

U.S. House and Senate Notification
Monday, January 6, 2014

To: Congressional Health Staff

From: Lauren Aronson
Director, Office of Legislation
Centers for Medicare & Medicaid Services

Re: CMS Issues 2015 Proposed Rule for Medicare Advantage and Prescription Drug Benefit Programs

The Centers for Medicare & Medicaid Services (CMS) issued today a proposed rule with comment period that would strengthen program integrity and beneficiary protections and improve health care quality and reduce costs for Medicare beneficiaries with private Medicare Advantage (MA) and Part D prescription drug plans starting in Contract Year (CY) 2015. The proposed rule would save \$1.3 billion over the five years 2015 – 2019 if finalized. The principal provisions of the proposed rule are summarized below:

New criteria for drug categories or classes of clinical concern: In the first year of the Medicare prescription drug benefit, CMS implemented a policy that required all Part D plans to include on their formularies “all or substantially all” Part D drugs within six drug classes—antineoplastics, anticonvulsants, antiretrovirals, antipsychotics, antidepressants, and immunosuppressants. The Affordable Care Act later codified this policy, and allowed CMS to specify criteria for identifying protected classes through notice and comment rulemaking. CMS proposes to change the categories or classes of Part D drugs of clinical concern using criteria established through this notice and comment rulemaking. Under the proposed criteria, CMS would require formulary inclusion of all drugs within the antineoplastic, anticonvulsant, and antiretroviral drug classes (subject to proposed exceptions), but would no longer require all drugs from the antidepressant and immunosuppressant drug classes to be on all Part D formularies. Although antipsychotics do not meet the proposed criteria, antipsychotics will remain protected at least through 2015 while CMS evaluates additional considerations and the need for any other formulary exceptions.

Increased competition: In response to anti-competitive tactics that have contributed to inconsistencies in bidding, payments, and market price signals for Medicare Part

D plans, the rule proposes to revise the regulatory definition of negotiated prices to require all price concessions from pharmacies to be reflected in negotiated prices. The proposed rule would require 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.

Improved MA risk-adjustment data validation (RADV) audit process: The proposed rule would strengthen RADV by streamlining the RADV audit process by combining error rate calculation appeals and medical record review-determination appeals into one combined process.

Require that Prescribers of Part D Drugs Enroll in Medicare: Section 6405 of the Affordable Care Act requires that physicians and non-physician practitioners who order durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) or certify home health care must be enrolled in Medicare. The statute also permits the Secretary to extend these Medicare enrollment requirements to physicians and non-physician practitioners who order or certify all other categories of items or services in Medicare, including covered Part D drugs. CMS is proposing to require that physicians and non-physician practitioners who write prescriptions for covered Part D drugs must be enrolled in Medicare for their prescriptions to be covered under Part D.

Permit Revocation of Medicare Enrollment for Abusive Prescribing Practices and Patterns: CMS is proposing to add authority to revoke a physician's 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 otherwise fails to meet Medicare requirements; or
- His or her Drug Enforcement Administration (DEA) Certificate of Registration is suspended or revoked; or
- The applicable licensing or administrative body for any state in which a physician or eligible professional practices has suspended or revoked the physician or eligible professional's ability to prescribe drugs.

The proposed rule is available at:

<http://www.ofr.gov/inspection.aspx?AspxAutoDetectCookieSupport=1>

The proposed rule will be published in the Federal Register on January 10, 2014. CMS will accept comments on the proposed rule until March 7, 2014.

A more extensive summary of the proposed rule is provided in the attached fact sheet and at: <https://www.cms.gov/Newsroom/Newsroom-Center.html>

More information on CMS' Strategy to Fight Part D Fraud and Abuse, including data on recent initiatives, is provided in the attached Part D Fraud and Abuse Fact Sheet, also available at: <https://www.cms.gov/Newsroom/Newsroom-Center.html>

A blog posting on CMS' Part D fraud strategy by CMS Principal Deputy Administrator Jon Blum is available at: <http://blog.cms.gov/>

If you have any questions, please contact the CMS Office of Legislation. Thank you.