Issue Brief

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KEY POINTS

- The CMS proposal relates to certain Medicare Advantage and Medicare Part D components beginning in 2019.
- CMS suggests that the changes are designed to support innovation in quality, accessibility and affordability and to improve beneficiaries' experiences.

CMS Proposes Policy Changes and Updates for Medicare Advantage and the Prescription Drug Benefit Program for Contract Year 2019

The Centers for Medicare & Medicaid Services issued a proposed rule regarding the "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 713-page rule is currently available at https://s3.amazonaws.com/public-inspection.federalregister.gov/2017-25068.pdf. The rule is scheduled for publication in the Federal Register on Tuesday, Nov. 28. A 60-day comment period ending January 16 is provided.

The rule's preamble states that the "primary purpose of this proposed rule is to make revisions to the Medicare Advantage program (Part C) and Prescription Drug Benefit Program (Part D) regulations based and to implement certain provisions of the ***Comprehensive Addiction and Recovery Act and the 21st Century Cures Act***." Further, the rule states that the "proposed changes are necessary to (1) Support Innovative Approaches to Improving Quality, Accessibility and Affordability; (2) Improve the CMS Customer Experience; and (3) Implement Other Changes."

PATIENTS OVER PAPERWORK INITIATIVE

CMS notes that it recently launched the Patients Over Paperwork Initiative, a cross-cutting, collaborative process that evaluates and streamlines regulations with the goal of reducing unnecessary burden, increasing efficiencies and improving the beneficiary experience. CMS says the proposed rule furthers this initiative, and it would empower patients and doctors in making decisions about patient health care. Specifically, the proposed rule would reduce unnecessary regulatory burdens by:

- allowing plans to send more materials electronically to Medicare beneficiaries;
- eliminating requirements that plans submit, in addition to their bids, similar and overlapping accounting information;
- streamlining government review and approval of materials plans use to communicate with beneficiaries; and
- eliminating burdensome enrollment requirements for providers that bring value to Medicare Advantage beneficiaries.

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PROPOSED POLICY CHANGES TO MEDICARE ADVANTAGE AND THE PRESCRIPTION DRUG BENEFIT PROGRAM

Ensure Additional Transparency for Star Ratings

CMS annually calculates and publishes Star Ratings for participating Part C and Part D plans. CMS says beneficiaries rely on the Star Ratings to help inform plan choice, and CMS uses the ratings to calculate Quality Bonus Payments for plans. CMS historically announces changes to the Star Rating framework, measures and methodology through the Call Letter.

In the proposed rule, CMS is proposing to codify key aspects of the Part C and D Star Ratings methodology, including the principles for adding, updating and retiring measures, as well as the methodology for calculating and weighting measures. CMS also is proposing:

- new rules related to how contract consolidations affect stars to more accurately reflect performance of the surviving and consumed contracts, and
- new methods for applying scaled reductions when CMS determines that the data for the appeals measures is not complete to allow for smaller reductions for less serious data issues.

Artificial Limits on Medicare Advantage Plan Variety

Current regulations place "artificial limits" (called "meaningful difference" requirements) on the variety of plans an MA organization can offer in the same county.

CMS is proposing to eliminate the requirement that MA plans offered by the same organization in the same county comply with artificial limits. CMS is concerned the current requirement may result in organizations reducing the value of certain benefit offerings in order to make their benefit packages comply with these artificial limits. This may include instances where differences in benefit packages exist but are not incorporated in the agency's evaluation (e.g., unique benefit packages based on enrollee health conditions). CMS expects that eliminating the artificial limits will improve the plan options available for beneficiaries. New flexibilities in benefit design and more sophisticated approaches to consumer engagement and decision-making should help beneficiaries, caregivers and family members make more informed plan choices.

Flexibility in the Medicare Advantage Uniformity Requirements

CMS included a preamble discussion regarding changes to its interpretation of requirements around the uniformity of Part C benefits offered to MA enrollees. These changes give MA organizations new tools to improve care and outcomes for the most vulnerable enrollees by allowing MA organizations the ability to reduce cost sharing for certain covered benefits, offer specific tailored supplemental benefits and offer different deductibles for beneficiaries that meet specific medical criteria. CMS is announcing this new benefit design as an option for all MA plans.

MA plans will be able to exercise the uniformity flexibility within each segment of an MA plan. These flexibilities would be available to plans beginning in CY 2019. The upcoming call letter will address the operational details of this policy.

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Allowing Electronic Delivery of Certain Beneficiary Documents

CMS is proposing to separate the delivery date of the Annual Notice of Change from the Evidence of Coverage so Medicare beneficiaries receive the ANOC first as a stand-alone document. CMS believes this change would allow beneficiaries to better focus on the most important information, such as the upcoming changes to their current plan. In addition, CMS is proposing to permit MA and Part D sponsors to provide certain materials, such as the EOC, electronically. When doing so, plans would be required to provide beneficiaries with easy access to hardcopy materials, if they prefer.

Updates to the Definition of Marketing

Currently, a variety of materials that are not intended to steer a beneficiary into a particular plan fall under the regulatory definition of marketing and related requirements. Because of this, a statutory requirement that these materials be subject to CMS review applies.

