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Spotlight Story: CMS Releases Medicare Part D Proposed Rule

AMCP is Pleased the Proposed Rule Incorporates Several of Its Recommendations

The Centers for Medicare and Medicaid Services (CMS) has released a much anticipated [proposed rule](#) titled “Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program.”

The proposed rule, released Nov. 16, amends regulations for Medicare Part C and Medicare Part D to implement provisions of the Comprehensive Addiction and Recovery Act (CARA) and the 21st Century Cures Act. It also makes changes to improve program quality, accessibility, and affordability and also adopts the updated NCPDP script standard for electronic prescribing. CMS estimates that the proposed rule has a net savings of \$80 to \$100 million for each of the next five years.

The 713-page proposed rule is robust and includes several major policy provisions that impact managed care pharmacy, both positively and negatively. AMCP previously provided [detailed comments](#) to CMS on how the Medicare Part C and D programs can be transformed through innovation to best meet the individual health needs of Medicare beneficiaries. AMCP is pleased to see that the proposed rule incorporates several of the recommendations put forth by AMCP including:

- Categorization of biosimilars as applicable drugs under Medicare Part D during catastrophic cost sharing;

- Increased flexibility to implement midyear formulary changes;
- Revisions to the MLR calculation to include in the MLR numerator expenditures related to fraud reduction activities (including fraud prevention, fraud detection, and fraud recovery) and Medication Therapy Management (MTM) programs;
- Adoption of the revised NCPDP SCRIPT standard for e-prescribing; and
- Electronic delivery of certain required notifications.

However, there are also several provisions in the proposed rule that AMCP is concerned about and is seeking stakeholder feedback on. A summary of the key AMCP issues contained in the proposed rule, as well as specific areas AMCP is seeking stakeholder feedback on, is [available here](#). AMCP also hosted a webinar on Dec. 6th to deep-dive the major provisions of greatest impact to managed care pharmacy and the webinar is [archived here](#).

Comments on this proposal must be submitted to CMS by **Jan. 16, 2018 at 5pm EST**. AMCP will work with stakeholders to develop comments to CMS to ensure the perspective of managed care pharmacy is voiced as changes to the Medicare Part C and D program are considered. You may provide feedback via email to Soumi Saha, Director of Pharmacy & Regulatory Affairs, at ssaha@amcp.org by **Friday, Jan. 5, 2018** on any of the provisions included in the proposed rule. AMCP's final comments to CMS will be available on the AMCP website.

Legislative Update

AMCP Looks to 2018: Policy and Advocacy Agenda

The AMCP Board of Directors has approved the AMCP Policy and Advocacy Focus Areas for 2018. These broad topics will help AMCP staff, the Board, and the Public Policy and Legislative and Regulatory Committees identify legislation and regulations focused on achieving these goals. AMCP will also use these broad focus areas to guide its development and dissemination of practice-based materials and resources for managed care pharmacy professionals.

The key issues identified as priorities for AMCP are:

- ***The Rising Cost of Medications:*** This priority will focus on how managed care pharmacy professionals improve value and outcomes for patients.
- ***Shift from Fee-for-Service to Value-Based Care:*** In this area, AMCP will advocate for legislative and regulatory initiatives that focus on shifting away from traditional payment systems to policies that provide incentives to improve outcomes. AMCP will also examine practices in value-based contracts to disseminate best practices.
- ***Opioid Management:*** In this priority area, AMCP will continue its work in key areas of opioid management, including drug management programs or lock-ins for Medicare Part D; promoting health plan and pharmacy benefit manager access to prescription drug monitoring programs; and promoting managed care pharmacy strategies that promote the

Advocacy Tip

Work with Staff

Legislators utilize staff to assist in policymaking. Advocates should understand that staff is critical to the process of effective policymaking. A good relationship with staff can make the difference in an advocacy effort. Advocates should realize that the purpose of any meeting with staff is not to impart all of your wisdom; rather, it is to leave a positive impression of helpfulness and knowledge with the staff. Ultimately you want the staff to recognize you as a resource that they can call upon for assistance.

appropriate use of opioids for pain and also access to medications for addiction treatment.

A webinar on the Policy and Advocacy Agenda will be held on Tuesday, Jan. 30, 2018 from 2-3pm ET to discuss the focus areas and to seek your input on ways for AMCP to make an impact in those areas. This information will be used to develop an action plan moving forward. Details on the webinar will be posted at www.amcp.org/calendar/.

Update on Opioid Management Initiatives

Food and Drug Administration (FDA) to Host Public Meeting on Opioid Policy and Strategy on Jan. 30, 2018

FDA recently announced that it plans to hold a meeting, Opioid Policy Steering Committee - Prescribing Information - Exploring a Strategy for Implementation, on January 30th to consider steps to combat the opioid crisis. Some of the “steps” under consideration include requiring sponsors to create a nationwide prescription drug monitoring program, mandating additional prescriber documentation when prescribing opioids above a certain threshold, potentially imposing additional requirements to improve patient storage and handling of opioids and requiring sponsors to create mandatory opioid take-back programs. AMCP has submitted a request to speak at the event. Public comments will be accepted until March 16, 2018. To submit comments, please email tlwilkins@amcp.org by Monday, Feb. 26, 2018.

