

CLIENT ALERT

CMS's Proposed Rule for Contract Year 2019 Is a Mixed Bag for Medicare Advantage Organizations and Prescription Drug Plan Sponsors

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On November 28, 2017, CMS issued a [notice of a proposed rulemaking](#) for contract year 2019 policy and technical changes for the Medicare Advantage and Medicare Prescription Drug Programs. The major provisions of the Proposed Rule address implementation of the Comprehensive Addiction and Recovery Act of 2016 to combat the opioid epidemic, updating Part D E-prescribing standards, revisions to disclosure requirements, and the development of a preclusion list for providers. Additionally, the Proposed Rule modifies the medical loss ratio (MLR) requirement to allow Medicare Advantage organizations (MAOs) and Part D Plan (PDP) sponsors to include the full value of fraud reduction expenses, fraud prevention activities and medication therapy management programs as quality improvement activities in the numerator of the MLR. The Proposed Rule also simplifies the MLR reporting obligation for MAOs and PDP sponsors. CMS characterizes many of the proposed changes as implementation of [President Trump's Inauguration Day Executive Order](#) directing agencies to alleviate regulatory burdens and costs imposed by the Affordable Care Act. Comments on the Proposed Rule, summarized below, are due January 16, 2018.

Table of Contents

- [II.A. Supporting Innovative Approaches to Improving Quality, Accessibility, and Affordability](#)
- [B. Improving the CMS Customer Experience](#)
- [C. Implementing Other Changes](#)

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

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

The Proposed Rule describes CMS's plans for implementing section 704 of the Comprehensive Addiction and Recovery Act of 2016. Section 704, which amends Section 1860D-4(c) of the Social Security Act (the Act), provides CMS with new authority to establish a voluntary drug utilization management (DUM) program targeted to beneficiaries "at risk for prescription drug abuse or misuse" for standalone PDP sponsors and Medicare Advantage Prescription Drug (MA-PD) plans effective January 1, 2019. This authority allows CMS to define processes for PDP sponsors and MA-PD plans for identifying and communicating with providers and beneficiaries engaged in high-risk drug prescribing and utilization practices, respectively; to provide and monitor care management; and to implement "lock-in" programs that limit beneficiaries to obtaining drugs from specific pharmacies or prescribers.

The Precedent Behind the "New" Provisions, With New Policy Drivers

Not surprisingly, CMS's release of the Proposed Rule's voluntary DUM provisions aligns with the attention that the

Trump Administration has dedicated to addressing the opioid crisis and the October 26, 2017 [declaration](#) by the HHS Acting Secretary that the opioid crisis is a “nationwide Public Health Emergency.” But PDP sponsors and MA-PD plans will quickly see that the proposed regulations largely codify already existing DUM program policy established through guidance related to the [Part D Opioid Drug Utilization Review \(DUR\) Policy and Overutilization Monitoring System \(OMS\)](#) first announced in the [April 2012 Final Call Letter](#), formally established in July 2013, then updated in subsequent years (defined as the “current policy” in the Proposed Rule).

Under the current policy, PDP sponsors were expected to implement the following medication safety-focused approach regarding beneficiaries’ potential misuse and abuse of opioids:

- appropriate plan-level claim controls at point-of-sale (POS);
- identification of beneficiaries at high risk for opioid-related adverse events through retrospective drug utilization reviews; and
- case management with prescribers to identified beneficiaries followed by beneficiary-specific POS edits to prevent Part D coverage of opioid overutilization.

CMS proposes to add the voluntary DUM program definitions and required processes to existing regulations at 42 CFR §§ 423.100, 423.153, and 423.38. Overall, these provisions follow the detailed framework provided at new section 1850D-4(c)(5) of the Act to provide additional layers of due process for PDP sponsors and MA-PD plans to adhere to when running their opioid-related DUMs, but provide less discretion to PDP sponsors and MA-PD plans to implement their own internal processes to identify drugs and beneficiaries as candidates for DUM.

New Definitions and Processes for Voluntary DUM Programs Focused on Opioids

Key definitions include the “clinical guidelines” PDP sponsors and MA-PD plans must use to determine who are “at-risk beneficiaries;” what “frequently abused drugs” are; and “exempted beneficiaries” whom PDP sponsors and MA-PD plans would not need to account for in implementing their DUM programs (*e.g.*, hospice or cancer patients, or residents of a facility that receives drugs through single-pharmacy contracts).

“Frequently abused drugs” currently only include opioids, but the proposed provisions would allow for the HHS Secretary to add other drugs to this category based on schedule designation by the Drug Enforcement Administration, government or professional guidelines that describe a drug as frequently abused or misused, and other analyses of Medicare drug utilization or scientific data. CMS anticipates publishing updates to the list of “frequently abused drugs” in annual Call Letters or other guidance subject to public comment. For 2019, CMS proposes the following “clinical guidelines” to identify “at-risk beneficiaries:”

- average daily use of opioids greater than or equal to of 90 mg (morphine milligram equivalent units) for any duration in the most recent six months; and
- either:
 - four or more opioid prescribers and four or more dispensing pharmacies; or
 - six or more opioid prescribers, regardless of the number of opioid dispensing pharmacies.

Of note, “prescribers associated with the same single Tax Identification Number” would be counted as a single prescriber, and pharmacies with multiple locations that “share real-time electronic data” would be collectively treated as one pharmacy (e.g., chain pharmacy locations).

The voluntary DUM program procedure-related provisions in the Proposed Rule (which would be codified at § 423.153(f)) require PDP sponsors and MA-PD plans to document programs in written policies and procedures approved by their Pharmacy & Therapeutics (P&T) Committees that meet CMS’s standards for retroactively identifying at-risk beneficiaries and for case management in collaboration with prescribers. These procedure-related regulatory proposals also set forth specific notice and appeal requirements that PDP sponsors and MA-PD plans must implement when contacting prescribers for at-risk beneficiaries to pursue case management, and when communicating at-risk determinations to the beneficiaries themselves.

CMS plans to develop language for PDP sponsors and MA-PD plans to use for initial notices sent to beneficiaries under the CARA-authorized voluntary DUM programs. In these notices, potential at-risk beneficiaries would first receive information about: (1) why they were identified as such; (2) the availability of and how to access state and federal public health resources aimed at addressing prescription drug abuse; (3) their ability to submit additional information to the PDP sponsor or MA-PD plan to inform the final determination and provide their choices of prescribers or pharmacies if the beneficiary becomes the subject of “lock-in” limitations; and (4) the “meaning and consequences of being identified as an at-risk beneficiary.” One such consequence other than the imposition of “lock-in” limitations is that individuals are restricted from switching plans through certain special enrollment periods (SEPs) because of being identified as a potential at-risk beneficiary.¹

Even where a beneficiary can switch plans, the determination as a potential at-risk beneficiary (or as an at-risk beneficiary) may follow them, so the PDP sponsor or MA-PD plan may rely on those determinations for their own proprietary DUM programs, if they implement one. This continuity also allows efficiency for data sharing purposes and for advancing the voluntary DUM program through the case management phase through lock-in limitation, beneficiary-specific POS edits, or, ideally, the successful reduction or elimination of the identified drug misuse and abuse. PDP sponsors and MA-PD plans would still have to ensure that at-risk beneficiaries maintain reasonable access to frequently abused drugs where beneficiary-specific claim edits or “lock-in” limitations imposed, which would account for the geographic location and proximity, beneficiary preference, or the beneficiary’s “predominant usage” of a prescriber, pharmacy, or both.

