Issue Brief

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

The Centers for Medicare and Medicaid Services issued a final rule that will update the Medicare Advantage and the prescription drug benefit program. A copy of the 1,156-page document currently is available at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/CY2019-Medicare-Advantage-Part-D-Final-Rule.pdf.

Note: This document has not been submitted to the Office of the ***Federal Register*** for publication and has not yet been placed on public display or published in the ***Federal Register***. The document may vary slightly from the published document if minor editorial changes have been made during the OFR review process. The document published in the ***Federal Register*** will become the official HHS approved document.

CMS says that the "final changes will result in an estimated $295 million in savings a year for the Medicare program over five years (2019 through 2023) – resulting in lower premiums or additional benefits."

Comment

Washington Perspectives' target audience is providers. Therefore, the material that follows has been extracted from CMS fact sheets rather than the highly detailed rule itself.

The following is from the CMS Fact Sheet that summarizes many of the rule's changes. A copy of the fact sheet is at https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2018-Fact-sheets-items/2018-04-02-2.html.

FINAL 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 (Medicare Advantage) and Part D plans.

CMS is codifying key aspects of the Part C and D Star Ratings methodology, including the principles for adding, updating and removing measures, and the methodology for calculating and weighting measures. CMS is also setting:

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- New rules related to how Star Ratings are assigned when contracts consolidate to more accurately reflect the performance of all contracts (surviving and consumed) involved in the consolidation for consolidations approved on or after Jan. 1, 2019, as required by the ***Bipartisan Budget Act of 2018*** provision, and
- New methods for applying scaled reductions when CMS determines that the data for the appeals measures are not complete to allow for reductions proportionate to the seriousness of the data issue. These changes are intended to increase Star Ratings predictability.

Unnecessary Limits on Medicare Advantage Plan Variety

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

CMS is eliminating the requirement that MA plans offered by the same organization in the same county comply with unnecessary limits, beginning with CY 2019 MA bid submissions.

Flexibility in the Medicare Advantage Uniformity Requirements

CMS has reinterpreted uniformity requirements for Part C benefits offered to MA enrollees. The final rule highlights how the new benefit design will be an option for all MA plans.

Allowing Electronic Delivery of Certain Beneficiary Documents

CMS is separating the delivery date of the Annual Notice of Change from the Evidence of Coverage so Medicare beneficiaries first receive the ANOC as a stand-alone document.

In addition, MA and Part D sponsors now can provide certain materials, such as the EOC, electronically. When doing so, plans would be required to provide beneficiaries with easy access to hard-copy 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 its related requirements, including a statutory requirement that these materials be subject to CMS review. CMS is changing the definition to include only materials that are most likely to lead to a beneficiary to make an enrollment decision.

CMS says this "change lessens the burden of marketing submission on plans and CMS reviewers." To account for those materials that will now fall outside of the new marketing definition, CMS is adopting 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 implement drug management programs. Under such programs, a sponsor can limit at-risk beneficiaries' access to coverage for frequently abused drugs beginning with the 2019 plan year. CMS will designate opioids and benzodiazepines as frequently abused drugs.

The clinical guidelines used to determine if a beneficiary is potentially at-risk, which are based on using opioids from multiple prescribers and/or multiple pharmacies, will be expanded from

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those of CMS' existing Overutilization Monitoring System.

Sponsors will be allowed to limit an at-risk beneficiary's access to frequently abused drugs to a selected prescriber(s) and/or pharmacy(ies) ("lock-in"), and through the use of beneficiary-specific point-of-sale claim edits, which already are permitted under the current policy. Part D sponsors may not implement such limitations unless they have engaged in case management with the prescribers of these drugs, and beneficiaries can submit prescriber and pharmacy preferences.

CMS will exempt beneficiaries who are being treated for active cancer-related pain, are receiving palliative or end-of-life care, or are in hospice or long-term care from drug management programs. CMS is limiting 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 drug management programs. At-risk determinations, which include prescriber and pharmacy lock-in, will be subject to the existing beneficiary appeals process.

