

CMS' Final Rule on 2015 Health Insurance Marketplace Requirements Requires Plans to Provide Expedited Medication Exceptions Process

May 19, 2014

On Friday, May 16 the Centers for Medicare and Medicaid Services (CMS) released its final rule for health insurance marketplace plan requirements for 2015. The final rule primarily includes technical provisions regarding risk corridors and reinsurance for health plans, but also includes provisions for an expedited exceptions process in certain circumstances for certain non-formulary medications.

New Expedited Exceptions Process

Health plans in the marketplace would have to provide an exceptions process in certain exigent circumstances, defined as when an enrollee has a certain disease state or is already prescribed a certain non-formulary medication. Plan decisions in these circumstances must be rendered within 24 hours and both the enrollees and the appropriate prescribers notified. CMS expects plans to update certification of coverage to reflect availability of the process and instructions for use and ensure rapid communication with pharmacy benefit managers and pharmacies.

CMS clarifies that the 24-hour review process begins *when the plan or designee receives the exception request* based on exigent circumstances. The rule encourages plans to begin the review process even they're missing some information considered procedural; plans also should not require overly burdensome or irrelevant information. Information may be submitted by the prescriber, the enrollee or the enrollee's designee. Plans must be able to accept the information electronically, in writing, or by telephone.

The definition of exigent circumstance is vague. CMS indicates that it "believes" an exigency exists when an enrollee either has a condition that may seriously jeopardize his or her life, health, or ability to regain maximum function or is currently using the non-formulary medication. The request for an expedited review should include the following support:

- Information related to the existence of the exigency and a description of the harm that could reasonably occur to the enrollee if the requested drug is not provided in the timeframe; and
- Justification supporting the need for the non-formulary medication to treat the enrollee's condition, including a statement that all covered formulary medications, on any tier, will be or have been ineffective, are less effective, or would result in adverse effects.

CMS notes that plans are not required to provide coverage of the medication during the review process. If a plan issues a favorable determination, CMS will require that the medication be provided for the duration of the exigency. CMS will continue to monitor the issue and determine whether further rulemaking is necessary. However, the rule notes that states, not CMS, have primary enforcement responsibility for health plans, and therefore, enrollees who experience difficulties should first contact the state department of insurance.

The final rule will be officially published in the *Federal Register* on May 27, 2014. Until then, it is available at the following site: <https://www.federalregister.gov/articles/2014/05/27/2014-11657/exchange-and-insurance-market-standards-for-2015-and-beyond-patient-protection-and-affordable-care>. In the pre-publication version, the information related to the exceptions process is on pages 268-274.

AMCP Resources

For more information on prescription drug requirements in health insurance marketplace plans, AMCP members may access an archived webinar held on May 13, 2014, titled *Prescription Drug Coverage in Health Insurance Marketplaces, What to Expect in 2015 and Beyond*. Click here to access: <http://www.amcp.org/webinars/>

AMCP has also commented on health insurance marketplace standards in the following letters:

- Quality in the Exchanges (January 24, 2014)
- Response to CMS in Opposition to Mandatory Transition Supplies in the Exchanges (February 21, 2014)
- Response to CMS Opposing Mandatory Exceptions Process (April 22, 2014)

Click here to access these letters listed chronologically:

<http://www.amcp.org/PolicyIssuesandAdvocacy/letter-statements/>

For more information regarding health insurance marketplace standards, please contact Mary Jo Carden, AMCP Director, Federal Regulatory Affairs at 703-684-2603 or mcarden@amcp.org.