement of consistently lower pricing in preferred networks	No
Preferred cost-sharing network for any willing pharmacy	No
Elimination of preferred pricing for one-month supplies from mail-order pharmacies	No
Expansion and other changes to medication therapy management program requirements	No
Mail-order fulfillment turnaround times	No
New criteria for protected status of drugs	No
Allowing a sponsor only one enhanced Part D plan per region	No
Miscellaneous fraud and abuse provisions	Yes
MA medical record reviews must be designed to determine coding accuracy	No
MA plan can only submit risk adjustment data after reconciliation to correct overpayment	Yes
Deleting January 31 deadline for submission of risk-adjustment data	No
Risk-adjustment data validation (RADV) appeals	Yes
Modification of Star rating termination provision	No

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