

Summary of CY2019 Final Medicare Advantage and Part D Policy & Technical Changes



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Overview

The Centers for Medicare and Medicaid Services (CMS) recently released the Final Rule outlining **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**. In the wide-ranging 1,156-page document, CMS details policy updates and comments focused on:

- implementing CARA and the Cures Act,
- supporting innovative approaches to improve program quality, accessibility, and affordability,
- offering beneficiaries more choices and better care,
- improving the CMS customer experience and maintaining high beneficiary satisfaction,
- addressing program integrity policies,
- providing an update to the official Medicare Part D electronic prescribing standards, and
- clarifying program requirements and certain technical changes regarding treatment of Medicare Part A and Part B appeal rights related to premiums adjustments.

Our summary emphasizes the material that Wakely views as most relevant to product design and MA/PD bid preparation, and should not be viewed as all-inclusive. It has been written for those who are familiar with MA/PD programs and methods.

The final policy and technical change document in its entirety can be found here:

<https://www.gpo.gov/fdsys/pkg/FR-2018-04-16/pdf/2018-07179.pdf>

The CMS Fact Sheet summarizing the final policy changes can be found here:

<https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2018-Fact-sheets-items/2018-04-02.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=descending>

The Highlights

The Final Rule comprises a broad array of product design, operational, quality, and compliance matters for Medicare Advantage Organization (MAO) and Part D plan sponsors. Below we briefly summarize a few of the highlights. Refer to the [Detailed Outline](#) section for a more robust summary of finalized provisions.

Pharmacy Point of Sale Rebates and Price Concessions

The Final Rule did not include any provisions regarding pharmacy price concessions at the point of sale (POS). This will be addressed in future policies and rulemaking.

Star Ratings

The Star Rating treatment of contract consolidations will be based on the enrollment-weighted mean of the measure scores of the surviving and consumed contracts (whereas current policy only considers the surviving contract performance). CMS also codified key elements of the Star Rating program, including its approach to modifying measures and calculation methodologies, with an eye toward improving visibility for MAOs around future measure modifications and weight changes.

Minimum Medical Loss Ratio (MLR)

CMS finalized expanding the definition of MLR Quality Improvement Activity (QIA) to include all fraud reduction activities and Medication Therapy Management (MTM) program expenses. The changes serve to increase the numerator of the MLR calculation. CMS is also drastically reducing the breadth of the minimum MLR reporting requirements to only include four data fields (organization name, contract number, adjusted MLR, remittance amount). CMS still reserves the right to audit MAO data and MLR calculations.

Plan Design Flexibility

CMS finalized the following provisions, allowing for more plan design flexibility:

- Removing meaningful difference requirements for MA plans.
- Allowing varying MA supplemental benefits by segment (in addition to segment-level variation by premium and cost sharing, which is already permitted).
- Providing MA organizations the ability to reduce cost sharing for certain covered benefits, offer specific tailored supplemental benefits, and offer lower deductibles for enrollees that satisfy specific clinical criteria.
- Eliminating Part D Enhanced Alternative (EA) meaningful difference requirements for plans offered by the same organization in the same region.

Implementation of the Comprehensive Addiction and Recovery Act of 2016 (CARA) – Proposed Changes

The final rule implements CARA and includes new authority for Part D drug management programs effective January 1, 2019, with minor operational changes from the proposed rule. CMS codified a framework for Part D plan sponsors to establish a drug management program for beneficiaries at risk for prescription drug abuse. Under the rule Part D sponsors may limit “at-risk” beneficiaries’ access to coverage of frequently abused drugs to a selected prescriber(s) and/or network pharmacies.

Enrollment Provisions

There are a number of enrollment operational provisions in the Final Rule:

- CMS is codifying specific limits on default enrollments for "seamless continuation of coverage" which allow MAOs to transition its Medicaid managed care plan members into MA Dual Special Needs Plans (D-SNPs) upon initial Medicare eligibility.
- In order to promote continuity of care, CMS is also allowing passive enrollment for Full Benefit Dual Eligible Beneficiaries from a non-renewing integrated D-SNP to another comparable plan (in consultation with a State Medicaid agency and with various conditions being met).
- The current open-ended Special Election Period (SEP) for dual-eligible and Low Income Subsidy (LIS) beneficiaries is being limited. So long as the beneficiary has not been flagged as "at-risk" by pharmacy management programs, such individuals will be eligible to change plans once per quarter in each of the first three quarters.
- Finally, beginning in 2019, CMS establishes a new Open Enrollment Period (OEP) per the 21st Century Cures Act. The OEP will run from January 1st through March 31st each year and allow enrollees in an MA plan to make a one-time election to join another MA plan or original Medicare.

Detailed Outline of Proposed Policy & Technical Changes

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1) Executive Summary and Background

A. Executive Summary

1. *Purpose*

- (a) Support innovative approaches to improving quality, accessibility, and affordability
- (b) Improve the CMS customer experience
- (c) Implement other changes
- (d) Provide increased flexibility to serve patients
- (e) Reduce MA-PD burden
- (f) Address the opioid epidemic
- (g) Mitigate impact of increasing drug costs

2. *Summary of Major Provisions*

- (a) Implementation of the Comprehensive Addiction and Recovery Act of 2016 (CARA)
 - The proposed rule implements CARA and includes new authority for Part D drug management programs effective January 1, 2019.
 - CMS proposes a framework for Part D plan sponsors to establish a drug management program for beneficiaries at risk for prescription drug abuse.
- (b) Revisions to Timing and Method of Disclosure Requirements
 - CMS will allow plans to submit some documents electronically (which were formally required to be submitted via hard copy) such as Evidence of Coverage (EOC) forms.
 - CMS is changing the deadline for EOC document submissions to be the first day of the Annual Election Period (AEP). Previously, the deadline was 15 days prior to AEP
- (c) Preclusion List Requirements
 - Part D
 - a. Currently, physicians must enroll in or validly opt-out of Medicare in order for a drug that they prescribe to be covered.
 - b. The Final Rule replaces the enrollment requirement with a provision that requires covering health care items/services furnished by individuals/entities not on the "preclusion list."
 - Part C
 - a. Currently, physicians must be enrolled in Medicare in order to provide health care items/services to an MA enrollee.
 - b. The Final Rule replaces the enrollment requirement with a provision that requires covering health care items/services furnished by individuals/entities not on the "preclusion list."
 - c. The same list will be used for both Parts C & D benefits.