The regulations then require a second notice to the at-risk beneficiaries (as well as to their prescribers through reasonable efforts) to inform them of the PDP sponsor or MA-PD plan’s determination regarding at-risk status, any limitations imposed due to that determination, and the beneficiaries’ rights to seek a redetermination by the PDP sponsor or MA-PD plan. The fulfillment of the two-step notice requirement, except under limited circumstances where an identified at-risk beneficiary switches plans, is a prerequisite to the PDP sponsor or MA-PD plan implementing “lock-in” restrictions against a beneficiary to certain prescribers or pharmacies. Furthermore, the proposed regulations would require the PDP sponsors and MA-PD plans to obtain the prescribers’ agreement to such limitations as well. Any

restrictions imposed by a PDP sponsor or MA-PD plan would be limited to a 12-month period or the demonstration by the beneficiary that he or she is no longer an at-risk beneficiary.

The Proposed Rule's preamble discusses how it takes six months of data to even identify beneficiaries as "potentially at-risk", and that it takes three to six months on average to pursue case management. Furthermore, the beneficiary notice requirements impose timing requirements ranging from 30 to 90 days. As a result, there is a long lead time to the imposition of restrictions on beneficiaries identified as at-risk. The Proposed Rule does not specifically address how CMS would handle the identification of problem prescribers and pharmacies, but the provisions at § 423.153(f)(9) allow a PDP sponsor or MA-PD plan to "override" the beneficiary's choice of prescriber or pharmacy if there is strong evidence of inappropriate action by the prescriber, pharmacy, or beneficiary such that using the beneficiary's preferred prescriber or pharmacy would "contribute to prescription drug abuse or drug diversion by the beneficiary." Presumably, the CARA provisions that expanded the activities of Medicare Drug Integrity Contractors and other fraud prevention-related sections provide additional ways that CMS intends to address problem prescribers and pharmacies.

Areas for Stakeholder Comment

Ultimately, the purpose of these voluntary DUM provisions is to identify at-risk beneficiaries who may be receiving unsafe doses of opioids from multiple prescribers and/or pharmacies, then require the PDP sponsors and MA-PD plans to engage directly with prescribers to reduce abuse and misuse of the drugs at issue. Among other topics, CMS is specifically seeking comment on the following aspects of the CARA-related regulations as proposed:

- whether CMS should incorporate or codify additional features of the current policy;
- whether CMS should allow PDP sponsors and MA-PD plans to continue implementing the current policy for non-opioid medications (e.g., claim edits);
- on the alternative clinical guidelines proposed in the Regulatory Impact Analysis section of the Proposed Rule and other proposals that may increase or decrease the number of identified at-risk beneficiaries;
- whether additional categories of beneficiaries should be exempted from the voluntary DUM provisions (e.g., those receiving palliative or end-of-life care or recipients of medication-assisted treatment for substance abuse disorders);
- whether prescriber agreement should be required prior to implementing pharmacy lock-in limitations; and
- whether the six-month waiting period required to precede any imposition of limitations on an at-risk beneficiary would reduce provider burden sufficiently to outweigh the additional case management, clinical contact and prescriber verification that providers may experience if a sponsor believes a beneficiary's access to coverage should be limited.

CMS is counting on the success of the existing OMS program to continue through the implementation of the CARA-related regulations. The agency estimates that the implementation of the new provisions will result in \$13 million in net savings in 2019 due to reduced unnecessary opioid prescriptions, with an anticipated increase of these annual savings to about \$14 million in 2023. CMS expects that the implementation of the process enumerated in the new provisions will cost PDP sponsors and MA-PD plans approximately \$2.8 million per year. However, CMS did not provide a dollar estimate associated with the general "benefits of preventing opioid dependency in beneficiaries," and the DUM program as proposed is merely voluntary. The Proposed Rule essentially nullifies current policy, so unless PDP sponsor and MA-

PD plan participation in the new, more prescriptive regulatory framework would be on par with what occurs under current policy, the estimated benefits might be overstated. The Government Accountability Office has already been tasked with assessing the effectiveness of the at-risk beneficiaries for prescription drug abuse drug management programs authorized by section 1860D-4(c)(5), but the report will not be due to Congress until July 2019, after the voluntary DUM program is implemented.

2. Flexibility in the Medicare Advantage Uniformity Requirements

The Proposed Rule reflects a change in CMS's interpretation of the uniformity requirements related to Part C benefits. Previously, CMS required MA plans to offer all enrollees access to the same benefits at the same level of cost sharing. Under the new interpretation, CMS will permit MA organizations the ability to reduce cost sharing for certain covered benefits, offer specific tailored supplemental benefits, and offer lower deductibles for beneficiaries who meet specific medical criteria.

CMS cautioned that as MAOs consider this new flexibility they must still ensure compliance with non-discrimination rules. CMS will be concerned about potential discrimination if an MA plan is targeting cost sharing reductions and supplemental benefits for a large number of disease conditions while excluding other higher-cost conditions. MA plans must use medical criteria that are objective and measurable, and enrollees must be diagnosed by a plan provider or have their existing diagnosis certified by a plan provider.

CMS is considering whether to issue further clarification regarding this new flexibility.

3. Segment Benefits Flexibility

Previously, CMS allowed MA plans to vary premium and cost sharing by each segment of an MA plan. Segments are county-level portions of a plan's overall service area. Under the Proposed Rule, MA plans could vary supplemental benefits, in addition to premium and cost sharing, by each segment of an MA plan. The benefits, premium, and cost sharing would still have to be uniform within each segment of an MA plan's service area.

4. Maximum Out-of-Pocket Limit for Medicare Parts A and B Services (§§ 422.100 and 422.101)

Currently, MA plans must establish limits on enrollee out-of-pocket cost sharing for Parts A and B services that do not exceed the annual limits CMS establishes. All cost sharing (deductibles, coinsurance, and copayments) for Parts A and B services, excluding plan premium, must be included in each plan's Maximum Out-of-Pocket (MOOP) amount. CMS affords greater flexibility in establishing Parts A and B cost sharing to MA plans that adopt a lower, voluntary MOOP limit than to plans that adopt the higher, mandatory MOOP limit. Still, the percentage of eligible Medicare beneficiaries with access to an MA plan offering a voluntary MOOP limit decreased from 97.7% in 2011 to 68.1% in 2017.