AMCP Provides Congressional Diabetes Caucus Information on Value Based Contracting

On Dec. 15, AMCP responded to a request for information on value based contracting from the Congressional Diabetes Caucus, co-chaired by Reps. Diana DeGette (D-CO) and Tom Reed (R-NY). AMCP provided the consensus definition of value based contracting created during the AMCP Partnership Forum, [Advancing Value-Based Contracting](#), described the opportunity for VBCs to address drug prices and additionally outlined solutions to current regulatory barriers to VBC adoption, such as Medicaid Best Price and the Anti-Kick Back Statute. The full letter may be [read here](#).

Regulatory Update

CMS to Suspend MTM Pilot Audits in 2018

CMS announced Dec. 6 that the Medication Therapy Management (MTM) pilot audit protocol is being suspended and will not be conducted in 2018. CMS notes in its 2018 *Program Audits* memo that it continues to evaluate the information learned from the MTM pilot audits conducted in 2016 and 2017. AMCP had previously advocated for consistency in MTM pilot audit protocols and transparency in what was expected of MTM programs given inconsistencies in audit

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requirements. AMCP looks forward to next steps from CMS on how to assess the quality of MTM programs in a consistent and transparent manner.

AMCP Submits Recommendations to Transform Medicare and Medicaid Programs

On Nov. 20, AMCP submitted comments to the Center for Medicare and Medicaid Innovation (CMMI) on how the Medicare and Medicaid programs can be transformed through innovation to best meet the individual health needs of beneficiaries. AMCP's comments focused on the following key areas: Medication Therapy Management (MTM); Quality; Formulary Design and Utilization Management; Expansion of Value Based Contracting (VBC) for Medicare and Medicaid; Expansion of Biosimilar Use in the United States; Health Information Technology and Data Interoperability; Opioid Management; and Fraud, Waste, and Abuse. AMCP's full comments are [available here](#).

AMCP Submits Comments to the FTC on Strategies to Improve the Generic Marketplace

On Dec. 8, AMCP submitted comments to the Federal Trade Commission (FTC) on how to improve the generic marketplace. AMCP supported efforts to prohibit patent settlement agreements between brand name and generic manufacturers that result in the generic manufacturer delaying market entry of a generic drug. AMCP also discouraged authorized generics, which are intended to discourage generic competition. AMCP also requested the opportunity to meet with FTC leadership to further discuss potential solutions to ensure a competitive generic marketplace in the United States, as well as strategies for ensuring a competitive biosimilars marketplace. AMCP's full comments are [available here](#).

AMCP Submits Comments to FDA on Presentation of Risk Information in DTC

AMCP submitted comments Nov. 20 to the FDA on how risk information should be presented in direct-to-consumer (DTC) advertising. AMCP commended the FDA for taking the initiative to help improve how risk information in DTC advertising is presented to ensure that it is clear, adequate, comprehensive, useful, comprehensible, and memorable for consumers. AMCP was encouraged by FDA's *limited risks plus disclosure strategy* proposal and believes that it is a step in the right direction to present a fair balance of risk information to avoid a misleading presentation regarding a drug's risk-benefit profile. However, prior to finalization and adoption, AMCP recommended that FDA consider the following:

- FDA should require that risk information be presented in a manner that aligns with the Agency for Healthcare Research and Quality (AHRQ) Health Literacy Universal Precautions;
- FDA should include pharmacists in the disclosure statement; and
- FDA should conduct additional research and cognition testing on consumers.

AMCP's full comments are [available here](#).

AMCP Submits Comments to CMS on HHS Notice of Benefit and Payment Parameters for 2019

AMCP submitted comments Nov. 27 to CMS on a proposed rule that would give states additional flexibility in the definition of essential health benefits (EHBs) in the individual and small group markets beginning in 2019. AMCP's comments focused on the following areas of the proposed rule: Suggestions for reducing prescription drug costs and promote drug price transparency (Preamble); Access to mental and behavioral health records (Part 153(g)(vi)); Essential Health Benefits and formulary and prescription drug coverage (Part 156); and Medical Loss Ratio (Part 156). AMCP's full comments are [available here](#).

Upcoming Comment Periods

AMCP is seeking stakeholder feedback on the following proposals that are open for comment. Please respond via email to Soumi Saha, Director of Pharmacy & Regulatory Affairs, at ssaha@amcp.org by the dates listed for incorporation into AMCP's comments. All of AMCP's final comment letters are available on the AMCP website [here](#).

<i>Topic</i>	<i>Feedback Due to AMCP</i>	<i>Comments Due</i>
CMS – Medicare Part D Proposed Rule	Jan. 5	Jan. 16
FDA – Opioid Policy & Strategy	Feb. 26	March 16

Upcoming AMCP Webinars

Implications for Managed Care Pharmacy from the 2019 Medicare Part D Call Letter and Star Ratings Release

Tuesday, Feb. 27, 2018, 2-3pm EST

[Registration](#)

Join AMCP for a first look at the provisions contained in the draft 2019 CMS Medicare Part D Call Letter that is scheduled to be released by the Centers for Medicare and Medicaid Services (CMS) on February 2, 2018. This webinar will deep dive the policy provisions of importance to managed care pharmacy including medication therapy management, opioid management, specialty pharmacy, and Star Ratings for 2019 and beyond. Be one of the first to know and help inform AMCP's comments to CMS!

Speakers:

- Babette Edgar, PharmD, MBA, FAMCP
AMCP Immediate Past President, 2016-2017

Principal, BluePeak Advisors

- Mitzi Wasik, PharmD, BCPS, FAMCP, FCCP
AMCP President Elect, 2018-2019
Lead Business Strategy Consultant Southeast Region, Aetna

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