3. *Summary of Cost and Benefits*

- (a) Implementation of CARA
 - Estimated to save \$19 million in 2019, \$20 million in 2023
 - Costs are estimated to be \$2.8 million/year to the industry
- (b) Revisions to Disclosure Requirements
 - Estimated to save \$54.7 million/year to the industry
- (c) Preclusion List
 - Estimated to save \$34.4 million to the providers in 2019
 - No savings beyond 2019

- In 2019, costs to PBMs and/or part D sponsors will be \$9.3 million
- Negligible costs beyond that
- (d) Physician Incentive Plan
 - Estimated to save \$204.6 million in required reinsurance in 2019, rising to \$281.8 million in 2023

B. Background

1. *There were 1,669 comments received.*
2. *Comments for finalized provisions are addressed in various sections.*
3. *Comments to non-finalized provisions will be addressed later.*

2) Provisions of the Proposed Regulation

A. Supporting Innovative Approaches to Improving Quality, Accessibility, and Affordability

1. Implementation of the Comprehensive Addiction and Recovery Act of 2016 (CARA) Provisions

- (a) The proposed rule implements CARA and includes new authority for Part D drug management programs effective January 1, 2019.
- (b) Implements CARA Part D drug management provisions by integrating them with the current Part D Opioid Drug Utilization Review (DUR) Policy and Overutilization Monitoring System (OMS).
 - “Current policy” encompasses Part D overutilization management via retrospective Drug Utilization Review (DUR).
- (c) CMS proposes a framework for Part D plan sponsors to voluntarily establish a drug management program for beneficiaries at risk for prescription drug abuse, although CMS expects all Part D plan sponsors to adopt such programs.
 - Part D sponsors may limit at-risk beneficiaries’ access to coverage of frequently abused drugs to a selected prescriber (“prescriber lock in”) and/or network pharmacies (“pharmacy lock-in”).
 - Part D sponsors may limit access to opioids through point-of-sale (POS) claim edits or by requiring beneficiaries to obtain opioids from selected pharmacies or prescribers (after case management and notice provided to beneficiary)
- (d) Limits use of the Special Enrollment Period (SEP) for low income subsidy (LIS)-eligible beneficiaries who are identified as potential at-risk beneficiaries.
- (e) Clinical guidelines must be met to substantiate that the beneficiary is taking a high-risk dose of opioids over a sustained time period, and obtaining opioids from multiple prescribers and multiple pharmacies.
 - Part D sponsors may evaluate enrollees for overutilization management more frequently than current CMS policy (quarterly review with 6-month lookback)
- (f) CMS expects that all Part D plan sponsors will implement such drug management plans.
- (g) CMS will publish a list of frequently abused drugs for purposes of Part D drug management programs (to be included in future Call Letters).
- (h) Beneficiaries with cancer, in hospice, or in long-term care would be exempt.
- (i) CMS details the operational parameters and requirements of drug management programs focused on opioid abuse, including prescriber and beneficiary notification requirements.
- (j) Noteworthy Changes to CARA from the Proposed Rule
 - CMS removed the proposed 6-month waiting period before a plan sponsor may impose limits for an at-risk beneficiary to a prescriber.

- Beneficiaries receiving non-hospice palliative and end-of-life care but have not elected hospice are exempt from Part D drug management program.
- Prescriber agreement to pharmacy lock-in is not required prior to placing an at-risk beneficiary in pharmacy lock-in.
- Only one prescriber needs to agree to prescriber lock-in or a beneficiary-specific POS edit (as compared to all prescribers of frequently abused drugs for the beneficiary in the proposed rule)
- CMS finalized an initial 12-month lock-in period, but added the ability for the sponsor to extend limitations for up to an additional 12 months (total of 24 months).
- CMS shorted the second beneficiary notification timeline for at-risk beneficiary status to 60 days (vs. 90 days in the proposed rule).

2. *Flexibility in the Medicare Advantage Uniformity Requirements*

- (a) CMS has adopted their proposal to allow MA organizations to reduce cost sharing for certain covered benefits, offer specific tailored supplemental benefits, and offer lower deductibles for enrollees that meet specific medical criteria, provided that similarly situated enrollees (i.e., any enrollees who meet the specified criteria) are treated equitably. The benefit package designed for enrollees must be medically related to the specific condition or health status of the eligible enrollees.
- (b) CMS clarified that cost sharing reductions may be restricted to those participating in a disease management program related to the health status or disease.
- (c) The flexibility above does not extend to premiums; all enrollees must have uniform premiums.
- (d) Plans offering additional benefits with specific conditions can market to potential enrollees in the same manner as any other benefit.
 - For example, reduced cost sharing flexibility would allow an MA plan to offer diabetic enrollees \$0 cost sharing for endocrinologist visits along with a lower deductible.
- (e) This new interpretation has limits, as MA regulations still require non-discrimination in terms of limits based on health-status related factors.
- (f) CMS's updated interpretation of protecting against discrimination is to protect high-acuity enrollees from adverse treatment, and CMS will review benefit designs to ensure this is not happening.
- (g) Targeted cost-sharing reductions and supplemental benefits should be for services related to the disease conditions.
- (h) Criteria for eligible enrollees must be objective and measurable.
- (i) CMS's value based insurance design differs from CMS's reinterpretation of uniformity in a few ways, including VBIDs ability to target Part D benefits, the restriction to certain medical conditions and requiring application to participate in the VBID demonstration.
- (j) Beginning in 2020, CMS will also allow "chronic" supplemental benefits. These benefits differ from benefits described above in that they can address the individual needs of vulnerable plan members. As such, they can receive a waiver from CMS' uniformity requirements. Chronic supplemental benefits are required to "have a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollee and may not be limited to being primarily health related benefits." These benefits are not required to be primarily health related; they can address issues beyond specific medical conditions, such as social supports.