CMS's goal is to establish future MOOP limits based on the most relevant and available data that reflects beneficiary health care costs in the MA program and maintains benefit stability over time. Currently, Medicare Fee-for-Service (FFS)

data is the most relevant and available data. Under CMS's current methodology to set MOOP limits, it uses the 85th and 95th percentiles of projected beneficiary out-of-pocket Medicare FFS spending.

While CMS intends to continue using this methodology to set MA MOOP limits for the immediate future, CMS proposes to amend the regulation to incorporate authority for CMS to balance other factors. These factors include:

- increasing the voluntary MOOP limit;
- increasing the number of service categories that have higher cost sharing in return for plans offering a lower MOOP limit;
- additional levels of MOOP limits; and
- modifying cost sharing to encourage plan offerings with lower MOOP limits.

Prior to bid submission, CMS will continue to publish annual limits and a description of how the methodology was used in the annual Call Letter. This will allow MAOs to comment and prepare for changes.

5. Cost Sharing Limits for Medicare Parts A and B Services (§§ 417.454 and 422.100)

CMS determines on an annual basis the level at which certain cost sharing for Parts A and B services becomes discriminatory under § 422.100(f)(6). CMS identifies the presumptively discriminatory level by using FFS data to analyze parameters of Parts A and B services that are more likely to have a discriminatory impact on beneficiaries. The Proposed Rule would amend § 422.100(f)(6) to clarify that CMS may use Medicare FFS data to establish non-discriminatory cost sharing limits.

CMS also intends to use MA encounter data to inform patient utilization scenarios in its setting of presumptively discriminatory levels of cost sharing. CMS is soliciting comment on whether to codify the use of MA encounter data in this analysis.

CMS notes that the change would permit CMS to use the most "relevant and appropriate" information in determining cost sharing thresholds.

6. Meaningful Differences in Medicare Advantage Bid Submissions and Bid Review (§§422.254 and 422.256)

Currently, CMS will only approve a bid submitted by an MAO if its plan benefit package is substantially different than those of other plans offered by the MAO in the same service area based on CMS's meaningful difference evaluation standards. CMS proposes to eliminate this meaningful difference requirement.

CMS is concerned that the current meaningful difference methodology forces MAOs to design benefit packages to meet CMS standards rather than beneficiary needs. For example, MAOs may have to change benefit coverage or cost sharing in certain plans to satisfy the meaningful difference requirement, even if substantial difference exists based on factors CMS does not incorporate into the evaluation (such as tiered cost sharing and unique benefit packages based on enrollee health conditions).

By removing the meaningful difference requirement, CMS seeks to promote innovative benefit designs that address beneficiary needs and affordability. CMS does not anticipate an increase in the number of similar plan options offered by the same MAO or increased confusion in beneficiary decision-making as a result of this change.

7. Coordination of Enrollment and Disenrollment Through MA Organizations and Effective Dates of Coverage and Change of Coverage (§§ 422.66 and 422.68)

CMS proposes to establish limits and requirements for default enrollments into MA plans by individuals currently enrolled in a non-MA plan offered by an MAO at the time he or she becomes eligible for Medicare. Specifically, the Proposed Rule seeks to limit default enrollments to enrollment into dual eligible special needs plans (D-SNPs) and subject them to 5 substantive conditions:

- The individual is enrolled in an affiliated Medicaid managed care plan and is dually eligible for Medicare and Medicaid;
- The state has approved the use of the default enrollment processes and has provided Medicare eligibility information to the MAO;
- The individual does not opt out of the default enrollment;
- The MAO provides notice to the individual that meets certain CMS requirements; and
- CMS has approved the MAO to use the default enrollment process.

CMS seeks to limit default enrollment, in part, due to the statutory requirement that CMS remove SSNs from all Medicare cards by April 2019. With this new requirement, MAOs will be limited in their ability to enroll newly eligible Medicare beneficiaries without their Medicare numbers. Organizations operating Medicaid managed care plans have better access to member data through the state, including the individual's Medicare number.

With respect to CMS's approval of MA plans' default enrollment, CMS requests comment regarding whether to place a time limit on the approval (*e.g.*, two to five years), such that CMS would have to routinely re-evaluate the processes used by an MA organization in order to ensure compliance with the regulation.

CMS also seeks to permit a simplified election process for individuals who are electing coverage in an MA plan offered by the same entity as the individual's non-Medicare coverage. This new mechanism would allow for a less burdensome process for MAOs to offer enrollment in their MA plans to their non-Medicare members who are newly eligible for Medicare.

8. Passive Enrollment Flexibilities to Protect Continuity of Integrated Care for Dually Eligible Beneficiaries. (§ 422.60(g)).

CMS proposes to expand its regulatory authority to initiate passive enrollment for certain dually eligible beneficiaries in an effort to protect the continuity of integrated care for dually eligible beneficiaries. Integrated care provides dually eligible beneficiaries with the full array of Medicaid and Medicare benefits for which they are eligible through a single delivery system.

The current regulation at § 422.60 limits the use of passive enrollment to two situations: (1) where there is an immediate termination of an MA contract; and (2) when CMS determines that remaining enrolled in a plan poses potential harm to beneficiaries. CMS proposes to add authority to passively enroll full-benefit dually eligible beneficiaries who are currently enrolled in an integrated D-SNP into another integrated D-SNP under the following conditions:

- When necessary to promote integrated care and continuity of care;
- Where such action is taken in consultation with the state Medicaid agency;
- Where the D-SNP receiving passive enrollment contracts with the state Medicaid agency to provide Medicaid services; and
- Where certain other conditions are met to promote continuity and quality of care.

The Proposed Rule includes use of the existing notification and opt-out procedures and special election period under the current passive enrollment authority. It also would require that, in order to receive passive enrollments, the D-SNP must meet minimum quality standards based on MA Star Ratings. CMS's goal with this proposed requirement is to ensure that D-SNPs receiving passive enrollments provide high quality care, coverage, and administration of benefits.

9. **Part D Tiering Exceptions (§§ 423.560, 423.578(a) and (c)).**

Enrollees in a Part D plan with a tiered formulary can request an exception to higher copays or cost sharing associated with drugs in a higher tier if that drug is determined by the plan to be medically necessary. Plans are required to establish a process to evaluate such requests. This process has generally permitted plans to exclude generic and specialty tiers from the exceptions process.

CMS proposes to change the exceptions process to make it more congruent with the increasing complexity of tiered formularies. The preamble noted that nearly all plans now have five or six tiers, including two generic-labeled tiers, which might also include brand name drugs. Because a plan sponsor can currently exempt any dedicated generic tier from its tiering exceptions procedures, according to CMS, almost two-thirds of all tiered PBPs could exempt three of their five or six tiers from tiering exceptions without any consideration of medical need or placement of preferred alternative drugs.

