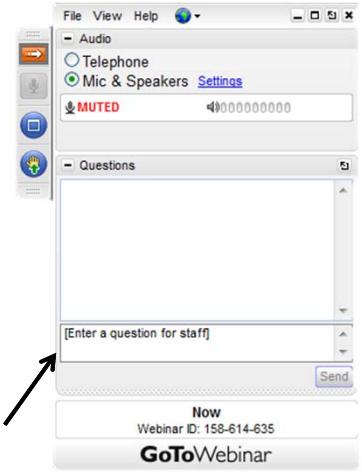
The CMS Medicare Part D Proposed Rule: Understanding the Implications to Managed Care Pharmacy

December 6, 2017

AMCP Academy of Managed Care Pharmacy®

Disclaimer

How to Ask A Question



Type your question in the 'Questions' area

www.amcp.org

AMCP Academy of Managed Care Pharmacy

Today's Speakers

Mary Jo Carden, RPh, JD
Vice President, Government & Pharmacy Affairs
mcarden@amcp.org

Soumi Saha, PharmD, JD
Director, Pharmacy & Regulatory Affairs
ssaha@amcp.org

www.amcp.org

AMCP Academy of Managed Care Pharmacy

4

Agenda

- Review of RFI Process & AMCP's Comments
- Key Policy Issues for AMCP
- Next Steps
- Question & Answer

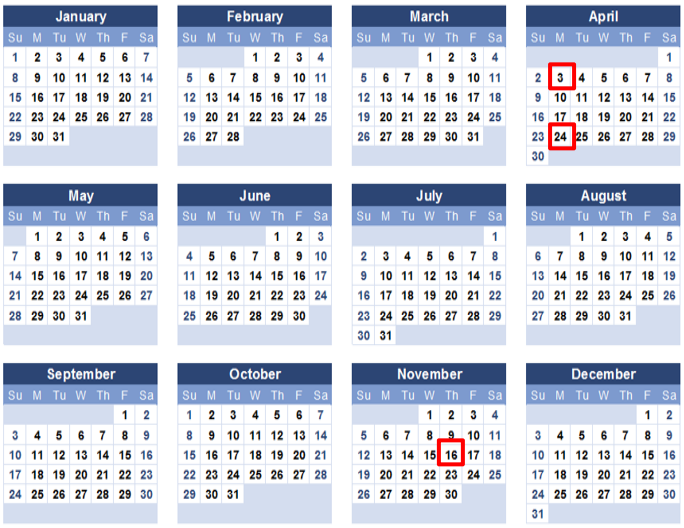
www.amcp.org

AMCP Academy of Managed Care Pharmacy®

Review of RFI Process & AMCP's Comments

AMCP Academy of Managed Care Pharmacy®

Timeline



4.3.17 → MA & Part D RFI announced as part of 2018 Final Call Letter

4.24.17 → RFI comments due

11.16.17 → Proposed rule released

1.16.18 → Proposed rule comments due

www.amcp.org

AMCP Academy of Managed Care Pharmacy

AMCP Comments on MA & Part D RFI

- Available at: http://bit.ly/2piyVKR

Medication Therapy Management (MTM)

- Include MTM Programs in the MLR as QIA
- Modernize, Test, and Validate Alternate Formats of the Medicare Part D MTM Program Standardized
- Consider the Inclusion of Alternate Records to Satisfy the Medication Reconciliation Measure
- Reconsider Targeting & Eligibility Criteria for MTM Services
- Reevaluate the Burden Estimate for CMRs
- Monitor Successes from the eMTM and Implement Changes as Best Practices are Identified

Quality

- Support the Shift Towards Outcomes-Based Measurements
- Establish Preferred Pharmacy Networks that Reward the Provision of Improved Outcomes for Beneficiaries

Formulary Design and Utilization Management

- Reconsider Criteria for Managing Medications in Protected Classes
- Categorize Biosimilars as Applicable Drugs under Medicare Part D
- Reconsider Its Interpretation of "Applicable Lower Cost-Sharing Tier"

www.amcp.org

AMCP Academy of Managed Care Pharmacy

AMCP Comments on MA & Part D RFI

Health Information Technology and Data Interoperability

- Adopt the National Council of Prescription Drug Programs Standard for eRx and ePA
- Encourage the Adoption of SNOMED CT Codes
- Ensure Access to Part A and Part B Data