Maximum Out-of-Pocket and Cost Sharing Limits

CMS is revising the regulations controlling maximum out-of-pocket limits to enable future changes to CMS' existing methodology of using the 85th and 95th percentiles of projected beneficiary out-of-pocket Medicare Fee-For-Service spending, beginning no earlier than CY 2020.

Default Enrollment

CMS is codifying changes to a current enrollment mechanism that allows MA organizations to provide seamless continuation of coverage for their beneficiaries once they become Medicare eligible.

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

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

Part D Tiering Exceptions

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

Limitation to the Part D Special Enrollment Period for Dual and Other Low-Income Subsidy-Eligible Beneficiaries

To ensure that Part D plan sponsors are better able to administer benefits,

including coordination of Medicare and Medicaid benefits, CMS is revising the Special Election Period for dual-eligible and LIS beneficiaries from an open-ended monthly SEP to one that may be used only once per calendar quarter during the first nine months of the year. The final rule also establishes separate SEPs that can be used in the following circumstances: (1) within a certain period after a CMS or state-initiated enrollment, and (2) 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 clarifies Part D rules and CMS expectations regarding statutorily-required any willing pharmacy provisions, and revises the definition of retail pharmacy. This provision also establishes deadlines by which Part D sponsors must respond to requests for standard pharmacy contracting terms and conditions.

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

To reduce waste, CMS is conforming the transition supply provided in the long-term care setting (currently 90 days) to the transition supply provided in the outpatient setting (currently 30 days) so that the transition supply in both settings is for the same period. CMS also is changing the "30-day transition supply" to "an approved month's supply" so that it will now be equivalent to the approved month's supply for the applicable plan bid. Thus, Part D sponsors will be required to provide an approved month's supply in both the long-term care and outpatient settings.

Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes

The final rule provides more formulary flexibility by, for instance, permitting Part D sponsors to immediately substitute generics for brand name drugs on the same or lower cost-sharing tier if they meet certain requirements, which include 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.

Similar Treatment of Biosimilar and Interchangeable Biological Products and Generic Drugs for Purposes of Low-Income Subsidy Cost Sharing

This provision encourages the use of lower-cost alternatives by applying generic cost-sharing to biosimilar and interchangeable biological products for LIS Part D enrollees throughout all phases of the benefit. This policy alone is expected to generate savings to the Medicare program of $10 million in 2019.

Part D Meaningful Differences between Enhanced Alternative Plans

CMS is eliminating an unnecessary limit – the "meaningful difference" requirement – for PDP Enhanced Alternative benefit designs offered by the same organization in the same region. CMS is not changing this requirement as it applies between PDP Basic and EA prescription drug plan offerings.

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

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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, including newly MA-eligible individuals, 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.

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

CMS is lengthening 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. This change will provide additional time to adjudicate payment requests in situations where beneficiaries already have obtained the requested medications.

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

CMS also is removing 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.

Update to Part D Electronic Transaction Standard

CMS is updating 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. CMS is adopting the NCPDP SCRIPT Standard, Version 2017071 beginning on Jan. 1, 2020. The prior version (NCPDPD Version 10.6) was adopted Nov. 1, 2013.

Preclusion List Requirements for Prescribers in Part D and Individuals and Entities in Medicare Advantage, Cost Plans and PACE

CMS is eliminating the prescriber and provider enrollment requirement for Part C and Part D, and instead is compiling a "Preclusion List" of prescribers, individuals and entities that fall within either of the following categories: (a) are currently revoked from Medicare, are under an active 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 prescriber, 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.

Under this option, CMS will make the Preclusion List available to Part D prescription drug plans and Medicare Advantage plans. Plans would be required to deny payment for claims submitted by, or associated with, prescriptions written by prescribers and providers on the list.