The proposed revisions would establish rules that base eligibility for tiering exceptions on the lowest applicable cost sharing for the tier containing the preferred alternative drug for treatment of the enrollee's health condition in relation to the cost sharing of the requested, higher-cost drug, and not based on tier labels, such as preferred, non-preferred, brand or generic.

CMS proposes to revise § 423.578(a)(6) to specify that a Part D plan sponsor could refuse to offer a tiering exception for a brand name drug to a preferred cost-sharing level that applies only to generic alternatives. Plans would be required to approve tiering exceptions for non-preferred generic drugs when the plan determines that the enrollee cannot take the preferred generic alternative, regardless whether the lower tier includes only generic or a mix of generic and brand alternatives.

CMS also proposes at § 423.578(a)(6) to establish specific tiering exceptions policy for biological products. “If a Part D plan sponsor maintains a specialty tier . . . the sponsor may design its exception process so that Part D drugs and biological products on the specialty tier are not eligible for a tiering exception.” However, while plans can limit tiering exceptions for drugs on the specialty tier to a more preferable cost sharing tier, the specialty tier is not exempt from being considered a preferred tier for purposes of tiering exceptions, if the specialty drug has more favorable cost sharing compared to alternatives.

CMS also proposes to allow plans to limit the availability of tiering exceptions for the following drug types to a preferred tier that contains the same type of alternative drug(s) for treating the enrollee’s condition:

- Brand name drugs for which an application is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)), including an application referred to in section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(2)); and
- Biological products, including follow-on biologics, licensed under section 351 the Public Health Service Act.

Likewise, CMS would codify at § 423.578(a)(6)(i) that plans are not required to offer tiering exceptions for brand name drugs or biological products at the cost-sharing level of alternative drugs for treating the enrollee’s condition, where the alternatives include only the following drug types:

- Generic drugs for which an application is approved under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)), or
- Authorized generic drugs as defined in section 505(t)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(t)(3)).

Finally, CMS intends to codify current policy that cost sharing for an approved tiering exception request is assigned at the lowest applicable tier when preferred alternatives sit on multiple lower tiers. Under this proposal, assignment of cost sharing for an approved tiering exception must be at the most favorable cost-sharing tier containing alternative drugs, unless such alternative drugs are not applicable pursuant to limitations set forth under proposed § 423.578(a)(6).

10. Establishing Limitations for the Part D Special Election Period (SEP) for Dually Eligible Beneficiaries (§423.38)

Currently, all subsidy-eligible beneficiaries—such as full-benefit dual eligible (FDBE) and low-income subsidy (LIS) beneficiaries—are permitted to make Part D enrollment changes at any time during the year via a continuous SEP. CMS is required, under the MMA, to enroll FDBE beneficiaries into a PDP if they do not enroll in a Part D Plan. The SEP was intended to provide beneficiaries the opportunity to select a different Part D Plan if they so choose, without having to wait for the annual election process.

Now, having reviewed more than a decade of plan experience and trends, CMS is proposing to limit the SEP as follows:

- Dual or other LIS-eligible beneficiaries who also meet the newly proposed definition of an at-risk beneficiary or potentially at-risk beneficiary in § 423.100, could use the SEP once per year;

- Dual or other LIS-eligible beneficiaries who have been assigned to a plan by CMS or a state could use the SEP either before the assignment is effective or within two months of their enrollment in the assigned plan; and
- Dual or other LIS-eligible beneficiaries who have a change in their Medicaid or LIS-eligible status could use the SEP the later of two months within the change in status or two months within their notice of the change.

CMS proposes that these SEP would be considered separate and unique from one another such that an eligible beneficiary could make use of multiple SEPs depending on the circumstances. The SEP otherwise would be limited to one use per year.

CMS has invited comment on this proposal as well as two alternative proposals that it has considered. First, CMS considered applying a simple numerical limit of two or three uses of the SEP per year. Second, CMS considered limiting the use of the SEP by prohibiting its use to elect a non-integrated MA-PD plan but permit continuous use of the SEP to allow eligible beneficiaries to enroll in FIDE SNPs or comparably integrated plans such as model tests under Section 1115(A).

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

CMS proposes to codify the existing Star Ratings System for the MA and Part D programs with some changes including more clearly delineating the rules for adding, updating, and removing measures and modifying how CMS calculates Star Ratings for contracts that consolidate. The proposed changes would be effective for the 2019 measurement period and 2022 quality bonus payments (QBPs). Despite codifying the Star Ratings System, CMS would continue to publish the Technical Notes during the plan preview periods as well as use the draft and final Call Letters to provide subregulatory application, interpretation and guidance.

The lengthy preamble identifies areas for possible future change on which CMS solicits comments as well as summarizes proposed changes including:

- Contract Ratings. CMS proposes codifying the current practice of calculating Star Ratings at the contract level and all PBPs under the contract would have the same overall and/or summary ratings. CMS notes that it has considered whether data should be collected and measures scored at the plan level, and has explored the feasibility of separately reporting quality data for individual D-SNP PBPs, instead of the current reporting level. CMS solicits comments on balancing the improved precision associated with plan level reporting (relative to contract level reporting) with the negative consequences associated with an increase in the number of plans without adequate sample sizes for at least some measures. CMS seeks comments about this for D-SNPs and for all plans. Comments and suggestions are also sought on requiring reporting at different levels (for example, parent organization, contract, plan, or geographic area) by measure.
- Contract Consolidations. CMS proposes to change its current practice of assigning the Star Rating of the surviving the contract in the event of a contract consolidation. Under the Proposed Rule, CMS would assign and display Star Ratings based on the enrollment-weighted mean of the measure scores of the surviving and consumed contracts so that the Star Ratings reflect the performance of all contracts involved in the consolidation. The calculation of the

measure, domain, summary, and overall ratings would be based on these enrollment-weighted mean scores.

CMS would use enrollment-weighted means of the measure scores of the consumed and surviving contracts to calculate ratings for the first and second years following contract consolidation. The process of weighting the enrollment of each contract and applying the proposed approach would vary depending on the specific types of measures involved. In the third year and subsequent years after consolidation, the performance period for all measures would be after the contracts were consolidated so the proposal would not be applicable.

CMS would also treat ratings for determining QBP status differently than displayed Star Ratings for the first year following a consolidation involving the same parent organization and plans of the same type. In these situations, CMS would calculate the QBP rating for the first year following consolidation using the enrollment-weighted mean, using traditional rounding rules, of what would have been the QBP rating of the surviving and consumed contracts using contract enrollment in November of the year the Star Ratings were released. CMS believes that, since the same parent organization is involved, many administrative processes and procedures are identical in the MAOs offered by the sponsoring organization, and using a weighted mean of what would have been their QBP ratings accurately reflects their performance for payment purposes. Starting the second year following the consolidation, QBP status would be determined based on the consolidated entity's Star Rating posted on Medicare Plan Finder. The measure, domain, summary, and in the case of MA–PD plans the overall Star Ratings, posted on Medicare Plan Finder for the second year following consolidation would be based on the enrollment-weighted measure scores and would include data from all contracts involved. As a result, the ratings used for QBP status determinations would reflect the performance under both the surviving and consumed contracts.