Opioid Management

- Work Collaboratively With Other Federal Agencies to Address the Opioid Epidemic
- Implement the Drug Management Program Provisions of CARA in a Timely Manner
- Continue to Provide Access to Medication Assisted Treatment for Medicare Beneficiaries
- Advocate for the Modification of Federal Regulations Governing the Confidentiality of Drug and Alcohol Treatment and Prevention Records
- Develop a Robust Education Strategy for Prescribers Related to Opioid Prescribing Guidelines
- Seek Legislative Changes to Allow Part D Sponsors Access to Prescription Drug Monitoring Program Data

Fraud, Waste, and Abuse

- Address Fraud, Waste, and Abuse in Medicare Part D
- Attribute Investments in Fraud Prevention Activities as Expenses to Incurred Claims for Medical Loss Ratio Reporting Purposes
- The CMS Center for Program Integrity Should be Adequately Funded by Congress

AMCP Summary of Proposed Rule

- Available at: http://bit.ly/2zUhszN

AMCP Summary: ***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***

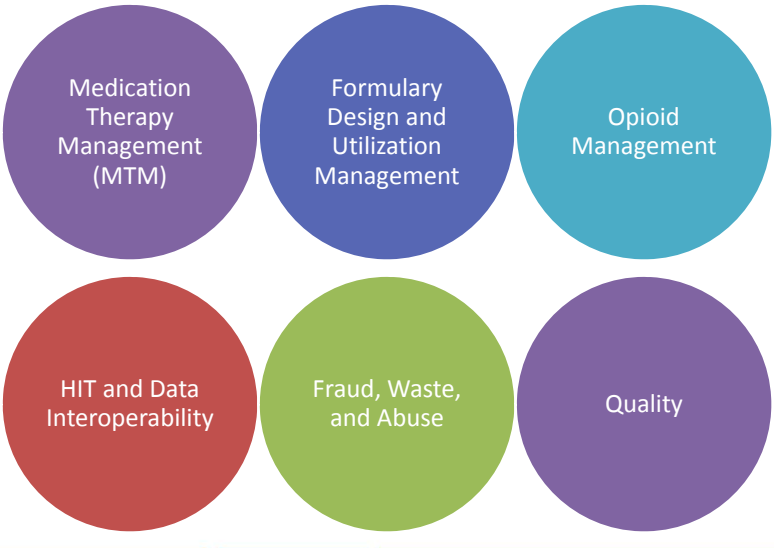
Released: ***November 16, 2017***

Comments Due: ***January 16, 2018***

Key Policy Issues for AMCP

AMCP Academy of Managed Care Pharmacy®

Key Policy Issues for AMCP



www.amcp.org

AMCP Academy of Managed Care Pharmacy®

Medication Therapy Management (MTM)

- Medical Loss Ratio (MLR)
  - CMS proposes that that all MTM programs that comply with § 423.153(d) and are offered by Part D sponsors (including MA organizations that offer MA-PD plans) are Quality Improving Activities (QIA) and therefore will be included in the MLR calculation

AMCP strongly supports the inclusion of MTM programs in the medical loss ratio (MLR) as quality improving activities. AMCP believes the inclusion of MTM programs in the MLR as a quality improving activity will further encourage and incentivize providers to strengthen their MTM programs, resulting in increased healthcare outcomes and decreased healthcare costs.

Formulary Design & Utilization Management

- Biosimilars
  - CMS proposes to revise the definition of generic drug to include follow-on biological products approved under section 351(k) pathway for the purpose of non-LIS catastrophic cost sharing and LIS cost sharing

AMCP supports the classification of biosimilars as applicable drugs under Medicare Part D and believes CMS' proposal is a step in the right direction. However, AMCP remains concerned that biosimilars will continue to be treated as non-applicable drugs during the "donut hole" and encourages CMS to work with Congress to address this.