3. *Segment Benefits Flexibility*

- (a) CMS has adopted their proposal that MA plans may vary supplemental benefits by segment (in addition to segment-level variation by premium and cost sharing, which is already permitted).

4. *Maximum Out-of-Pocket (MOOP) Limit for Medicare Parts A and B Services*

- (a) CMS has adopted its proposal to maintain its methodology for how it calculates the mandatory and voluntary MOOP limits for now, but seeks additional flexibility in how it is allowed to establish annual MOOP limits.
- (b) CMS's goal is to set MOOP limits that are based on the most relevant and available data.
- (c) These changes will happen no earlier than CY2020 and would be explained in advance in annual Call Letters. CMS expects to transition any major changes.

5. *Cost Sharing Limits for Medicare Parts A and B Services*

- (a) CMS has adopted their proposal to use FFS data as well as MA utilization encounter data to inform patient utilization scenarios used to help identify MA plan cost sharing standards and thresholds that are not discriminatory.
- (b) Like for the prior section, these changes will happen no earlier than CY2020 and would be explained in advance in annual call letters. CMS expects to transition any major changes.

6. *Meaningful Differences in Medicare Advantage Bid Submissions and Bid Review*

- (a) CMS has adopted their proposal to eliminate meaningful difference rules for MA plans (stand-alone PDP plans would still be subject to meaningful difference requirements) intended to increase competition and innovation.
 - CMS notes that current methodology makes it difficult to objectively measure meaningful differences between plans.
 - CMS suggests that current methodology may force MA organizations to design benefit packages to meet CMS standards rather than beneficiary needs.
- (b) CMS will maintain requirements that allow it to discontinue plans that fail to attract sufficient membership over a sustained period and that forbid plans from misleading beneficiaries in their communication materials.
- (c) CMS expects that eliminating the meaningful difference requirement will improve the plan options available for beneficiaries. However, CMS does not believe the number of similar plan options offered by the same MA organization in each county will necessarily increase significantly or create confusion in beneficiary decision-making.
- (d) CMS noted that comments to this proposal were mixed, with many commenters opposed to a complete elimination of meaningful difference requirements. CMS states that they will monitor the impact of meaningful difference elimination to ensure that organizations are not engaging in practices that are discriminatory or that confuse or mislead beneficiaries. Additionally, CMS will work with organizations that offer a large number of apparently similar plans to raise concerns. CMS expects plans within a contract, plan type and county to be distinguishable by beneficiaries.

7. *Coordination of Enrollment and Disenrollment through MA Organizations*

- (a) CMS is establishing limits on default enrollments for "seamless continuation of coverage" and also establishing a simplified opt-in process.
 - Seamless continuation is an optional process (available since 2006, but new applications have been suspended since 2016) where MA plans can establish that an enrollee is automatically enrolled in an MA product offered by the MCO upon initial Medicare eligibility (i.e. age-in, disability) provided the MCO covered the

enrollee in a non-MA product (Commercial, Medicaid) offered by the same parent company.

- (b) Going forward, CMS is permitting default enrollment only for Medicaid managed care enrollees who are newly eligible for Medicare and who are enrolled into a D-SNP or a FIDE-SNP administered by an MA organization (under the same parent organization that operates the Medicaid managed care plan).
- (c) CMS will approve default enrollment for no longer than a 5-year period, but can rescind approval if MAO is non-compliant.
- (d) Conditions for default enrollment:
 - State has approved the default enrollment process and provided eligibility to the MAO.
 - State approval must be prior to any enrollment.
 - Individual is in an affiliated Medicaid managed care plan and is dually eligible.
 - Plan provides required notice to the individual.
 - Individual does not opt out of the default enrollment.
 - The MAO has a star rating of at least 3 stars or is a low enrollment contract or a new MA plan.
 - The MAO does not have any prohibition on new enrollment.
- (e) MA organizations must get approval from CMS before implementing the default enrollment.
- (f) MA organization must issue a notice at least 60 days before the default enrollment effective date to the enrollee.
- (g) CMS is establishing a simplified “opt-in” election process that would be available to all MA organizations (not just those offering D-SNPs) for the MA enrollment of newly-eligible Medicare members for their commercial, Medicaid or other non-Medicare plan members.

8. *Passive Enrollment Flexibilities to Protect Continuity of Integrated Care for Duals*

- (a) CMS is expanding the passive enrollment for FIDE-SNPs and highly integrated D-SNPs (defined in § 422.2 and § 422.102(e)) in instances where integrated care coverage would otherwise be disrupted.
- (b) Adds authority to passively enroll full-benefit duals who are currently enrolled in an integrated D-SNP into another integrated D-SNP under certain circumstances.
- (c) Examples where this rule could apply:
 - Where an MCO loses a Medicaid contract during re-procurement but retains its MA contract, CMS could passively enroll members into a different contract that is integrated across Medicare & Medicaid.
 - If an MAO non-renews its D-SNP (MA) contract, but maintains Medicaid contract with the State, CMS could passively enroll duals into a different integrated MCO.
 - When remaining enrolled in a plan poses potential harm.
- (d) Permitted only when ALL of the following conditions are met by the receiving plan:
 - Must be highly integrated.
 - Must have similar provider networks to promote integrated care and continuity of care.
 - Must have a minimum star rating of at least 3 stars or be a low enrollment or a new MA contract.
 - Must not have any prohibition on new enrollment.

