



Summary: CMS Proposed 2016-2017 Revisions for Qualified Health Plans in Federally-Facilitated Marketplaces and Essential Health Benefits Include Changes to Prescription Drug Offerings

December 2014

On November 21, 2014, the Centers for Medicare and Medicaid Services (CMS) released a proposal for changes, updates, and additions to 2016-2017 requirements for qualified health plans (QHPs) that participate in the federally-facilitated marketplaces. Beginning in 2017, CMS will begin allowing plans to use QHPs available in 2014 as the selected benchmark rather than using a plan that existed before the implementation of the *Affordable Care Act* (ACA). The proposal also includes changes to prescription drug coverage provisions. Comments to CMS are due on December 22, 2014. Below is a summary of the provisions impacting AMCP members with areas where CMS seeks comment italicized. If you would like to provide comments, please specify the section and the topic for comment and email to mcarden@amcp.org by Friday, December 12, 2014.

To access the proposed rule published in the *Federal Register* on November 26, 2014, please click here: <http://www.gpo.gov/fdsys/pkg/FR-2014-11-26/pdf/2014-27858.pdf>

A. Pharmacy & Therapeutics (P&T) Committees and Compendia Selection for Formulary Development

Use of Pharmacy & Therapeutics (P&T) Committees to Establish Formularies Rather than Relying on United States Pharmacopoeia (USP) Categories and Classes

Beginning in 2017, proposes to rely primarily on P&T committees to make formulary determinations rather than using the USP categories and classes for formulary development and drug counts. Since the implementation of marketplace plans in 2013, most stakeholders, including QHPs, pharmacy benefit management companies, and the pharmaceutical industry, have criticized the use of USP categories and classes as a the basis for formulary development and drug counts in the marketplaces. USP's category and class system was developed specifically for the Medicare Part D program has not been suitable for formularies in marketplace plans because of the slow process for change and the lack of specialty products. CMS finds that relying on P&T committees to make formulary determinations would result in qualitative, not quantitative formulary decision-making. The current quantitative process relies primarily on drug counts based on USP category and class designations.

CMS will require that P&T Committees meet standards established by Medicare Part D or the National Association of Insurance Commissioners (NAIC). (Information regarding these requirements may be found in the Medicare Prescription Drug Benefit Manual, Chapter 6; Section 30.1, available here: <http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter6.pdf>; and in NAIC's 2003 Prescription Drug Benefit Management Model Act that includes P&T Committee provisions in <http://www.naic.org/store/free/MDL-22.pdf>). CMS also specifically enumerates several recommendations and requirements for P&T committees:

- Should include specialists with expertise in the clinical specialties impacting enrollees.
- Should primarily be composed of practicing physicians, practicing pharmacists, and other practicing health care professionals. *CMS seeks comments on whether the definition of other health care professional should be limited to those who prescribe.* CMS also notes that a health care professional with multiple licenses, for example, a physician who is also a pharmacist, be counted only as one person in regard to the P&T committee composition.
- Must ensure that conflicted members recuse themselves during votes where the conflict exists. CMS' proposal recommends that at least 20% of the P&T committee have no conflicts with the pharmaceutical industry or the issuer. The P&T committee must define a conflict of interest and propose requiring members to sign conflict of interest statements describing the nature of the conflict. *CMS seeks general comments on this provision and examples of permissible relationships with pharmaceutical companies.* After this provision is finalized, CMS might issue further guidance in regard to conflicts of interest and P&T committees.
- Must meet at least quarterly and maintain documentation regarding decisions.

CMS notes that states would have oversight over P&T committees. *CMS seeks general comments on its proposal to use P&T committees to develop formularies rather than rely on the USP categories and classes.*

Consideration of AHFS Drug Information (AHFS) as a Suitable Alternative to P&T Committees or USP Categories and Classes

As an alternative to the P&T process and the use of USP categories and classes, CMS proposes the use of AHFS as an alternative compendium. CMS notes that AHFS must be licensed and therefore, access to it may be more difficult than to USP which, according to CMS is publicly available. CMS also indicates that AHFS includes more categories and classes of medications. *The proposal seeks comment on the use of AHFS as an alternative to USP and/or P&T committees; whether other standards exist for formulary development; and how the drug count process could be implemented using P&T committees and/or AHFS rather than USP.*

B. General Formulary Provisions

P&T committees must ensure that formularies cover a broad range of medications to treat all disease states and not discourage enrollment among individuals with chronic diseases. CMS encourages P&T committees to use national treatment guidelines in making formulary decisions.

As an example, the proposal suggests using the National Guideline Clearinghouse (NGC), an online compilation of clinical evidence and information on medications sponsored by the Agency for Health Research and Quality and may be found here:

<http://www.ahrq.gov/professionals/clinicians-providers/guidelines-recommendations/index.html>.