Formulary Design & Utilization Management

- Midyear Formulary Changes
  - CMS proposes to provide sponsors with more flexibility to implement generic substitutions by permitting sponsors to immediately remove, or change the preferred or tiered cost-sharing of, brand name drugs and substitute or add therapeutically equivalent generic drugs provided specified requirements are met
  - CMS also proposes reducing the 60 day advanced notice period for 30 days

AMCP supports increased flexibility for sponsors to implement midyear formulary changes.

Formulary Design & Utilization Management

- Tiering Exceptions
  - CMS proposes to make regulatory changes to prohibit sponsors from excluding non-preferred generic-drug tiers from tiering exceptions
  - CMS proposes to base eligibility for tiering exceptions on the tier that contains the preferred alternative drug to the higher-cost requested drug, rather than based on tier labels established by the plan

AMCP does not support CMS' interpretation of "applicable lower cost-sharing tier" and believes it undermines the development of evidence-based formularies which enhance the quality of patient care by selecting the most appropriate medications for patients with the goals of reducing treatment failures, adverse drug events and hospitalizations and improving patient adherence and health outcomes.

Formulary Design & Utilization Management

- Manufacturer Rebates & Price Concessions
  - The proposed rule includes a RFI soliciting comment on potential policy approaches for applying some manufacturer rebates and all pharmacy price concessions to the price of a drug at the point of sale

AMCP seeks feedback on how a point-of-sale rebate policy would impact sponsors and premiums? Would adoption of a point-of-sale rebate policy make the Part D market more competitive and efficient?

HIT & Data Interoperability

- NCPDP SCRIPT Standard
  - CMS proposes to adopt the NDPDP SCRIPT Standard Version 2017071, and retire the current NCPDP SCRIPT Version 10.6, as the official electronic prescribing standard for transmitting prescriptions and prescription-related information

AMCP supports adoption of the updated NCPDP SCRIPT standard for e-prescribing. However, CMS' proposal does not require use of the NCPDP electronic prior authorization (ePA) standard. AMCP supports the adoption of the ePA standard approved by NCPDP to improve efficiencies in the prior authorization process, improve patient outcomes, reduce POS rejections, and improve the Medicare Part D member experience.

HIT & Data Interoperability

- Disclosure Requirements
  - CMS proposes to allow the electronic delivery of certain information normally provided in hard copy documents such as the Evidence of Coverage (EOC) to alleviate plan burden related to printing and mailing, an estimated savings to plans of $55 million in 2019
  - CMS also proposes to change the timeframe for delivery of the EOC to the first day of the Annual Election Period (AEP) rather than fifteen days prior to that date to separate it from delivery of the Annual Notice of Change (ANOC)

AMCP supports the electronic delivery of documents required under Medicare as it alleviates plan burden, decreases administrative costs on the healthcare system, and also reduces the number of paper documents that beneficiaries receive from plans.

Fraud, Waste, & Abuse

- Quality Improving Activities (QIA)
  - CMS proposes to remove the current exclusion of fraud prevention activities from QIA and to expand the definition of QIA to include all fraud reduction activities, including fraud prevention, fraud detection, and fraud recovery
  - CMS proposes to no longer include in incurred claims the amount of claims payments recovered through fraud reduction efforts, up to the amount of fraud reduction expenses

AMCP strongly supports the inclusion of fraud prevention expenditures in incurred claims for MLR reporting purposes. AMCP believes that including fraud, waste, and abuse expenses in the MLR calculation, rather than treating them as administrative costs, will encourage health plans to field more robust fraud detection programs and avoid efforts to pare back those activities.

Fraud, Waste, & Abuse

- Days' Supply Requirements
  - CMS proposes to change the transition supply requirements for long-term care patients from 91 – 98 days to 30 days due to concerns with waste and costs
  - CMS clarifies the transition supply requirements for outpatient is one month and not necessarily 30 days to account for medications that are packaged as 28 day supplies

AMCP supports a decrease in the transition supply requirements to help address waste and decrease overall costs for beneficiaries.