- Must have limited premium and cost-sharing.
- Must agree to receive the enrollments and have operational capacity.
- (e) Passive enrollment also requires either one or two beneficiary notices (depending on type of passive enrollment)
- (f) Passively enrolled individuals will also get a SEP where they can opt out. The SEP has been aligned with the SEP for Medicaid managed care passive enrollment.
- (g) CMS did not implement the cost-effectiveness test for passive enrollment.

9. Part D Tiering Exceptions

- (a) Significant changes in the prescription drug landscape have led to increased use by plan sponsors of two generic-labeled drug tiers and mixed drug tiers that include brand and generic products on the same tiers.
- (b) The Final Rule revises and clarifies requirements for how tiering exceptions are to be adjudicated and effectuated.
- (c) Specifically, CMS eliminated the provision to exclude a dedicated generic tier from the tiering exception process. Plans are permitted to limit tiering exceptions by drug type (e.g. brand or specialty).
- (d) The changes are intended to ensure that eligibility for tiering exceptions is based on the lowest applicable cost sharing for the tier containing the preferred alternative drug(s) for treatment of the enrollee's health condition (as compared to cost sharing for the requested, higher-cost drug).

10. Establishing Limitations for the Part D Special Election Period (SEP) for Duals

- (a) CMS has observed that few duals/LIS enrollees use the special enrollment period.
- (b) CMS believes it may be disadvantageous for dual enrollees to change plans once or multiple times.
- (c) CMS is making the SEP for Full Benefit Dual Eligibles (FBDE) and other subsidy-eligible individuals available only in certain circumstances:
 - Dual and LIS beneficiaries that are not at-risk could use the SEP once per each of the first three calendar quarters. In the last quarter the AEP will be available.
 - A separate SEP will be available to beneficiaries assigned to a plan by CMS or a State.
 - Beneficiaries with a change in Medicaid or LIS status would have a SEP three-month window to make a change.
 - Further detail will be provided in subregulatory guidance.

11. Medicare Advantage and Part D Prescription Drug Plan Quality Rating System

- (a) Introduction. The Final Rule codifies much of the current process for measuring quality of Medicare Advantage Contracts with some changes being finalized as proposed, including:
 - Clearly delineating the rules for adding, updating, and removing measures.
 - Modifying how CMS calculates star ratings for consolidating contracts.
- (b) Background. This section contains the history, the guiding principles, and the proposed rule changes for star ratings.
- (c) Basis, Purpose and Applicability of the MAPD Quality Rating System.
 - The current system and procedures for modifying Star ratings will stay in place for the 2019 and 2020 star ratings. That is, the regulation will be applicable starting with the 2019 measurement period and the associated 2021 star ratings released prior to the 2021 contract year.
 - Clarifies that the 5-star rating system will also apply to Part D Plans.
- (d) Definitions. This section defines terms used throughout the regulation.

- (e) Contract Ratings
 - Data reporting and star ratings currently are done at the contract level except for a few SNP-specific measures. The Final Rule codified this will continue to be the case.
 - Clarified that the CAI and the reward factor are applied in the calculation of the summary rating.
- (f) Contract Consolidations
 - CMS will use enrollment-weighted means of the measure scores of the consumed and surviving contracts to calculate ratings for the first and second plan years following the contract consolidations.
 - This will apply to consolidating plans of the same plan type under the same parent organization.
 - The process of weighting the enrollment of each contract and applying this general rule will vary depending on the specific types of measures involved in order to take into account the measurement period and data collection processes of the measures.
 - See the Final Rule for specific rules on how the measures will be combined for years 0, 1, and 2 following their consolidation.
- (g) Data Sources
 - The Final Rule codifies parallel provisions for the collecting quality data for the Part D program as the MA program.
 - Requires Part D sponsors to participate in collecting, analyzing and reporting data on a timely basis.
- (h) Adding, Updating and Removing Measures
 - Now that the Quality Rating System has become more established, the goal is to lessen the year over year changes in quality measures to allow plans more stability to organize multi-year initiatives.
 - Proposed changes will begin for measure data collected starting in 2019 (impacting payment year 2022).
 - The following process will be followed:
 - a. Substantive changes will need to be made through proposed regulation.
 - b. Non-Substantive changes will be announced through the Advanced Notice and Final Call Letter and feedback will be requested.
 - Measures will be removed if there is either:
 - a. a change in clinical guidelines, indicating the measure is no longer an indicator of plan quality, or
 - b. reliability issues.
 - If a measure is to be added, the following process must be followed:
 - a. CMS will request feedback on potential changes to quality measures via the advance and final Call Letter each year.
 - b. New performance measures will be incorporated into the display page for at least two years before they are built into the Star Rating calculation. This is consistent with current practice but is now required.
- (i) Performance Periods Beginning on or after Jan 1, 2019
 - Removed measures:

- a. Beneficiary Access and Performance Problems-Removed as both a Part C and Part D Measure
- Added measures:
 - a. Statin Therapy for Patients with Cardiovascular Disease (SPC)- Added as a Part C Measure
 - b. Statin Use in Persons with Diabetes (SUPD) - Added as a Part D Measure
- (j) Improvement Measures
 - Based on measures that have:
 - a. numeric value scores in both the current and prior year,
 - b. no substantive specification change during those years, and
 - c. did not have any data that already focused on improvement.
 - Measures included in the improvement measure would be announced annually.
 - Changes were made to the hold harmless provision included to avoid unintended consequences for contracts that score 5 stars on a subset of measures for each of the two years.
 - a. When calculating the Quality Improvement Measure for a contract, CMS looks at the change in measures that have at least two years of data and determines if the change is statistically significant. CMS is implementing a new rule to state that if a contract's measure was 5 stars for both years but the actual measure value dropped significantly, to count this as 0 change as to not punish the high performing contract measure.
 - b. Currently, to determine whether or not the Quality Improvement Measure should be used in the Overall Star Rating for an MA-PD contract, if the contract's star rating without quality improvement is either greater than 4 stars or less than 2 stars, the contract receives whichever rating is greater: their star rating with a quality improvement factor or without.
 - i. The intention of this adjustment is to not punish high performing contracts (those with star ratings of at least 4), for not continuing to improve.
 - ii. An unintended consequence is to also protect low performing contracts (those with star ratings of 2 or less), by giving them whichever of their star ratings is higher.
 - c. CMS is changing their methodology to always use the quality improvement measure for contracts that have star ratings less than 4 stars.
- (k) Data Integrity
 - CMS clarified they will continue their current process of reducing contract stars for instances where data integrity has been incomplete, inaccurate, or biased. Current processes include:
 - a. Reducing HEDIS measures to 1 star if through an audit, the data is deemed "biased" by the auditor.
 - b. Reducing Part C and D Reporting Measures to 1 star when they do not receive at least 95% completeness.
 - CMS has also finalized a third rule introducing a scaled measure level reduction where data completeness issues are identified. If an MAO is deemed to have

- failed to submit data to an Independent Review Entity (IRE), it may be subject to a reduction in the measure level star rating if the following issues are to occur:
- a. Failure to submit at least 20% of potential total cases.
 - b. Failure to submit at least 10 cases in a 3-month period.
- The Star reduction will vary from 1-4 depending on the assumed percent of total cases not submitted.
- (l) Measure-Level Star Ratings
 - Cut points will be determined using either a clustering or a relative distribution and significance testing methodology.
 - Clustering will be used for all measures except CAHPS.
 - (m) Hierarchical Structure of the Ratings
 - Hierarchical structure of measure, domain, Part C summary, Part D summary and overall levels.
 - Measure scores are converted to a 5-star scale ranging from 1 to 5 (5 being the best), with whole star increments for the cut points.
 - Domains will also be a whole star increments.
 - Summary and overall ratings are at half-star increments.
 - (n) Domain Star Ratings
 - Nine domains grouped for display on Medicare Plan Finder -- five for Part C measures for MA-only and MA-PD plans and four for Part D measures for stand-alone PDP and MA-PD plans.
 - (o) Part C and Part D Summary Ratings
 - Reflect weighted mean of the measure-level Star Ratings for Part C and Part D respectively, with an adjustment for rewarding consistent high performance and the application of the CAI.
 - Must have scores for at least 50% of the measures to have a summary rating calculated (not including the improvement measure).
 - (p) Overall Rating
 - Consistent with current practice, the overall rating will be calculated using the weighted mean of Part C and Part D.
 - (q) Measure Weights
 - Improvement gets weight of five.
 - Outcome and intermediated outcome get a weight of three.
 - Patient experience/complaint measures get a weight of two.
 - Access measures receive a weight of two.
 - Process measures receive a weight of one.
 - Following exceptions apply:
 - a. All new measures will have a weight of one.
 - b. Puerto Rico will have zero weight on Part D adherence measures, and a weight of three on adherence for calculating the improvement measure.
 - (r) Application of the Improvement Measure Scores
 - The proposed rule indicated that the improvement measure for plans with summary ratings of 2 stars or less would not be applied. This proposal is not being finalized.
 - All plans, outside of those affected by the hold harmless described above, will have the improvement measure applied.
 - (s) Reward Factor (formerly referred to as integration factor)

- This factor rewards contracts with consistently high performance.
- Final Rule maintains the current application of the reward factor.
- (t) Categorical Adjustment Index
 - CAI was introduced in 2017 Star Ratings as an interim adjustment and will be continued until a long-term solution is found.
 - Only certain measures are included in the CAI adjustment, as identified in the Final Rule.
 - The CAI model for Puerto Rico is different.
- (u) High and Low Performing Icons
 - 5-Star contracts will receive a high-performing icon.
 - Contracts will get a low-performing icon if they have star ratings of 2.5 or lower in all three years of data (current and past two years). Contracts must have a rating in all three years to be considered for the low-performing icon.
- (v) Plan Preview of Star Ratings
 - Plans get preview periods before each Star Rating release.

12. Any *Willing Pharmacy Standards Terms and Conditions and Better Define Pharmacy Types*

- (a) A Part D plan sponsor must contract with any pharmacy that meets the Part D plan sponsor's standard terms and conditions for network participation. Further, a Part D plan sponsor must have a standard contract with reasonable and relevant terms and conditions of participation whereby any willing pharmacy may access the standard contract and participate as a network pharmacy.
- (b) Although Part D sponsors may continue to tailor their standard terms and conditions to various types of pharmacies, Part D plan 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.
 - Clarification is given that to the extent a pharmacy serves multiple roles, that pharmacy may be counted toward multiple access standards.
- (c) CMS revised the definition of retail pharmacy to "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 without being required to receive medical services from a provider or institution affiliated with that pharmacy."
 - CMS did not finalize the proposed definition of mail-order pharmacies.
- (d) While CMS did not finalize specific accreditation standards, they will consider it in the future if they find that their current requirements are no longer sufficient.
- (e) CMS finalized deadlines by which Part D plan sponsors must furnish their standard terms and conditions to requesting pharmacies (within seven business days of request, documents must be ready as of September 15th for succeeding year).