- Adding, Updating and Removing Measures. CMS proposes the following general rules:
 - For data quality issues identified during the calculation of the Star Ratings for a given year, CMS proposes to continue its current practice of removing the measure from the Star Ratings.
 - New measures and substantive updates to existing measures would be added to the Star Ratings System based on future rulemaking but, prior to such a rulemaking, CMS would announce new measures and substantive updates to existing measures and solicit feedback using the Call Letter process.
 - Existing measures (currently existing or existing after a future rulemaking) used for Star Ratings would be updated with regular updates from the measure stewards (e.g., NCQA) through the Call Letter process when the changes are not substantive.
 - Existing measures (currently existing or existing after a future rulemaking) used for Star Ratings would be removed from use in the Star Ratings when there has been a change in clinical guidelines associated with the measure or reliability issues identified in advance of the measurement period. CMS would announce the removal using the Call Letter process. The removal might be permanent or temporary, depending on the basis for the removal.

- Data Integrity. CMS's current policy is to reduce a contract's measure rating if CMS determines that a contract's measure data are incomplete, inaccurate, or biased. CMS proposes specific rules for the reduction of measure

ratings when the agency identifies incomplete, inaccurate, or biased data that have an impact on the accuracy, impartiality, or completeness of data used for the impacted measures. Data may be determined to be incomplete, inaccurate, or biased based on a number of reasons, including mishandling of data, inappropriate processing, or implementation of incorrect practices that impacted specific measure(s).

- CMS would continue its current policy to reduce HEDIS measures to 1 star when audited data are submitted to NCQA with an audit designation of “biased rate” or BR based on an auditor’s review of the data if a plan chooses to report.
- CMS would continue to reduce Part C and D Reporting Requirements data to 1 star when a contract did not score at least 95 percent on data validation for the applicable reporting section or was not compliant with data validation standards/sub-standards for data directly used to calculate the associated measure.
- CMS would implement scaled reductions in Star Ratings for appeal measures in both Part C and Part D. The scaled reductions would range from a 1-star reduction to a 4-star reduction.

12. Any Willing Pharmacy Standards Terms and Conditions and Better Define Pharmacy Types (§§ 423.100, 423.505)

CMS makes several proposals to clarify the requirement that the Part D plan sponsor permit participation in its plan of “any willing pharmacy” that meets the standard terms and conditions.

First, CMS proposes to clarify that “similarly situated” pharmacies include any pharmacy that is capable of complying with standard terms and conditions for a pharmacy type, even if the pharmacy does not operate exclusively as that type of pharmacy. This proposal is made in response to anecdotal evidence that Part D plan sponsors exclude willing pharmacies from participation in their networks by relying on the traditional pharmacy type classifications. Under the proposal, Part D plan sponsors may tailor their standard terms and conditions to different types of pharmacies, but cannot exclude unique pharmacies from participating in their contracted pharmacy network on the basis of not fitting in the correct pharmacy type classification.

Second, CMS proposes to clarify and revise the definitions of retail and mail-order pharmacies. Since “mail-order pharmacy” has not previously been defined, CMS proposes to define it as: “a licensed pharmacy that dispenses and delivers extended days’ supplies of covered Part D drugs via common carrier at mail-order cost sharing.” Further, CMS proposes to revise 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 at retail cost sharing without being required to receive medical services from a provider or institution affiliated with that pharmacy.”

The proposed definition eliminates the confusing language: “any licensed pharmacy that is not a mail-order pharmacy.” CMS solicits comment regarding whether these definitions “strike the right balance to resolve confusion in the marketplace, afford Part D plan sponsor flexibility, and incorporate recent innovations in pharmacy business and care delivery models.”

Third, CMS solicits comment on the various practices of Part D plan sponsors that limit access to their network and to dispensing specialty drugs, including requiring specific pharmacy accreditations and waiving standard terms and

conditions for certain pharmacies. CMS proposes to clarify the regulatory requirement for what constitutes “reasonable and relevant” standard contract terms and conditions.

Finally, CMS proposes the imposition of deadlines on the requirement that Part D plan sponsors provide pharmacies with their standard terms and conditions. This proposal intends to address complaints from pharmacies that plan sponsors delay providing standard terms and conditions or require extensive paperwork to demonstrate eligibility to participate in the sponsor’s network.

Under the proposal, the Part D plan sponsor must:

- Have its standard terms and conditions readily available for requesting pharmacies no later than September 15th of each year for the succeeding benefit year;
- Clearly identify the method to request the standard terms and conditions; and
- Provide the applicable standard terms and conditions to the requesting pharmacy within two business days of receipt of either:
 - the pharmacy’s request for the terms, or
 - the executed confidentiality agreement, if required.

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

Part D plan sponsors must ensure certain enrollees access to a temporary supply of drugs within the first 90 days under a new plan (including drugs that are on a plan’s formulary but require prior authorization or step therapy under a plan’s utilization management rules). The temporary supply must be for at least 30 days of medication in the outpatient setting (unless the prescription is for a shorter period) and up to at least 91 days in the long-term care (LTC) and may be up to 98 days, consistent with the dispensing increment, unless a less amount is prescribed.

CMS proposes to reduce the required days’ supply in the LTC setting to match that in the outpatient setting. With respect to the outpatient setting requirement, CMS proposes to change the requirement from “30 days” to “a month’s supply.” With this change, the supply would have to be for at least the days’ supply that the applicable Part D plan has approved as its retail month’s supply in its PBP submitted to CMS, unless the prescription is written for less.

14. Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes (§§ 423.100, 423.120, and 423.128)

CMS proposes to provide Part D sponsors with more flexibility to implement generic substitutions by permitting sponsors to immediately remove brand name drugs (or to make changes in their preferred or tiered cost-sharing status), when those Part D sponsors replace the brand name drugs with (or add to their formularies) therapeutically equivalent newly approved generics--rather than having to wait until the direct notice and formulary change request requirements have been met. Certain requirements would apply 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.

CMS also proposes to also allow sponsors to make those specified generic substitutions at any time of the year rather than waiting for them to take effect two months after the start of the plan year.

The Part D transition policy would not be applicable to these situations. CMS notes that the purpose of the transition process is to make sure that the medical needs of enrollees are safely accommodated in that they do not go without their medications or face an abrupt change in treatment. If the proposal to permit Part D sponsors to immediately substitute generics for brand name drugs upon market release were finalized, most enrollees in this situation would not have had an opportunity to try the drug prior to the drug substitution to see how it worked for them.