Quality

- Quality Rating System
  - CMS proposes to codify key aspects of the Part C and D Star Ratings methodology, including the principles for adding, updating, and retiring measures (aka the Call Letter process), and the methodology for calculating and weighting measures
  - CMS proposes to increase the weight of patient experience/complaints and access measures

AMCP seeks feedback on:
- Additional opportunities to improve measures so that they further reflect the quality of health outcomes?
- How can the process for establishing the cut points for Star Rating be simplified?
- How should CMS should measure overall improvement across the Star Ratings measures?
- Should CMS consider additional adjustments to further account for unique geographic and provider market characteristics that affect performance?
- Should the weight of patient experience/complaints and access measures be increased?

Quality

- Any Willing Provider Standards
  - CMS clarifies that sponsors may not exclude pharmacies with unique or innovative business or care delivery models from participating in their contracted pharmacy network on the basis of not fitting in the correct pharmacy type classification
  - CMS proposes to redefine "retail pharmacy" to mean "any licensed pharmacy that is open to dispense prescription drugs to the *walk-in general public* from which Part D enrollees could purchase a covered Part D drug at retail cost sharing without being required to receive medical services from a provider or institution affiliated with that pharmacy"
  - CMS proposes to define "mail order pharmacy"
  - CMS declines to define "specialty pharmacy"

Quality

- Any Willing Provider Standards (cont)
  - CMS notes that it does not support the use of sponsor- or PBM-specific credentialing criteria, in lieu of, or in addition to, accreditation by recognized accrediting organizations
  - CMS also notes that it would not expect sponsors to limit dispensing of certain drugs or drugs for certain disease states to a subset of network pharmacies, except when necessary to meet FDA-mandated limited dispensing requirements or except as required by applicable state law(s) if the contracted network pharmacy is capable of and appropriately licensed under applicable state law(s) for doing so

Quality

- Any Willing Provider Standards (cont)
  - CMS also proposes to establish deadlines by which sponsors must furnish their standard terms and conditions to requesting pharmacies
    - Sponsors must have standard terms and conditions readily available no later than September 15 of each year for the succeeding benefit year
    - Sponsors must provide the standard terms and conditions document to a requesting pharmacy within two business days of receipt of the request
      - If a confidentiality agreement is required, it must be provided within two business days and the standard terms two days upon receipt of the signed confidentiality agreement

Quality

- Any Willing Provider Standards (cont)

AMCP seeks feedback on:

- Do the proposed definitions of "retail pharmacy" and "mail-order pharmacy" strike the right balance to resolve confusion in the marketplace, afford sponsor flexibility, and incorporate recent innovations in pharmacy business and care delivery models?
- Should sponsors be allowed to limit dispensing of certain drugs or drugs for certain disease states to a subset of network pharmacies?
- Should sponsors be allowed to develop sponsor or PBM specific credentialing criteria for network pharmacies in lieu of accreditation standards?
- Are the proposed deadlines for sponsors to furnish their standard terms and conditions to requesting pharmacies operationally realistic? Are longer timeframes needed?

Opioid Management

- Drug Management Programs (DMPs)
  - CMS proposes to integrate DMPs with the current Part D Opioid Drug Utilization Review (DUR) Policy and Overutilization Monitoring System (OMS), which would be codified
  - CMS proposes to limit frequently abused drugs to opioids only
  - CMS proposes use of the 2018 OMS criteria as clinical guidelines for DMPs
  - CMS proposes to add cancer patients to the list of exempted individuals
  - CMS proposes requiring a second notification 30 days after the initial notice

Opioid Management

- Drug Management Programs (DMPs) (cont)
  - CMS proposes requiring prescriber agreement prior to enrollment in a DMP
  - CMS proposes a maximum 12-month enrollment period

AMCP seeks feedback on the provisions of the proposed rule applicable to DMPs and their impact on best caring for at-risk beneficiaries. AMCP continues to work with stakeholders to understand the implications of the proposed rule and advocate for the implementation of DMPs in a manner that best meets the needs of at-risk beneficiaries to address the opioid epidemic.