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

- (a) CMS finalized the change that Part D sponsors are now required to provide as a minimum (unless prescriptions are written for fewer days) an approved month's supply for enrollees in both the outpatient and LTC settings.
- (b) However, this transition process is not applicable in cases where a Part D sponsor substitutes a generic drug for a brand name drug.

14. *Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes*

- (a) Under the generic substitution rules that CMS has finalized, beneficiaries will receive advance general notice that certain generic substitutions may occur immediately, as well as direct notice thereafter. In addition, Part D sponsors are required to provide Part D enrollees with at least 30 days' prior notice of other midyear formulary changes.

- (b) CMS finalizes a rule that Part D sponsor may immediately remove a brand name drug if it previously could not have included the brand name drug's therapeutically equivalent generic because the generic drug was not available on the market at the time the Part D sponsor submitted its initial formulary for approval. Further, CMS will require that Part D sponsors add a therapeutically equivalent generic drug to its formulary "on the same or lower cost sharing tier."
- (c) In finalizing the change to the transition requirements, CMS plans to use the term "an approved month's supply" rather than "a month's supply."

15. Treatment of Follow-on Biological Products as Generics for Non-LIS Catastrophic

- (a) CMS did not revise the definition of a generic drug with this Final Rule.
- (b) Instead, CMS will now distinguish biosimilar and interchangeable biological products by applying generic cost-sharing to these drugs for LIS Part D enrollees throughout all phases of the benefit.

16. Eliminating the Requirement to Provide PDP Enhanced Alternative (EA) to EA Plan Offerings with Meaningful Differences

- (a) Effective for Contract Year 2019, CMS will eliminate the PDP EA to EA meaningful difference requirement, while maintaining the requirement that enhanced plans be meaningfully different from the basic plan offered by a plan sponsor in a service area.

17. Request for Information Regarding the Application of Manufacturer Rebates and Rx Price Concessions at the Point of Sale (POS)

- (a) The proposed rule solicited feedback on approaches for applying point of sale rebates and other price concessions.
- (b) No finalized provisions are occurring at this time.
- (c) CMS will review the feedback and any new requirements will be proposed in the future.
- (d) CMS believes that statute provides for allowance of this requirement.

B. Improving the CMS Customer Experience

1. Restoration of the Medicare Advantage Open Enrollment Period

- (a) CMS is establishing the "new Open Enrollment Period" (OEP), per 21st Century Cures Act.
- (b) Beginning in 2019, the "new OEP" will be January 1 through March 31 each year.
- (c) Allows enrollees in an MA plan to make a one-time election to join another MA plan or original Medicare. Part D coverage can change.
- (d) The OEP is also available to newly MA-eligible individuals who enroll in an MA plan.
- (e) Allows:
 - MA-Only to MA-Only
 - MA-Only to MA-PD
 - MA-PD to MA-Only
 - MA-PD to MA-PD
 - MA-Only or MA-PD to Original Medicare without PDP
 - MA-Only or MA-PD to Original Medicare with PDP
 - Switching between PBPs of one organization
- (f) Beneficiaries in original Medicare and Cost plans cannot use the new OEP, regardless of Part D coverage. Also enrollment into a cost plan during OEP is not allowed.
- (g) MA Plans can choose to not accept OEP requests.
- (h) Marketing to MA enrollees is prohibited during the OEP.
- (i) As part of the new OEP, the Medicare Advantage Disenrollment Period (MADP) is eliminated.

- (j) CMS estimates that increasing the amount of time MA enrollees are given to switch plans will lead to slightly more beneficiaries selecting plans that receive Quality Bonus Payments.
2. *Reducing the Burden of the Compliance Program Training Requirements*
 - (a) CMS continues to hear complaints from first-tier downstream and related entities (FDRs) who have not utilized the new compliance training module and CMS has concluded that their standard compliance training module has not fulfilled its intended purpose (i.e. removing the burden on FDRs). Therefore, CMS has finalized its proposal to end their compliance training model for FDRs and hold sponsors accountable for their FDRs' compliance.
 3. *Medicare Advantage Plan Minimum Enrollment Waiver*
 - (a) CMS will review and approve minimum enrollment waivers as part of the initial MA application process rather than reviewing annual requests from MA plans in each of the first three years.
 - (b) Reminder regarding minimum enrollment requirements:
 - MA Organizations in urbanized area: 5,000 members
 - Provider Sponsored Organizations (PSO) in urbanized area: 1,500 members
 - MA Organizations outside urbanized area: 1,500 members
 - PSOs outside urbanized area: 500 members
 4. *Revisions to Timing and Method of Disclosure Requirements*
 - (a) CMS is finalizing its proposal to revise regulations to include language that requires sponsors to provide EOC, provider network information, formulary, pharmacy directory, etc. (information required to be posted on their website) in hard-copy format to enrollees "upon request".
 - (b) CMS will add an additional two weeks to the current deadline for plans to prepare these documents.
 5. *Revisions to Parts 422 and 423, subpart V, Communication/Marketing Materials and Activities*
 - (a) CMS has adopted their proposal to narrow the definition of "Marketing" for purposes of what materials CMS must review. In CMS' view, the term "Marketing" was too broadly defined. CMS has introduced new definitions for "Communications" and "Communication Materials", which include materials which would have previously been considered "Marketing Materials".
 - (b) Communication materials will be subject to less stringent requirements than marketing materials.
 - (c) Items such as membership communication materials, subscriber agreements, member handbooks and wallet card instructions to enrollees will no longer be considered marketing materials, but instead are "member communications".
 - (d) All advertisements – whether in print, on billboards, on television, radio or the internet - remain "marketing" and marketing materials will still need to be submitted to and reviewed by CMS.
 - (e) In general, materials that include information about benefit structure, cost-sharing or ranking standards (like Star Ratings) are considered "Marketing." This excludes post-enrollment materials like EOCs.
 - (f) CMS's definition for "Marketing" includes materials and activities that aim to influence enrollment decisions (for both prospects and current enrollees), as opposed to simply providing information about benefits or the sponsor. This definition is informed by CMS's review of what materials have the greatest opportunity to confuse or mislead beneficiaries.