Focusing Plans on Improving Chronic Condition Management

CMS is removing the Quality Improvement Project from the Quality

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Improvement requirements. The removal of the QIP and the continued implementation of the Chronic Care Improvement Program allows MA plans to focus on one project that supports improving the management of chronic conditions, a CMS priority, while reducing the duplication of other QI initiatives.

Reducing Unnecessary Paperwork Burden: Medical Loss Ratio

CMS is finalizing the proposal to significantly reduce the amount of MLR data that MA organizations and Part D sponsors submit to CMS on an annual basis. Under these new rules, MA organizations and Part D sponsors only will report the MLR percentage and amount of any remittance owed to CMS for each contract.
CMS also is finalizing its proposal to revise the MLR calculation to include in the MLR numerator all expenditures related to fraud reduction activities (including fraud prevention, fraud detection and fraud recovery) and Medication Therapy Management programs.

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

CMS is codifying the existing policy of treating FFS premium adjustments as initial determinations, which gives beneficiaries subject to these adjustments full appeal rights.

2019 MEDICARE ADVANTAGE AND PART D RATE ANNOUNCEMENT AND CALL LETTER

(a copy is at https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2018-Fact-sheets-items/2018-04-02-2.html.) Some items reported in this fact sheet overlap with the regulatory fact sheet.

2019 RATE ANNOUNCEMENT

Net Payment Impact

The chart below indicates the impact of the policy changes on plan payments relative to last year. The per capita cost growth in Medicare Fee-For-Service has grown over the past year. Because the MA growth rates are linked to the overall Medicare FFS per capita growth rate, the FFS trend carries over to MA plans.

Impact	2019 Advance Notice	2019 Rate Announcement
Effective Growth Rate	4.35%	5.28%
Rebasing/Repricing	N/A	0.49%
Change in Star Ratings	-0.2%	-0.26%
Medicare Advantage coding intensity adjustment	0.01%	0.01%
Risk Model Revision	0.28%	0.28%
Encounter Data Transition	-0.04%	-0.04%
Employer Group Waiver Plan Payment Policy	-0.3%	-0.1%
Normalization	-2.26%	-2.26%
Expected Average Change in Revenue	1.84%	3.40%

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The Expected Average Change in Revenue reported above does not include an adjustment for underlying coding trend. For 2019, CMS expects the underlying coding trend to increase risk scores, on average, by 3.1 percent.

2019 Part C Risk Adjustment Model

For 2019, CMS is finalizing an updated model that incorporates most of the proposed changes to the Part C risk adjustment model, such as adding mental health, substance use disorder and chronic kidney disease conditions to the risk adjustment model, as well as a variety of additional technical updates. CMS is not finalizing a model for 2019 that takes into account the number of conditions an individual beneficiary may have in order to provide stakeholders more time to understand its implications, but announced it plans to begin implementing the "Payment Condition Count Model" in 2020 in accordance with the ***21st Century Cures Act*** requirements.

Using Encounter Data

CMS calculates risk scores using diagnoses for each beneficiary, whether they were enrolled in Medicare FFS or MA. Historically, CMS has used MA diagnoses submitted into CMS' Risk Adjustment Processing System.

In recent years, CMS began collecting encounter data from MA organizations, which also includes diagnostic information. In 2016, CMS used diagnoses from encounter data to calculate risk scores, by blending 10 percent of the encounter data-based risk scores with 90 percent of the RAPS-based risk scores. For 2017 and 2018, CMS continued to use a blend to calculate risk scores, by calculating risk scores with 25 percent encounter data and 75 percent RAPS in 2017, and 15 percent encounter data and 85 percent RAPS in 2018.

For 2019, CMS is finalizing the proposal to calculate risk scores by adding 25 percent of the risk score calculated using diagnoses from encounter data and FFS diagnoses with 75 percent of the risk score calculated with diagnoses from RAPS and FFS diagnoses.

CMS also will calculate the encounter data-based risk scores exclusively with the new risk adjustment model, as proposed, while maintaining use of the current risk adjustment model for calculating risk scores with RAPS data.

