New Proposed Medicare Advantage and Part D Rules

This roundtable discussion is sponsored by the Medicare Advantage and Part D Affinity Group of the Payers, Plans, and Managed Care (PPMC) Practice Group.

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Overview

- Part D Program Changes
- Program Integrity-Related Proposals
- Risk Adjustment Data/Appeals
- Program Audits
Proposed Rule

- No MA/Part D regulations issued in 2013 (other than MLR)
- 2015 contract year proposed changes (some exceptions)
- Projected savings: $1.3 billion over 5 years (2015 – 2019)
- Comments due March 7, 2014
Part D Proposals

- Protected Drug Classes
- Preferred Pricing
- Negotiated Prices
- MAC Pricing Timing
- Expansion of MTM
- Limitation on Number of Plans
Protected Drug Classes (42 CFR §423.120)

- New Criteria for Protected Classes:
  - for a typical individual with a condition treated by such drugs: hospitalization, disability, or death are likely to result within 7 days of a prescription being presented if that prescription is not filled;
  - more specific formulary requirements cannot adequately address the total possible drug-and-disease-specific applications necessary for treatment in the category or class.
Preferred Pricing (42 CFR §423.120)

- Part D sponsors can continue to offer plans with reduced beneficiary cost sharing in a “subset of network pharmacies, as long as such preferred cost sharing is offered…with consistently lower negotiated prices than…the rest of the pharmacy network.”

- The proposed rule would provide that any pharmacy willing to accept a Part D sponsor’s lower reimbursements and other terms and conditions must be allowed to be part of the preferred cost sharing network.

- CMS proposes to eliminate preferred pricing for 1-month supplies filled by mail order pharmacies.
Negotiated Prices (42 CFR §423.100)

- proposed rule would re-define “negotiated price” to include “all price concessions and any other fees” from network pharmacies. Price concessions from pharmacies that could not be calculated at point of sale would be eliminated.

- contingent payments to pharmacies that cannot be predicted in advance, such as fees paid by Part D Sponsors to incentivize generic drug dispensing, would be permitted;
MAC Pricing Timing (42 CFR §423.505)

- CMS proposes to modify existing rules to specify that any methodology based on drug cost, whether the cost is publicly available or not, must change within 7 days of the latest update. This would include drug pricing based on maximum allowable cost (MAC).

- CMS also proposed to require that sponsors disclose all drug price updates (including MAC prices) to pharmacies in advance of their use for reimbursement if the source of the pricing standard is not publicly available.
Expansion of MTM (42 CFR §423.153)

- MTM eligibility criteria would require sponsors to target beneficiaries:
- who have two or more chronic diseases, with at least one being from a list of chronic diseases specified in the regulation,
- (ii) who are taking two or more Part D drugs, and
- (iii) who are likely to incur annual Part D drug costs exceeding $620
Limitation on Number of Plans (42 CFR §423.265)

- Proposal to allow CMS authority to deny the application for a stand-alone Part D plan (PDP) in a region if another subsidiary of the applicant’s parent organization has a contract in the same region.

- In addition, Part D sponsors would be limited to offering no more than two stand-alone PDPs in each region—one basic and one enhanced.
Program Integrity-Related Proposals

- Report and Return of Identified Overpayments
- Part D Prescriber Medicare Enrollment Requirements
- Denial or Revocation of Part D Prescriber Medicare Enrollment For Improper Prescribing Practices/Patterns
- Authority To Directly Request Information From FDRs
Report and Return of Overpayments
(42 CFR §422.326 and §423.360)

- Addresses the requirements added by the Affordable Care Act for MA and Part D plans to report and return an overpayment within 60 days after the overpayment is identified. An overpayment exists when the MA or Part D plan has funds to which it is not entitled after reconciliation.

- An overpayment has been identified when an MA organization or Part D sponsor has actual knowledge of the existence of an overpayment, or acts in reckless disregard or deliberate ignorance of the existence of the overpayment.
Report and Return of Overpayments
(42 CFR §422.326 and §423.360)

- If an MA organization or Part D sponsor receives information that an overpayment might exist, the organization must exercise reasonable diligence to identify whether there has been an overpayment.

- Organization is deemed to have satisfied the 60 day rule if it notifies CMS and takes other actions that CMS specifies to submit corrected data. CMS will then recover overpayments through its routine processing.
Part D Prescriber Enrollment Requirements  
(42 CFR §423.120)

- Implements ACA §6405(c): (provides Secretary with authority to require that Part D prescribers be enrolled in Medicare)
- As of 1/1/15, prescriber of Part D drugs must have either:
  - Approved enrollment record in FFS Medicare program; or
  - Valid opt-out affidavit filed with CMS A/B MAC
- If not met, prescription not eligible for Part D coverage
- Ensures Part D drugs prescribed only by qualified prescribers (i.e., those with an active professional health care license that conveys prescribing privileges under applicable state law)
Part D Prescriber Enrollment Requirements
(42 CFR §423.120)