- (g) CMS prohibits marketing to individuals eligible for the new Open Enrollment Period added by the “21st Century Cures Act”.
- 6. *Lengthening Adjudication Timeframes for Part D Payment Redeterminations and Independent Review Entity (IRE) Reconsiderations*
 - (a) CMS finalized this provision as proposed: to change the timeframe for issuing decisions on payment redeterminations from seven calendar days from the date the plan sponsor receives the request to 14 calendar days.
- 7. *Elimination of Medicare Advantage Plan Notice for Cases Sent to the IRE*
 - (a) Current regulations provide MA enrollees with the right to request reconsideration of a health plan's initial decision to deny Medicare coverage. When the MA plan upholds initial payment or service denials, in whole or in part, it must forward the member's case files to an Independent Review Entity (IRE).
 - (b) CMS has finalized its proposal that the IRE would be responsible for notifying enrollees upon forwarding all cases - including both standard and expedited cases.
 - (c) CMS has finalized the proposed changes that would result in a slight reduction of burden to Part C plans by no longer requiring a Notice of Appeal Status for each case file forwarded to the IRE.
- 8. *E-Prescribing and the Part D Prescription Drug Program; Updating Part D E-Prescribing Standards*
 - (a) CMS is adopting the NCPDP SCRPT Standard, Version 2017071 beginning on January 1, 2020.
 - (b) However, CMS is conditioning the effective date of adoption of the proposal on corresponding regulatory action being taken to update the Health IT Certification Criteria.
- 9. *Reduction of Past Performance Review Period for Applications Submitted by Current*
 - (a) In April 2010, CMS clarified their authority to deny contract qualification applications from organizations that have failed to comply with the requirements of a Medicare Advantage or Part D plan sponsor contract they currently hold.
 - (b) CMS has a policy to review the applicant's previous 14 months' performance when considering approval of the contract's application. CMS is finalizing its proposal to change the prior review period from 14 months to 12 months.
- 10. *Preclusion List Requirements for Prescribers in Part D and Individuals and Entities in MA, Cost Plans, and PACE*
 - (a) Currently, physicians must enroll in or validly opt-out of Medicare in order for a drug that they prescribe to be covered.
 - (b) In order to reduce the burden for providers without compromising the payment safeguard, CMS will focus on preventing payment for Part D drugs prescribed by demonstrably problematic prescribers by creating a preclusion list.
 - (c) Plans are required to deny payments for claims submitted by prescribers on the list.
 - (d) These problematic prescribers will be defined as those who have engaged in behavior for which CMS:
 - has revoked their enrollment, or
 - could have revoked their enrollment if he or she had been enrolled in Medicare.
 - (e) Part D plan sponsors must reject a pharmacy claim for a Part D drug prescribed by an individual on the preclusion list.
 - (f) The preclusion list would be updated on a monthly basis.
 - (g) CMS will eliminate the current "enrollment" required for MA providers and suppliers.

- This is intended to minimize the burden on MA providers and suppliers while allowing CMS to concentrate their efforts on preventing MA payments to providers and suppliers that pose an "elevated risk".
- (h) CMS will focus on individuals and entities that are currently revoked from Medicare (or would be if they participated) as described in prior section.
- (i) Consistent with Part D, MAOs are required to deny payments for claims submitted by prescribers on the list.
- (j) The preclusion list will be shared between Parts C and D to reduce administrative burden.
- (k) As part of the preclusion rule, CMS will amend existing data submission requirements for risk adjustment to require MA organizations to include provider NPIs as part of encounter data submissions. This is because CMS intends to use the NPI data to identify individuals and entities that may be included on the preclusion list.

11. *Removal of Quality Improvement Project for Medicare Advantage*

- (a) In the years following the 2003 Medicare Modernization and Improvement Act, CMS created and refined requirements for all Medicare Advantage Organizations to have defined Quality Improvement Programs and Chronic Care Improvement Programs. CMS suggests that these strict requirements and data reporting requirements have created duplicative efforts for MAOs that were already performing their own quality improvement either for general care management or for the benefit of Quality Star Ratings.
- (b) Because of this, CMS has removed some QIP and CCIP requirements and related reporting requirements as they have found they do not add significant value.
- (c) Remaining Quality Improvement and Chronic Care Improvement requirements should ensure no reduction in the quality of care patients receive, but this change should at least lessen the reporting burden MAOs and CMS face.

12. *Reducing Provider Burden*

- (a) In the proposed rule, CMS solicited comments from providers regarding the burden to comply with medical records documentation required under current law. CMS is particularly interested in the burden experience by solo providers and in relation to risk adjustment audits.
- (b) No finalized provisions are occurring at this time.
- (c) CMS will review the information received.