Coding Pattern Adjustment

Each year, as required by law, CMS makes an adjustment to plan payments to reflect differences in diagnosis coding between MA organizations and FFS providers. In CY 2019, CMS is finalizing its proposal to apply a coding pattern adjustment of 5.90 percent.

Medicare Employer Retiree Plans

Medicare Employer Retiree Plans (Employer Group Waiver Plans) serve specific employer groups, and are either offered through negotiated arrangements between MA plans and employer groups or by the employer directly. CMS supports an MA program that includes robust participation of Part C EGWPs that are accurately reimbursed for their services. To address concerns raised by commenters, for 2019, CMS will finalize the 100 percent phase in which adjustments based on the proportion of EGWP enrollment in PPOs vs. HMOs. CMS intends to seek comment on modifications to this policy for 2020 that include adjustments for regional PPOs and rural local PPOs.

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2019 FINAL CALL LETTER

Improving Drug Utilization Review Controls (Opioids)

Opioid medications ("opioids") have serious risks such as addiction, overdose and death.

CMS is finalizing a number of new policies for 2019 to further help Medicare plan sponsors prevent and combat prescription opioid overuse. While the strategies collectively work towards the same goal, an overall reduction in opioid overuse and overdoses, CMS has tailored each approach to address the distinct populations of Medicare Part D prescription opioid users (e.g., new opioid users, chronic users, those with uncoordinated care, those that concurrently use opioids with benzodiazepines, etc.).

CMS also recommends that beneficiaries who are residents of a long-term care facility, in hospice care or receiving palliative or end-of-life care, or being treated for active cancer-related pain are excluded from these interventions. In addition, CMS says that it is also very important that beneficiaries' access to medication-assisted treatment, such as buprenorphine, is not impacted.

- Opioid naïve patients: To reduce the potential for chronic opioid use or misuse, CMS expects all Part D sponsors to implement a hard safety edit to limit initial opioid prescription fills for the treatment of acute pain to no more than a seven days' supply.
- High risk opioid users: CMS is building upon and expanding the Overutilization Monitoring System. The OMS retrospectively identifies those beneficiaries CMS considers at significant risk (using high levels of opioids from multiple prescribers and pharmacies). Sponsors review these cases and perform case management with the beneficiaries' prescribers.

Through parallel rule-making, CMS proposed to implement the ***Comprehensive Addiction and Recovery Act of 2016*** drug management program in 2019, integrating those policies with the OMS process. Under the proposal, Part D sponsors will be able to limit at-risk beneficiaries' coverage for frequently abused drugs to certain prescribers and pharmacies ("lock-in") and apply beneficiary-specific point-of-sale claim edits. The OMS also will be enhanced to include revised metrics to track high opioid overuse and to provide additional information to sponsors about high-risk beneficiaries who take opioids and "potentiator" drugs (which when taken with an opioid, increase the risk of an adverse event).

- Chronic opioid users: CMS expects all sponsors to implement real-time safety alerts at the time of dispensing as a proactive step to engage both patients and prescribers about overdose risk and prevention.

CMS recognizes that a tailored approach is needed to better address chronic opioid overuse at the POS. CMS expects all sponsors to implement an opioid care coordination edit at 90 morphine milligram equivalent per day. This formulary-level safety edit should trigger when a beneficiary's cumulative MME per day across their opioid prescriptions reaches or exceeds 90 MME. In implementing this edit, sponsors should instruct the pharmacist to consult with the prescriber, document the discussion, and if the prescriber confirms intent, use an override code that specifically states that the prescriber has been consulted. Sponsors will have the flexibility to include a prescriber and/or pharmacy count in the opioid care coordination edit. Sponsors also will have the flexibility to implement hard safety edits (which can only be overridden by the sponsor) and set the threshold at 200 MME or more, and may include prescriber/

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pharmacy counts.