- Aligns with other efforts to ensure qualified prescribers (i.e., valid NPIs on claims, PDE records)
- Ensure prescriber credentials verified by MACs (NPIs self-reported)
- Sponsors remain responsible for ensuring prescriber authorized under state law
- Part D Sponsor must deny (or require PBM to deny) pharmacy claims where valid NPI not on claim
- Part D Sponsor must deny (or require PBM to deny) pharmacy claims where prescriber does not meet Medicare enrollment or opt-out requirements (applies to beneficiary request for reimbursement)
Part D Prescriber Enrollment Requirements
(42 CFR §423.120)

- Part D Sponsors can only submit PDE records where prescriber is enrolled in Medicare/opt-out affidavit
- CMS will provide sponsors with approved list (eliminates requirement to check NPPES database for NPI)
- Over 1M physicians/eligible professionals; over 9K valid opt-outs
- CMS soliciting specific comments on:
  - Requiring all pharmacies to enroll in Medicare to dispense Part D drugs
  - Whether requiring FFS enrollment for network pharmacies is a “best practice” in pharmacy contracting by sponsors and should be part of sponsor FWA programs
  - Whether doctors of dental surgery/dental medicine should be subject to enrollment requirements
Denial or Revocation of Part D Prescriber Medicare Enrollment (42 CFR §424.535)

- CMS authority to deny/revoke physician/eligible professional Medicare enrollment application if:
  - DEA certificate is suspended or revoked or;
  - Applicable state licensing body suspends or revokes ability to prescribe drugs

- Clear indicators of misuse or abuse of authority

- Consistent with CMS requirement that providers and suppliers maintain compliance with all applicable licensure and certification requirements
Denial or Revocation of Part D Prescriber Medicare Enrollment (42 CFR §424.535)

- CMS authority to deny/revoke physician/eligible professional Medicare enrollment application if pattern or practice of prescribing Part D drugs that:
  - Is abusive and represents a threat to health and safety of Medicare beneficiaries
  - Fails to meet Medicare requirements (e.g., pattern of incorrect or inaccurate claims)
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Denial or Revocation of Part D Prescriber Medicare Enrollment (42 CFR §424.535)

- Criteria ("is abusive and represents health threat"):  
  - Whether diagnoses support indications for drugs  
  - Prescribing excessive controlled substances dosages  
  - Evaluation of patient could not have occurred (e.g., deceased, out of state, etc.)  
  - Controlled substances prescribed linked to patient overdoses  
  - Number/types of state board licensure disciplinary actions  
  - History of adverse actions  
  - Number/types of malpractice suit judgments and settlements  
  - State Medicare program suspensions, revocations, etc.  
  - Any other relevant information
Denial or Revocation of Part D Prescriber Medicare Enrollment (42 CFR §424.535)

- Criteria ("fails to meet Medicare requirements"): 
  - Pattern or practice of:
    - prescribing without valid prescribing authority
    - prescribing controlled substances outside of scope of DEA registration
    - Prescribing drugs for indications not medically accepted and evidence of acting in reckless disregard for health and safety of the patient

- CMS soliciting specific comments on whether to include pharmacies
Authority To Directly Obtain Information From FDRs
(42 CFR §423.504; §423.505)

- HHS/Comptroller General/Designees may obtain records directly from FDRs (first tier, downstream and related entities) for audit and inspection
- May also “collect” records (i.e., request information to be reviewed in another location other than onsite)
- Replaces Part D language that provides sponsors with choice of how to provide to government
Authority To Directly Obtain Information From FDRs
(42 CFR §423.504; §423.505)

- Guarantees direct, expeditious route to FDR
- Simultaneous notification to FDR and sponsor
- OIG reports: lack of authority to directly obtain information from FDRs (pharmacies, PBMs, and physicians) hinders ability to timely investigate FWA
CMS proposes to add a rule that would require that MA organizations design medical record reviews to determine the accuracy of diagnoses submitted for risk adjustment purposes.

MA organizations would be prohibited from designing medical record reviews only to identify diagnoses that would trigger additional payments from CMS.
RADV Appeals (42 CFR §422.311)

- The proposed rule would consolidate the process for medical record review-determination appeals and RADV payment error calculation appeals.
- The combined process would have 3 administrative steps: reconsideration, hearing officer review, and CMS administrator-level review.
- CMS also proposes to amend the rules to specify that the Secretary of the Department of Health and Human Services, along with CMS, may conduct RADV audits.
Changes to Audit and Inspection Authority  
(42 CFR §422.503; §423.504)

- Incorporates ACA §6408 right for Secretary to “timely” inspections and audits
- CMS may require MAO/PDP sponsor to hire an independent auditor to:
  - Conduct full or partial program audit; or
  - Provide CMS with information to determine if deficiencies found during audit or inspection (including by CMS) have been corrected and not likely to recur.
- Independent auditor must:
  - Work in accordance with CMS specifications; and
  - Be willing to attest that a complete and full independent review has been performed.
Changes to Audit and Inspection Authority
(42 CFR §422.503; §423.504)

- CMS will release guidance on specifications for audit contracts between sponsor and independent auditors
- Number of CMS audits constrained by limited resources
- Allows each MAO/Part D sponsor to undergo audit at least every 3 years
- More program performance data available to CMS
- CMS will continue to perform audits in limited scenarios and “look back” audits for independent auditors
Conclusion

Discussion/Q&A