C. *Implementing Other Changes*

1. *Reducing the Burden of the Medicare Part C and Part D Medical Loss Ratio Requirements*

- (a) CMS is changing the MLR Quality Improvement Activity (QIA) reporting requirements.
- (b) CMS is hoping that these changes will encourage plans to invest more in fraud prevention activities and Medication Therapy Management (MTM) programs.
- (c) CMS's ultimate goal is to reduce trust fund expenditures and permit lower member premiums or additional supplemental benefits to beneficiaries by reducing claims expenses through fraud reduction or improved medication compliance.
 - Fraud Prevention Expenses – CMS will
 - a. remove the current exclusion of fraud prevention activities from Quality Improvement Activities (QIA),
 - b. expand the definition of QIA to include all fraud reduction activities, including fraud prevention, fraud detection, and fraud recovery, and
 - c. exclude the amount of claims payments recovered through fraud reduction efforts up to the amount of fraud reduction expenses in incurred claims.

- (d) MTM Expenses – CMS will include all Medication Therapy Management (MTM) programs that are offered by Part D sponsors (including MA-PD sponsors) as QIA in the MLR calculation.
 - (e) Reduced Reporting Requirements - to reduce the complexity of reporting and reduce administrative costs both for the MAO and for CMS, Medicare MLR reporting requirements will be reduced to include only the following fields:
 - Organization Name
 - Contract Number
 - Adjusted MLR (which would be populated with Not Applicable or N/A for non-credible contracts)
 - Remittance Amount
 - (f) CMS is not proposing to change its authority to conduct selected audit reviews of the reported data and the accuracy of calculations.
2. *Medicare Advantage Contract Provisions*
- (a) Minor regulation wording changes to correct for inconsistencies within the regulations. All proposed changes have been finalized.
3. *Late Contract Non-Renewal*
- (a) Current regulations state that contract non-renewals effective at the end of the one-year contract term must be submitted to CMS in writing by the first Monday in June.
 - (b) CMS has finalized its proposal to clarify its operational policy that any request to terminate a contract after the first Monday in June is considered a request for termination by mutual consent.
4. *Contract Request for a Hearing*
- (a) There is an inconsistency in regulations regarding the date by which an MA organization must receive a decision from CMS on an appeal (September 1 vs. July 15th). The regulations have been revised to specify September 1st is the correct date.
5. *Physician Incentive Plans - Update Stop-Loss Protection Requirements*
- (a) Current regulations state that MA organizations must provide adequate and appropriate stop-loss insurance to all physicians or physician groups that are at substantial financial risk under the MA organization's physician incentive plan (PIP).
 - (b) Under the current regulation, an MA organization that operates a PIP must provide stop loss protection for 90 percent of actual costs of referral services that exceed the per-patient deductible limit to all physicians and physician groups at financial risk under the PIP. The stop loss protection may be per patient or aggregate.
 - (c) Proposed and finalized provisions are as follows:
 - CMS proposed to update the stop-loss deductible limits and codify the methodology used to update the stop-loss deductible limits in the future to account for changes in medical cost and utilization. This change has been finalized substantially as proposed, with modifications to adapt definitions to streamline regulation text. See the Final Rule for additional details. Page 873 includes a summary of the finalized changes.
 - CMS proposed to authorize MA organizations to use actuarially equivalent arrangements to protect against substantial financial loss under the PIP due to the risks associated with serving particular groups of patients. This change has been finalized substantially as proposed, with revisions to correct grammatical errors and to refer to the defined tables as appropriate.

- CMS proposed allowing non-risk patient equivalents (NPEs), such as Medicare Fee-For-Service patients (FFS) who obtain some services from the physician or physician group, to be included in the number of patients when determining the required stop-loss. This change has been finalized to permit the use of non-risk patient panel size in identifying the required stop-loss protection.
 - (d) CMS sought comment on whether the definitions of "substantial financial risk" and "risk threshold" contained in the current regulation should be revisited, including whether the current identification of 25 percent of potential payments remains appropriate as the standard in light of changes in medical costs. CMS is not finalizing any changes to the definition at this time.
 - (e) For physician groups who assume risk through capitation, CMS finalized replacing the current insurance schedule in the regulation with updated stop-loss insurance requirements that would allow insurance with higher deductibles. The new schedule will result in a significant reduction to the cost of obtaining stop-loss insurance.
6. *Changes to the Agent/Broker Compensation Requirements*
- (a) CMS finalized a minor update to remove regulatory language that is no longer relevant after a 2014 rule update to agent/broker compensation requirements.
 - (b) Since a 2014 rule update, agent/broker compensation rates for renewal enrollments have been tied to fair market value versus the prior (pre-2014) rule which tied renewal compensation to a percentage of initial enrollment compensation rates.
 - (c) The language removed refers to the payment associated with initial enrollment, which is no longer relevant (and has created confusion among plan staff and brokers).
7. *Changes to the Agent/Broker Requirements*
- (a) CMS has finalized its proposal to eliminate provisions that limit what MA organizations and Part D sponsors can do when they have discovered that a previously licensed agent/broker has become unlicensed.
8. *Codification of Certain Medicare Premium Adjustments as Initial Determinations*
- (a) CMS has finalized its proposal to change the current regulations regarding premium adjustments. This change codifies existing processes related to premium adjustments, and does not alter existing processes or procedures
 - (b) It applies only to Part A and Part B late enrollment and reenrollment penalties.
9. *Eliminate Use of the Term "Non-renewal" to Refer to a CMS-Initiated Termination*
- (a) CMS has finalized its proposal to add provisions to require that enrollees receive notice no later than 90 days prior to the December 31 effective date of a contract termination when CMS makes such determination on or before August 1 of the same year.
 - (b) CMS also made changes to grammatical errors and inconsistent language.

Please contact Julia Lambert at julia@wakely.com or your Wakely client manager with any questions or comments. Thank you to the following Wakely consultants who contributed to the development of this summary document: Nate Baehr, Dani Beierle, Brad Davis, Tim Courtney, Bob Moné, Tim Murray, Dave Neiman, and Kelsey Stevens.