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# New Changes Proposed for the Medicare Advantage and Prescription Drug Benefit Programs (CMS-4159-P)

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The Part D Medicare prescription drug benefit was enacted as part of the Medicare Modernization Act of 2003 and provides extensive drug coverage for seniors and the disabled, allowing them to get prescriptions as quickly as possible. In the time since Part D was enacted, some have argued that Medicare's focus on speedy delivery has its downsides. On January 6, 2014, the Centers for Medicare & Medicaid Services (CMS) issued a proposed rule designed to strengthen protections, improve health care quality, and reduce costs for Medicare beneficiaries with private Medicare Advantage (MA) and Part D prescription drug plans in contract year 2015.[1] It is intended to bring extensive reforms to the Medicare Advantage ("Part C") and Medicare Prescription Drug Benefit Program ("Part D"), partly through regulations implementing provisions of the Affordable Care Act (ACA).

This rule would set forth programmatic and operational changes to the MA and prescription drug benefit programs for contract year 2015. CMS states that it is their intent to "(1) clarify various program participation requirements; (2) make changes to strengthen beneficiary protections; (3) strengthen [its] ability to identify strong applicants for Part C and Part D program participation and remove consistently poor performers; and (4) make other clarifications and technical changes."

This 678-page rule covers a lot of territory with a significant portion of it devoted to addressing areas of fraud and abuse in these programs that require reform. There is no question that CMS has been overwhelmed as a result of all the new responsibilities arising from health care reform. The result is that enforcement and the mechanism associated with it have not received sufficient attention. With this rule change, CMS claims it would address these problems and save Medicare $1.34 billion over five years (contract years 2015 through 2019), if made into final rules. The following highlights some of the significant proposed changes:

1. No longer requiring the Part D plans to include substantially all drugs from two drug classes (antidepressant and immunosuppressant) to be on all Part D formularies. They will continue to require all Part D plans to cover basically all antineoplastic, anticonvulsant, and antiretroviral drugs and will reevaluate antipsychotics for 2016 and beyond.
2. Revising the regulatory definition of negotiated prices to require all price concessions from pharmacies to be reflected in negotiated prices so as to eliminate anti-competitive tactics that have contributed to inconsistencies in bidding, payments, and market price signals for Medicare Part D plans. It is intended to result in greater cost savings for beneficiaries in return for offering preferred cost

sharing so that sponsors cannot incentivize use of selected pharmacies, including the sponsors' own related-party pharmacies that charge higher rates than their competitors.

3. Requiring physicians and eligible professionals to formally enroll in Medicare to write prescriptions for covered Part D drugs to enrollees including verifying their credentials and disclosing professional discipline and criminal history during the enrollment process, as well as providing authority to CMS to exclude doctors who are not enrolled in Medicare from prescribing Part D-reimbursed drugs.
4. Giving CMS the power to revoke a physician or eligible professional's Medicare enrollment if CMS determines that he or she has a pattern or practice of prescribing Part D drugs that is "abusive and represents a threat to the health and safety of Medicare beneficiaries, or fails to meet Medicare requirements." This is in response to evidence of physician prescribing large quantities of "inappropriate" medications due to a lack of proper oversight that resulted in billions of dollars in waste on needlessly expensive drugs and that the Part D program is conducive to fraud. If a prescriber is involved in malpractice suits, this may deny them from participating in the Part D program.[2]
5. Prescription Drug Plan Sponsors offering no more than two Part D plans in the same service area to ensure that a plan sponsor's basic Part D bid represents its lowest-premium plan offering. This is designed to give consumers "meaningful differences" in coverage options, thereby purporting to reduce consumer selection of plans based solely on premium costs, which reduces consumer selection of plans that do not cover their choice medications or pharmacy. It is also intended to "provide a consistent bidding framework for all sponsors, allowing them to focus on quality, rather than quantity, in development of their bids."
6. Implementing the ACA requirement that MA plans and Part D sponsors report and return identified Medicare overpayments.
7. Expanding the release of unencrypted prescriber, plan, and pharmacy identifiers contained in prescription drug event (PDE) records to give researchers broader access to health care data. This would support CMS' growing role as a value-based purchaser of health care. The release of this data would still be subject to CMS' "minimum necessary," "legitimate researcher," and "non-release for commercial purposes" policies as required by law.
8. Expanding rewards and incentive programs that do not discriminate against any MA beneficiaries that focus on encouraging participation in activities that promote improved health, efficient use of health care resources, and prevent injuries and illness.
9. Providing authority for CMS to impose intermediate sanctions and civil monetary penalties. Currently, the Office of Inspector General (OIG) is the sole government agency with the authority to impose penalties for certain Medicare violations.
10. Granting power for CMS to exclude providers from Medicare if it identifies a pattern of abusive prescribing of Part D drugs, thereby purporting to reduce prescription drug abuse.
11. Stopping mail-order pharmacies from charging copayments at a lower rate than retail pharmacies by requiring one-month mail order-filled supplies (for prescriptions for 34 days or less) to have cost-sharing lower than a comparable one-month supply filled at retail outlets. This is intended to reduce the incentive to fill short order supplies of chronic medications through mail order.
12. Requiring U.S. citizenship and lawful presence as an eligibility requirement for enrollment in Part C and Part D plans.
13. Giving additional audit authority to CMS and auditing procedure pursuant to the ACA by requiring that each Part C and Part D contract provide CMS the right to "timely" inspect or otherwise evaluate the quality, appropriateness, and timeliness of services performed under the contract; inspect or otherwise evaluate facilities of the organization when there is reasonable evidence of need; and audit and inspect any

books, contracts, and records of the organization that pertain to the ability to bear the risk of potential financial losses.

14. Allowing CMS to request and collect information directly from pharmacy benefit managers, pharmacies, and other first-tier, downstream, or related entities that contract with Part D sponsors in order "to better detect fraud" and increase CMS' ability to collect identified Medicare overpayments from MA plans and Part D sponsors.

CMS seeks public comments to the proposed program changes, 60 days after the date of display of the proposed rule in the *Federal Register*. CMS will consider these comments in developing the final rule, which will generally be effective for contract year 2015 operations.

**Richard P. Kusserow** served as the U.S. Department of Health and Human Services (HHS) Inspector General for over 11 years. He is the founder and chief executive officer (CEO) of Strategic Management (www.compliance.com), a firm that has provided compliance advisory services and due diligence reviews to over 3000 organizations and entities since 1992. He is the author of nine books related to compliance. For more information, contact him at rkusserow@strategicm.com, or call him at 703/535-1411. ■

**Endnotes:**

1. Proposed rule was published in the *Federal Register* on January 10, 2014. CMS will accept comments on the proposed rule until March 7, 2014.
2. For a fact sheet on CMS' strategy to prevent fraud and abuse under Part D, please see www.cms.gov/Newsroom/Newsroom-Center.html.