Next Steps

Academy of Managed Care Pharmacy

AMCP Comments on Proposed Rule

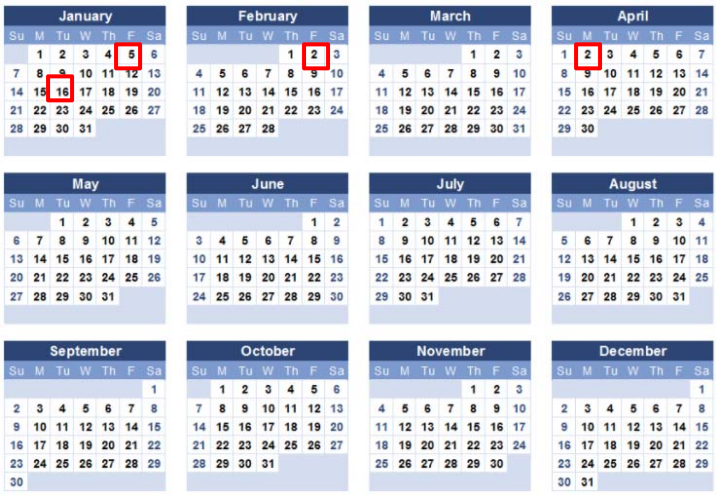
Comments on this proposal must be submitted to CMS by January 16, 2018 at 5pm ET

You may provide feedback via email to Soumi Saha at ssaha@amcp.org by Friday, January 5, 2018 to inform AMCP's comments to CMS

www.amcp.org

Academy of Managed Care Pharmacy

Timeline



1.5.18 → Stakeholder feedback on proposed rule due to AMCP

1.16.18 → Proposed rule comments due

2.2.18 → 2019 Draft Call Letter to be released

4.2.18 → 2019 Final Call Letter to be released

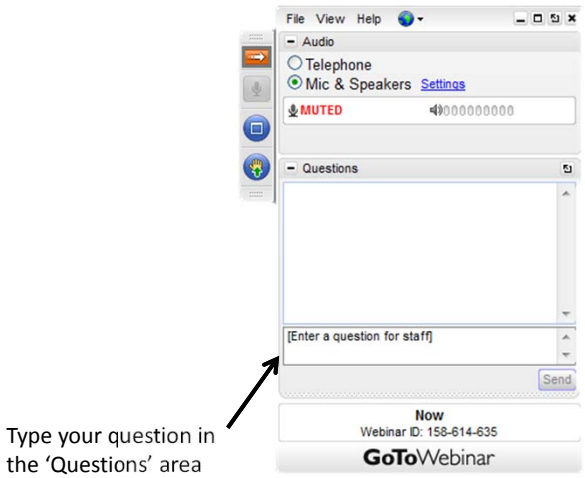
www.amcp.org

AMCP Academy of Managed Care Pharmacy®

Question & Answer

AMCP Academy of Managed Care Pharmacy®

How to Ask A Question



Type your question in the 'Questions' area

www.amcp.org

AMCP Academy of Managed Care Pharmacy

Policy Issue Groups

Sign up for late-breaking info. and the opportunity to be in the conversation: www.amcp.org/list

- Specialty/Biosimilars
- Health Care Reform Implementation
- Medicare Part D
- MTM
- HIT
- Quality initiatives

www.amcp.org

AMCP Academy of Managed Care Pharmacy

©2015 Academy of Managed Care Pharmacy

AMCP Staff Contacts

Mary Jo Carden, RPh, JD
Vice President, Government & Pharmacy Affairs
mcarden@amcp.org
703-684-2603

Soumi Saha, PharmD, JD
Director, Pharmacy & Regulatory Affairs
ssaha@amcp.org
732-266-5472

www.amcp.org

AMCP Academy of Managed Care Pharmacy®

35

AMCP Academy of Managed Care Pharmacy® WEBINAR

The CMS Medicare Part D Proposed Rule: Understanding the Implications to Managed Care Pharmacy

Thank you for attending!

AMCP Academy of Managed Care Pharmacy®