The care coordination edit and other opioid-related strategies implemented for Part D beneficiaries discussed in this Call Letter support adoption of the CDC Guideline for Prescribing Opioids for Chronic Pain. CMS believes it is important that MA-PDs set expectations for prescribers to implement the CDC's recommendations as a best practice through their provider contracts. PDPs also should reinforce these messages through interactions with prescribers as an integral component of sponsors' drug utilization management program.

- Opioid users also taking duplicate or key potentiator drugs: Lastly, CMS expects sponsors to implement additional soft safety edits to alert the pharmacist about duplicative opioid therapy and concurrent use of opioids and benzodiazepines.
- All opioid users: CMS also uses quality measures to track trends in opioid overuse across the Medicare Part D program. To drive performance improvement among plan sponsors, CMS will implement technical revisions to the Pharmacy Quality Alliance opioid overuse measures and add a new PQA measure, Concurrent Use of Opioids and Benzodiazepines.

Driving Patient Engagement

CMS is encouraging plans to adopt data release platforms for their enrollees that meet or exceed the capabilities of CMS' Blue Button 2.0. This would enable enrollees in MA plans to connect their claims data to the applications, services and research programs they trust. CMS also is signaling that it is contemplating future rulemaking in this area to potentially require the adoption of such platforms by MA plans in 2020.

Star Ratings Enhancements

Each year, CMS provides updates to the Part C and D Star Ratings through the Call Letter, including new measures and changes in existing measure specifications.

The more significant changes include adding the following new measures to the 2019 Star Ratings: Statin Use in Persons with Diabetes (Part D) and Statin Therapy for Patients with Cardiovascular Disease (Part C). These measures have previously been announced. Also previously announced, CMS will remove from the 2019 Star Ratings the Beneficiary Access and Performance Problems measure. As has been done in the past, the updated Categorical Adjustment Index values will be finalized in the Call Letter with analyses based on the 2018 Star Ratings data. Finally, based on feedback from plans, CMS will implement scaled reductions for data completeness issues for the Part C and D appeals measures. The scaled reductions will avoid potentially disparate impacts on plans and will ensure that the impact on plans is more commensurate with the identified issue.

Fostering Innovation in Benefit Design: Expanding Health-Related Supplemental Benefits

The policy change announced in the Call Letter will help drive patient access to types of services they do not have today. Some MA plans offer supplemental benefits so that enrollees have more health care benefits and options than what they would receive under the Medicare FFS Program. MA plans use rebate dollars and plan premiums to fund supplemental benefit offerings. The statute limits supplemental benefits to health care benefits; CMS interprets "supplemental health care benefit" as an item or service:

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1. not covered by Original Medicare,
2. that is primarily health-related, and
3. for which the MA plan must incur a direct medical cost.

Previously, CMS has not allowed an item or service to be eligible as a supplemental benefit if the primary purpose includes daily maintenance. However, in the final Call Letter, CMS discusses a reinterpretation of the statute to expand the scope of the primarily health-related supplemental benefit standard. Under this reinterpretation, CMS would allow supplemental benefits if they are used to diagnose, prevent or treat an illness or injury; compensate for physical impairments; act to ameliorate the functional/psychological impact of injuries or health conditions; or reduce avoidable emergency and health care utilization. This expansion will effectively increase the number of allowable supplemental benefit options and provide patients with benefits and services that may improve their quality of life and health outcomes.

Uniformity Flexibility

Analysis provided for MHA by Larry Goldberg, Goldberg Consulting

The final Call Letter reminds plans that CMS has determined that plans can provide certain enrollees with access to different benefits and services. Specifically, MA plans can offer targeted cost sharing and supplemental benefits for specific enrollee populations based on health status or disease state in a manner that ensures that similarly situated individuals are treated uniformly. This flexibility helps MA plans better manage health care services. CMS previously announced this new interpretation in the preamble to the Part C and D proposed rule for 2019, released on Nov. 28, 2017.