Beginning in 2016, CMS proposes that QHPs must publish on a publicly available website a list of complete and accurate formularies, including tiering restrictions, and the information must discern among formularies offered in different plans. *CMS seeks comments on whether formulary tiering should include cost-sharing such as the applicable pharmacy's deductible.* This information must be easily accessible to consumers, marketplaces, the Department of Health and Human Services (HHS), and the Office of Personnel Management (the agency responsible for managing federal government employee benefits) in a "machine-readable format specified by HHS." *CMS will consider whether a form should be submitted in a standard template designed by HHS, but seeks comment on this option and other technical considerations. CMS seeks comment on how often to update the website and other information that must be included.*

C. Proposal for Standard Formulary Exceptions Process

Beginning in 2016, CMS seeks to add to a new standard exceptions process in addition to the expedited exceptions process for "exigent circumstances" that will begin in 2015. The expedited exceptions process for exigent circumstances requires plans to make a determination 24 hours upon completion of information submission. CMS defines an exigent circumstance as "when an enrollee is suffering from a serious health condition that may seriously jeopardize the enrollee's life, health, or ability to regain maximum function or when an enrollee is undergoing a current course of treatment using a non-formulary drug." Upon rendering a determination, medications must be provided for the remainder of the exigency. (AMCP's summary of the CMS final marketplace rule for 2015 with the provision for the exigent exceptions process may be found here: <http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=18179>)

In the proposed rule, CMS seeks comment on its implementation of a 72 hour determination for a standard formulary exceptions process applicable to non-exigent circumstances. A positive exception determination would result in inclusion of the medication as an EHB for the enrollee, including all refills. All costs incurred by the individual for the medication would be included in the annual limit on cost sharing.

CMS also proposes that enrollees, their designee, or their prescriber may request an independent external review of denials in the same period as the exceptions process, 72 hours for standard exceptions and 24 hours for expedited exceptions. The organization providing the review must be accredited by a nationally recognized private accrediting firm. Plan issuers may use the same external reviewer for exceptions reviews as it does for its final external review. *CMS seeks comment on whether this arrangement would ensure consumer access to the exceptions process without additional burdens on issuers and states.*

CMS seeks comment on its proposal for a standard exceptions process and external review process for standard and exigent exceptions.

D. Mail Order Pharmacy v. Retail Pharmacy

CMS proposes to require that network pharmacies must include retail pharmacy options in addition to mail order. CMS is concerned that mail order only options discriminate against transient individuals without a fixed address and those needing treatment for acute illnesses, such as antibiotics for infection or pain medication. The proposed provision would continue to allow higher cost-sharing and other out-of-pocket spending at retail pharmacies in comparison to mail order. The higher out-of-pocket costs in retail pharmacy would count toward annual limits on cost sharing and actuarial value of plans. CMS adds QHPs may also continue to offer enrollees lower cost-sharing at in-network pharmacies.

E. Restricted Distribution of Certain Medications

CMS clarifies that certain medications require restricted distribution because of certain Food and Drug Administration requirements, such as special handling or the applicability of a Risk Evaluation and Mitigation Strategy to ensure appropriate and safe use. These medications, CMS notes, may not always be accessed through in-network retail pharmacies. However, CMS does not believe that additional education or counseling would automatically disqualify certain medications from retail pharmacy networks. If QHPs restrict distribution of medications for additional education or counseling, CMS proposes that this information be included on the publicly available formulary. *CMS seeks comment on this provision and whether any additional exemptions from receiving medications at retail pharmacies should be permitted.*

F. Transition Coverage in First 30 Days of Enrollment for Non-Formulary Medications

CMS recommends, but will not require, that plans provide a temporary supply of medications within the first 30 days that an individual enrolls in a new QHP. Coverage of these medications would be provided without application of step therapy or prior authorization. This is not the first time CMS has suggested transition supplies for marketplace plans in the same manner as required under Medicare Part D. In an interim final rule issued in December 2013, CMS also recommended that QHPs provide a 30-day transition supply and urged suspension of the use of managed care pharmacy tools. AMCP opposed this recommendation in a [December 20, 2013 letter to CMS](#). While CMS' current proposal only recommends that QHPs provide a transition supplies; the agency noted that it in the future it may consider implementing a requirement.

G. Non-Discrimination of Coverage and Access to Benefits

CMS' enrollment rules prohibit QHPs that discriminate against individuals who might require certain medications and health care services. CMS is concerned that exclusions and limits in some plans, including in the area of prescription drugs, may improperly discriminate against enrollment of certain individuals. CMS provides examples of potential discrimination, including, limiting access to long-acting or single agent products that are customarily prescribed for certain conditions and when all or most medications for certain conditions appear in the highest cost tier. CMS notes that all decisions regarding coverage determinations must be based on clinical guidelines and medical evidence. QHPs must also follow non-discrimination and civil

rights laws contained in the *Americans with Disabilities Act*; *Affordable Care Act*; the *Civil Rights Act of 1964*; the *Age Discrimination Act of 1975*; *Rehabilitation Act of 1975*; and, applicable state laws. CMS will continue to send letters to QHPs when it detects discrimination based on improper coverage restrictions.

H. Implementation of Quality Improvement Strategies in QHPs

CMS notes that will align public and private quality metrics as appropriate, including alignment with the National Quality Strategy and the CMS Quality Strategy. Areas of focus for quality initiatives as recommended by a technical expert panel assembled by CMS include reducing hospital readmissions, promote health and wellness, case management, care coordination, medication management, and reduce health disparities. CMS seeks to accomplish this in ways that are administratively efficient and allow for data collection and sharing among all stakeholders.

Beginning in 2016, QHPs participating in marketplaces for 2 years must implement and report information regarding a quality improvement strategy followed by annual updates and progress reports. (For example, a QHP entering the marketplace in 2016 would be required to submit an implementation plan in 2018.) While CMS currently does not require specific measurements, QHPs' strategies must include elements that align with CMS' goals of quality improvement as described above and include performance targets. CMS believes that a phased-in approach will allow QHPs to better understand enrollees and develop strategies targeted toward these individuals. *CMS seeks comment on this proposed timeline and implementation process.*

If you have any questions regarding this summary, please contact Mary Jo Carden, AMCP Senior Director of Regulatory Affairs at 703-684-2603 or mcarden@amcp.org.