CMS proposes to lessen the burden of marketing submission and review by focusing the definition of marketing on materials that are most likely to lead to an enrollment decision. To account for those materials that fall outside of the proposed new marketing definition, CMS is proposing to create more appropriate requirements and oversight for a new category of materials and activities called "communications."

Implementation of the Comprehensive Addiction and Recovery Act of 2016

CARA requires CMS to establish, through regulation, a framework that allows Part D sponsors to voluntarily implement a drug management program that limits "at risk" beneficiaries' access to controlled substances that CMS determines are "frequently abused drugs," beginning with the 2019 plan year.

CMS proposes to designate opioids (with limited exceptions) as frequently abused drugs; tie the definition of at-risk beneficiaries to the criteria used to identify potential opioid over-utilizers under CMS' existing Part D Opioid Drug Utilization Review Policy and Overutilization Monitoring System; and allow a plan to limit an at-risk beneficiary's access to opioids to a selected prescriber(s) and/or network pharmacy(ies), which would be an extension of CMS' DUR policy and OMS. CMS also proposes to exempt beneficiaries who have cancer or are in hospice or long-term care from the drug management program.

CMS proposes to limit the availability of the special enrollment period for dually- or other low-income subsidy-eligible beneficiaries who are identified as at-risk or potentially at-risk for prescription drug abuse under such a drug management program. At-risk determinations and any associated limitations on access to frequently abused drugs would be subject to the existing beneficiary appeals process.

Maximum Out-of-Pocket and Cost Sharing Limits

CMS proposes to revise the regulations controlling MOOP limits, so CMS might change its existing methodology of using the 85th and 95th percentiles of projected beneficiary out-of-pocket Medicare FFS spending in the future. Under these proposals, CMS would have authority to change and implement additional levels of MOOP limits, as well as provide flexibility to encourage plan offerings with lower MOOP limits. In addition, CMS would be able to issue and update guidance regarding discriminatory cost sharing.

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Default Enrollment

CMS is proposing to codify the current optional enrollment mechanism that allows MA organizations to provide seamless continuation of coverage by way of enrollment in an MA plan for newly MA-eligible individuals who are currently enrolled in other health plans offered by the MA organization (such as commercial or Medicaid plans) at the time of the individuals' initial eligibility for Medicare with significant limitations. In addition to other limits, CMS' proposal would limit default enrollments of this type to individuals remaining in a Medicaid managed care plan offered by the same parent organization offering the MA plan. CMS seeks comment on whether to allow such enrollments in other circumstances beyond Medicare managed care.

Passive Enrollment Opportunities to Protect Continuity of Integrated Care for Dually Eligible Beneficiaries

In an effort to promote integrated care and continuity of care, CMS is proposing a limited expansion of its regulatory authority in circumstances when beneficiary enrollment would be disrupted by changes in health plan participation. The proposal would allow passive enrollment for full-benefit dually eligible beneficiaries from a non-renewing integrated D-SNP to another comparable plan. This process would be conducted in consultation with a state Medicaid agency, and where other conditions are met to ensure continuity and quality of care.

Part D Tiering Exceptions

CMS is proposing to revise existing policy related to tiering exceptions, including the permissible limitations Part D plan sponsors may apply to tiering exception requests. CMS is proposing to eliminate the provision, allowing plans to exclude a dedicated generic tier from the tiering exceptions process, and establish a framework based on the type of drug (brand, generic, biological product) requested and the cost-sharing of applicable alternative drugs. CMS also is proposing to clarify appropriate cost sharing for approved requests when alternatives are on multiple lower tiers, and to codify that authorized generic drugs should be treated as generics for purposes of tiering exceptions.

Limitation to the Part D Special Enrollment Period for Dual and Other LIS-Eligible Beneficiaries

To ensure that Part D plan sponsors are better able to administer benefits, including coordination of Medicare and Medicaid benefits, CMS is proposing to change the Special Election Period for dual-eligible and LIS beneficiaries from an open-ended monthly SEP to one that may be used only in the following circumstances (and only if the beneficiary has not been identified as potentially at-risk or at-risk): (1) within a certain period of time after a CMS or State-initiated enrollment; or (2) as a onetime annual opportunity that can be used at any time of the year. The proposed rule would establish a separate SEP that can be used by any dual or other LIS-eligible beneficiary, including those who have been identified as potentially at-risk or at-risk, within a certain period after a change to an individual's LIS or Medicaid status.

Any Willing Pharmacy Standard Terms and Conditions and Better Define Pharmacy Types

This provision would clarify Part D rules and CMS expectations regarding statutorily required Any Willing Pharmacy provisions, and it proposes to add a clarifying definition of mail-order pharmacy and revise the definition of retail pharmacy.

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Changes to the Days' Supply Required by the Part D Transition Process

To reduce waste, CMS proposes to conform the transition supply provided in the long term care setting (currently 90 days) to that provided in the outpatient setting (currently 30 days) so that the transition supply in both settings is the same number of days. CMS also proposes to change the current 30-day transition supply requirement to a one-month supply (i.e., CMS is proposing to change the transition supply provided in the long term care setting and outpatient setting to a one-month supply).

Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes

The proposed provisions would provide more formulary flexibility by, for instance, permitting Part D sponsors to immediately substitute newly-released equivalent generics for brand name drugs at the same or lower cost sharing if they meet revised requirements, including generally advising enrollees beforehand that such changes can occur without a specific advance notice and later providing information to affected enrollees about any specific generic substitutions that occur.

Treatment of Follow-On Biological Products as Generics for Low Income Subsidy Cost Sharing and Non-LIS Catastrophic Cost Sharing

This provision is intended to encourage the use of lower-cost alternatives by classifying follow-on biological products as generics for the purposes of cost sharing for Part D enrollees who do not receive the LIS and are in the catastrophic portion of the benefit, and for LIS Part D enrollees throughout all phases of the benefit.

Part D Artificial Limits

CMS is proposing to eliminate an artificial limit (called the "meaningful difference" requirement) on Enhanced Alternative benefit designs offered by the same organization in the same region. CMS is not changing this requirement as it applies between Basic and EA prescription drug plan offerings.

Manufacturer Rebates and Pharmacy Price Concessions to Point of Sale

The proposed rule includes a Request for Information 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. CMS would use ideas and comments provided in response to the Request for Information to evaluate and consider proposals for rulemaking.

Restoration of the Medicare Advantage Open Enrollment Period

The ***21st Century Cures Act*** eliminates the existing MA disenrollment period that currently takes place from Jan. 1 through Feb. 14 of every year and, effective for 2019, replaces it with a new Medicare Advantage open enrollment period that will take place from Jan. 1 through March 31 annually. The new OEP allows individuals enrolled in an MA plan to make a one-time election to go to another MA plan or Original Medicare. Individuals using the OEP to make a change may make a coordinating change to add or drop Part D coverage.

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Codification of Part A and Part B Premium Adjustments as Initial Determinations

CMS is proposing to codify the existing policy of treating fee-for-service premium adjustments as initial determinations.

Lengthening Adjudication Timeframes for Part D Payment Redeterminations and Independent Review Entity Reconsiderations

CMS is proposing to lengthen existing timeframes for adjudicating enrollee payment appeal requests at the redetermination and independent review entity reconsideration levels from a maximum of seven calendar days to a maximum of 14 calendar days.

Reducing Burden on Plans by Eliminating MA Plan Notice of Forwarded Appeals

CMS also is proposing to remove the current requirement that MA plans send notice to an appellant when his/her appeal case file is forwarded to Medicare's Part C IRE. Under its contract with CMS, the Part C IRE will continue to notify MA enrollees of forwarded cases. Eliminating this redundant enrollee notice would ease burden on plans without adversely impacting enrollee protections.

Update to the Electronic Transaction Standard Used by Part D Plans

CMS is proposing to update the current electronic prescribing standard for the Part D e-Prescribing Program (the National Council for Prescription Drug Programs SCRIPT Standard). New versions of standards are created when standard setting organizations like the NCPDP review their existing standards, ballot and recommended changes and adopt new versions of existing standards. NCPDP recommended that CMS adopt the latest version of the NCPDP SCRIPT Standard, Version 2017071. The prior version (NCPDPD Version 10.6) was adopted November 1, 2013.

Preclusion List Requirements for Prescribers in Part D and Providers and Suppliers in Medicare Advantage, Cost Plans and PACE

CMS proposes eliminating the prescriber and provider enrollment requirement and compiling a "Preclusion List" of individuals and entities that fall within either of the following categories: (a) are currently revoked from Medicare, are under a reenrollment bar, and CMS determines that the underlying conduct that led to the revocation is detrimental to the best interests of the Medicare program; or (b) have engaged in behavior for which CMS could have revoked the individual or entity to the extent applicable if they had been enrolled in Medicare, and CMS determines that the underlying conduct that would have led to the revocation is detrimental to the best interests of the Medicare program.

Removal of Quality Improvement Project

CMS is proposing to remove the Quality Improvement Project from the Quality Improvement requirements. CMS determined that the QIP is duplicative of activities MA organizations are already doing to meet other plan needs and requirements.

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Reducing Unnecessary Paperwork Burden: Medical Loss Ratio

For CY 2014 and subsequent contract years, Medicare Advantage organizations and Part D sponsors are required to report their medical loss ratios. The MLR reflects how much of a plan's total revenue is spent on claims for medical services, medications and certain other qualifying expenses like quality improvement activities. Plans are subject to financial and other penalties for a failure to meet the statutory requirement that they have an MLR of at least 85 percent. CMS is proposing to significantly reduce the amount of MLR data that MA organizations and Part D sponsors submit to CMS on an annual basis. Under the proposed rule, MA organizations and Part D sponsors would only report the MLR percentage and amount of any remittance owed to CMS for each contract. CMS also is proposing to revise 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 programs.

Analysis provided for MHA by Larry Goldberg, Goldberg Consulting

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