15. Treatment of Follow-On Biological Products as Generics for Non-LIS Catastrophic and LIS Cost Sharing

Sections 1860D-2(b)(4) and 1860D-14(a)(1)(D)(ii-iii) of the Act provide for lower Part D maximum copayments for LIS eligible individuals for generic drugs and preferred drugs that are multiple source drugs (as defined in section 1927(k)(7)(A)(i) of the Act) than are available for all other Part D drugs. Currently the statutory cost sharing levels are set at the maximums. Under Part D, a “generic drug” is defined as a drug for which an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) is approved. Biosimilar and interchangeable biological products do not meet the section 1927(k)(7) definition of a multiple source drug or the CMS definition of a generic drug. As a result, follow-on biological products are subject to the higher Part D maximum copayments for LIS eligible individuals and non-LIS Part D enrollees in the catastrophic portion of the benefit applicable to all other Part D drugs.

CMS proposes to revise the definition of generic drug to include follow-on products approved under section 351(k) of the Public Health Service Act, but solely for purposes of the cost-sharing provisions of Sections 1860D-2(b)(4) and 1860D-14(a)(1)(D)(ii-iii). The proposed change is intended to further encourage the use of lower-cost alternatives.

16. Eliminating the Requirement to Provide PDP Enhanced Alternative (EA) to EA Plan Offerings with Meaningful Differences (§423.265)

CMS proposes to eliminate the “meaningful difference” requirement on Enhanced Alternative (EA) benefit designs offered by the same organization in the same region. In proposing this change, CMS notes its agreement with commenters to the draft CY2018 Call Letter that two enhanced plans offered by a plan sponsor could vary with respect to their plan characteristics and benefit design, such that they might appeal to different subsets of Medicare enrollees, but in the end have similar out-of-pocket beneficiary costs. The proposed change would be effective for CY2019. The requirement that enhanced plans must be meaningfully different from the basic plan offered by a PDP sponsor in the service area would not change.

Anticipated impacts to this change include: (1) a modest increase in the number of plans that would be offered by PDP sponsors (if the EA to EA meaningful difference requirement was the sole barrier to a PDP sponsors offering a second EA plan in a region) and (2) a potential decrease in the average supplemental Part D premium.

CMS also announced its future intent to reexamine how it defines the meaningful difference requirement between basic and enhanced plans offered by a PDP sponsor within a service area. CMS notes that the current out-of-pocket cost methodology is only one method for evaluating whether differences are meaningful.

17. Request for Information Regarding the Application of Manufacturer Rebates and Pharmacy Price Concessions to Drug Prices at the Point of Sale

CMS solicits comments on requiring sponsors to include at least a minimum percentage of manufacturer rebates and all pharmacy price concessions received for a covered Part D drug in the drug's negotiated price at the point of sale. Including such amounts in the point of sale price can reduce the price upon which beneficiary cost-sharing is determined. Amounts that are not included in the point of sale price, must be reported to CMS via the end of the year Direct and Indirect Remuneration (DIR) reporting requirement. Sponsors must also include an estimate for DIR in their annual bid submissions to CMS. CMS notes that to the extent that plan bids reflect accurate DIR estimates, the rebates and other price concessions that Part D sponsors and their PBMs negotiate, but do not include in the negotiated price at the point of sale, put downward pressure on plan premiums, as well as CMS's subsidies of those premiums. Any DIR received that is above the projected amount factored into a plan's bid contributes primarily to plan profits, not lower premiums

With respect to manufacturer rebates, CMS solicits comments on how it we might effectively design a policy requiring Part D sponsors to pass through at the point of sale a share of the manufacturer rebates they receive, in order to mitigate the effects of the DIR construct on costs to both beneficiaries and Medicare, competition, and efficiency under Part D. CMS is considering requiring Part D sponsors to include in the negotiated price reported to CMS for a covered Part D drug a specified minimum percentage of the cost weighted average of rebates provided by drug manufacturers for covered Part D drugs in the same therapeutic category or class.

Regarding pharmacy price concessions, CMS believes that the predominance of performance-contingent pharmacy payment arrangements under Part D does not, among other effects, achieve desired price transparency. CMS solicits comments on how to update the requirements governing the determination of negotiated prices to better reflect current pharmacy payment arrangements, so as to ensure that the reported price at the point of sale includes all pharmacy price concessions. CMS is considering revising the definition of negotiated price at § 423.100 to remove the "reasonably determined" exception and to require that all price concessions from pharmacies be reflected in the negotiated price that is made available at the point of sale and reported to CMS on the PDE, even when such concessions are contingent upon performance by the pharmacy. In the event a pharmacy's performance under a performance-based arrangement triggered a bonus payment or a smaller penalty than that assessed for the lowest level of performance), the difference between the negotiated price reported to CMS on the PDE and the final payment to the pharmacy would be reported as negative DIR.

B. Improving the CMS Customer Experience

1. Restoration of the Medicare Advantage Open Enrollment Period (§§ 422.60, 422.62, 422.68, 423.38 and 423.40)

The 21st Century Cures Act amended the Act to provide for a modified Open Enrollment Period (OEP) under Part C. Enrollees in MA plans are currently permitted to elect, between January 1 and February 14 of each calendar year, to disenroll from the MA plan to be covered instead by Original Medicare and to make a corresponding Part D enrollment. The Proposed Rule would implement the statutory change by providing an OEP for MA plans from January 1 through

March 31 of each calendar year, beginning with 2019. This OEP would allow MA enrollees to enroll in or disenroll from MA plans, elect Original Medicare, and make corresponding enrollments in PDPs.

2. **Reducing the Burden of the Compliance Program Training Requirements (§§ 422.503 and 423.504)**

Medicare regulations currently require, as a condition of contracting, that MAOs and PDP sponsors “[a]dopt and implement an effective compliance program” and set forth specific requirements for effective compliance programs. Among other things, MAOs and PDP sponsors “must establish and implement effective training and education” between the compliance officer and organization employees, the chief executive officer or administrator, managers and governing body members, and first-tier, downstream, and related entities (FDRs).

The imposition of training and education requirements on FDRs has been a subject of contention for several years. Vendors frequently act as FDRs to multiple MAOs and/or PDP sponsors can sometimes be subject to multiple sets of compliance training requirements that are similar to and duplicative of one another but separately imposed by virtue of the vendor’s several contracts. In response to these concerns, the May 2014 final rule included provisions to standardize training and education by requiring MAOs and PDP sponsors to accept completion of the standardized CMS compliance training as satisfactory completion of the MAO or PDP sponsor’s compliance training requirements. The Proposed Rule explains that problems with implementation of this provision prevented its successful mitigation of the duplicative requirements on FDRs.

The Proposed Rule would modify these training and education requirements by removing FDRs from the scope of MAOs and PDP sponsors’ obligations. CMS explains that the sophistication of compliance operations, as well as MAOs’ and PDP sponsors’ ultimate accountability, make the current burdensome requirements unnecessary.

3. **Medicare Advantage Plan Minimum Enrollment Waiver (§ 422.514(b))**

As a condition of contracting with CMS, MAOs must meet minimum enrollment requirements, generally of 5,000 beneficiaries. Waivers are available for the first year an MAO offers MA plans, and those waivers may be extended, upon annual re-application by the MAO, for the second and third years of operation. The Proposed Rule would eliminate the requirement for MAOs to reapply, explaining that reevaluation is unnecessary because CMS can decide on initial application whether the MAO can operate for its first three years with the minimum enrollment requirement waived.

4. **Revisions to Timing and Method of Disclosure Requirements (§§ 422.111 and 423.128)**

Under current regulations, both MAOs and PDP sponsors generally must provide annual disclosure notices to enrollees including the evidence of coverage, summary of benefits, and network directory, at least 15 days prior to the beginning of an OEP in electronic and hard copy. The Proposed Rule would require electronic notices of these documents, with hard copies available upon request, no later than the first day of open enrollment.

5. **Revisions to Parts 422 and 423, Subpart V, Communication/Marketing Materials and Activities**

Under the current regulations, many materials that are not intended to steer a beneficiary into a particular plan fall under the regulatory definition of marketing and related requirements and are therefore subject to CMS review as marketing materials. 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. CMS also proposes separate requirements for a new category of materials and activities called “communications.” These revisions are intended to narrow the scope of the requirements and focus on issues that are more problematic based on CMS experience.

CMS proposes to define “communications” as activities and use of materials to provide information to current and prospective enrollees, and to define “communications materials” as materials that include all information provided to current members and prospective beneficiaries. Marketing materials would be a subset of communications materials.

CMS also proposes to modify the definition of marketing to focus on materials and activities that aim to influence enrollment decisions. The proposed definition would also differentiate between factually providing information about the plan or benefits (such as the Evidence of Coverage) versus persuasively conveying information in a manner designed to prompt the beneficiary to make a new plan decision or to stay with their current plan (such as a flyer that touts a low monthly premium).

This prohibition ties to the 21st Century Cures Act that established a continuous OEP for MA and Part D Plans. The Act also prohibits unsolicited marketing and mailing marketing materials to individuals eligible for the new OEP. CMS is concerned that it may be difficult for plans to limit marketing to only those individuals not yet enrolled in a plan during OEP. CMS welcomes comments on this issue.

6. Lengthening Adjudication Timeframes for Part D Payment Redeterminations and IRE Reconsiderations (§§423.590 and 423.636)

CMS proposes to lengthen existing timeframes for adjudicating enrollee payment appeal requests at the redetermination and independent review entity (IRE) reconsideration levels from a maximum of 7 calendar days to a maximum of 14 calendar days. This change would reduce burden on plan sponsors and the Part D IRE by providing them additional time to adjudicate payment requests with little adverse impact on beneficiaries, who in payment appeals have already obtained the requested medications. CMS did not propose any changes to the existing requirements for making payment. Part D sponsors must make payment no later than 30 days from receipt of the request for redetermination, or the IRE reconsideration notice, respectively.

CMS notes that the proposed change to 14 calendar days will establish consistency in the adjudication timeframes for payment requests throughout the plan level and IRE processes since plan sponsors are required to notify enrollees of their determination no later than 14 calendar days after receipt of the request for payment. CMS believes affording more time to adjudicate payment redetermination requests (including obtaining necessary documentation to support the request) will ease burden on plan sponsors because it could reduce the need to deny payment redeterminations due to missing information.

7. Elimination of Medicare Advantage Plan Notice for Cases Sent to the IRE (§422.590)

Currently, MAOs are required to notify enrollees upon forwarding cases to the IRE. In addition, the Part C IRE is required, under its contract with CMS, to notify the enrollee when the IRE receives the reconsidered decision for review. CMS proposes to eliminate the redundant that MAOs send notice to an appellant when his/her appeal case file is forwarded to the Part C IRE.

8. **E-Prescribing and the Part D Prescription Drug Program; Updating Part D E-Prescribing Standards**

The Proposed Rule includes an update to the official standard for e-prescribing, which is a required capability for plans participating in the Part D program. CMS proposes the adoption of the National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard Version 2017071 as the e-prescribing standard for transmission of prescriptions and related information, and would retire the current SCRIPT 10.6. This change would become effective January 1, 2019.

Physicians and pharmacies that prescribe or dispense Part D covered drugs for eligible beneficiaries must use CMS-indicated standards when e-prescribing. The SCRIPT standard is developed and updated through a multi-stakeholder process run by NCPDP, and allows for the transfer of data elements including (but not limited to) new prescriptions, fill status, cancellations, medication history, and electronic prior authorization.

CMS notes that the newer version of the SCRIPT standard has many benefits and efficiencies for the community, including:

- Ability to electronically transmit prescriptions for multi-ingredient compounds (which previously had to be handwritten);
- Functionality that will allow notification when a beneficiary has left a long-term care facility, allowing for discontinuation of unnecessary medication;
- Improved Prescription Fill Status notification that would allow a prescriber to receive such notification from the pharmacy, so that the prescriber could potentially follow up with a patient who has not filled a prescription; and
- Support for data elements pertaining to diabetic supply prescriptions and elements required of the pharmacy that support medication adherence efforts.

CMS requests comment on the use of the new SCRIPT standard as well as the timeline for implementation, given the potential cost of systems switching over to the new standard.

9. **Reduction of Past Performance Review Period for Applications Submitted by Current Medicare Contracting Organizations (§§422.502 and 423.503)**

Currently CMS will deny MA and PDP contract applications from organizations that have failed to comply with the requirements of a current MAO or PDP sponsor contract, even if the submitted application otherwise demonstrates that the organization meets the program requirements. In making this determination, CMS reviews an applicant's prior contract performance for the 14-month period preceding the application submission deadline. Contracting organizations

have complained that the 14-month period is too long and is unfair since a non-compliance that occurs during January and February of a given year is counted against an organization in two consecutive past performance review cycles while non-compliance occurring in all other months is counted in only one review cycle. The result is that some non-compliance is “double counted” based solely on the timing of the non-compliance and can prevent an organization from receiving CMS approval of their application for two consecutive years.

CMS proposes to reduce the review period from 14 to 12 months. The change would establish a new review period for every application review cycle of March 1 of the year preceding the application submission deadline through February 28 (February 29 in leap years) of the year in which the application is submitted and would eliminate the counting of instances of non-compliance in January and February of each year in two separate application cycles.

CMS also proposes to change the minimum performance history requirement from 14 to 12 months.

10. Part D Prescriber Preclusion List

The Part D preclusion list is intended to reduce the burden on many prescribers of enrolling in Medicare as required by § 423.120(c)(6) ([May 23, 2014 Final Rule](#)). CMS estimates that about 400,000 prescribers still have yet to enroll in Medicare per the rule and CMS has concerns that for many, the burden outweighs the benefit. CMS proposes to assess providers based on the risk to Medicare beneficiaries and only focus on those who pose an elevated risk. CMS believes that this is the best way to alleviate the burden on prescribers without compromising safeguards.

The focus of § 423.120(c)(6) protections would move from an enrollment requirement to a claims payment approach. The process of evaluating who poses an elevated risk would consist of:

- 1. Research into relevant prescriber data, including whether CMS: (a) has revoked the prescriber’s enrollment and the prescriber is under an enrollment bar; or (b) could have revoked the prescriber if he or she is enrolled in Medicare.
- 2. Case-by-case basis review of each prescriber who: (a) is currently revoked from Medicare and under enrollment bar; or (b) has engaged in behavior for which CMS could have revoked the prescriber if he or she were enrolled in Medicare.
- Based on the results of 1. and 2., CMS would compile a “preclusion list” of prescribers who either (a) are currently revoked from Medicare, are under an enrollment bar, and CMS determines that the underlying conduct is detrimental to the best interests of the Medicare program; or (b) have engaged in behavior for which CMS could have revoked the prescriber to the extent applicable if he or she had been enrolled and CMS determines that the underlying conduct is detrimental to the best interests of the Medicare program.

The preclusion list would serve as an alternative to enrollment to reflect some prescribers’ more indirect connection in the Part D program. The PDP sponsor would be required to reject a pharmacy claim for Part D drugs prescribed by an individual on the preclusion list.

In determining whether underlying conduct is detrimental to Medicare, CMS would consider:

- The seriousness of conduct involved;
- The degree to which the conduct could affect the integrity of the Part D program; and
- Any other relevant evidence

Furthermore, CMS would have the ability to forgo these guidelines and include or remove someone from the preclusion list under exceptional circumstances based on (1) the degree to which beneficiary access to Part D drugs would be impaired; and (2) any other evidence that CMS deems relevant.

Other provisions of proposed § 423.120(c)(6) that are of note including the following:

- The preclusion list would be updated monthly, at which time the changed status of any prescriber would become effective.
- The length of time that a prescriber would have previously been on an unenrollment bar would apply to their time on the preclusion list.
- Beneficiaries would have a 90-day provisional coverage period to maintain coverage when their prescriber is newly placed on the preclusion list.
- Prescribers would have a right to appeal their placement on the preclusion list. This would be independent from claims payment denials or enrollment revocations. The placement of a prescriber on the preclusion list would constitute an “initial determination” which could then be appealed to multiple levels.

11. Part C/Medicare Advantage, Cost Plan and PACE Preclusion List (§422.224)

The Part C preclusion list goal is similar to Part D. It is aimed at reducing the burden on the estimated 120,000 Medicare Advantage-only providers and suppliers who remain unenrolled in Medicare, as well as their beneficiaries. As a result, CMS proposes to eliminate the enrollment requirement and to utilize the preclusion list, as proposed in Part D.

The process for including Part C individuals and entities on the preclusion list is similar to that detailed above for Part D providers and suppliers. The individuals and entities to be reviewed for inclusion on the list would be those that according to CMS’s internal data, MA organization data, state board information, and other relevant data are or who could become eligible to furnish health care services or items.

CMS also proposes to include the Part C individuals and entities and Part D providers and suppliers on a single, combined preclusion list for ease of administration.

Under the Proposed Rule:

- MAOs and PACE organizations would be required to follow a documented process to ensure compliance with the preclusion list provisions (Revised §§ 422.222, 422.224).
- MAOs and PACE organizations would be barred from paying any individual or entity that is included on the preclusion list.

- HMOs and CMPs would be required to agree to comply with the preclusion list provisions as a condition to their contractual agreements with CMS.
- MAOs would be required to submit provider NPIs as part of encounter data submissions in order to allow CMS to identify individuals and entities that may be included on the preclusion list.
- Individuals and entities on the preclusion list would be able to appeal their inclusion as an “initial determination” similar to the Part D preclusion list appeals process.

12. Removal of Quality Improvement Project for Medicare Advantage Organizations (§ 422.152)

CMS proposes to remove the Quality Improvement Project (QIP) from the Quality Improvement (QI) requirements for MAOs. CMS has determined that the QIP is duplicative of activities MAOs are already performing to meet other plan needs and requirements, such as the required Chronic Care Improvement Program and internal organizational focus on Star Rating metrics. According to CMS, the removal of the QIP and the continued implementation of the CCIP would allow MAOs to focus on one project that supports improving the management of chronic conditions while reducing the duplication of other QI initiatives.

13. Reducing Provider Burden – Comment Solicitation

CMS is soliciting comments relating to how requests by MAOs for medical record documentation (such as for RADV processes) burden providers, particularly sole practitioners. CMS seeks comments on the nature and extent of medical record requests and ideas for improving the processes around medical record requests by MAOs.

C. Implementing Other Changes

1. Reducing the Burden of the Medicare Part C and Part D Medical Loss Ratio Requirements (§§ 422.2420 and 423.2430)

When CMS promulgated regulations implementing the ACA’s MLR requirement for MA plans and PDPs, the regulations largely tracked the commercial MLR regulations. Now, however, CMS has reconsidered this alignment and proposes changes to the MA and PDP MLR rules based on the specific characteristics of the MA and Part D programs. The Proposed Rule would make three key changes.

First, the Proposed Rule would deviate from the commercial MLR rules by permitting fraud prevention activities to be included as Quality Improvement Activities (QIA). The definition of QIA also would be expanded to include all fraud prevention activities, such as fraud prevention, fraud detection, and fraud recovery. And the Proposed Rule would no longer include the amount of claims payments recovered through fraud prevention activities as incurred claims up to the amount of the fraud reduction expenses. CMS now believes that limiting or excluding amounts invested in fraud reduction—as is currently the practice for the commercial, Medicaid, and MA and PDP MLR rules—hinders antifraud efforts, increases costs to taxpayers, reduces savings, and does not improve patient safety or the quality of care. As such, it is contrary to the underlying policy rationale for imposition of an MLR requirement: ensuring that taxpayers and beneficiaries receive value from Medicare services.

Second, the Proposed Rule clarifies prior rulemakings regarding whether medication therapy management (MTM) activities are QIA. CMS would add a new paragraph (a)(4)(i) to §§ 422.2430 and 423.2430 stating that all MTM programs that comply with § 423.153(d) and are offered by PDP sponsors (including MAOs) are QIA. CMS already requires PDP sponsors to include MTM programs in their benefits and has a Star Rating measure for MTM Program Completion Rate for Comprehensive Medication Reviews. CMS hopes that adding express language to the MLR rule that MTM are QIA will provide more incentives for PDP sponsors to promote MTM, particularly in light of the opioid crisis.

Finally, the Proposed Rule overhauls the MLR reporting requirements for MA plans and PDPs. CMS proposes a simplified report that would include only four data fields: (1) the organization's name; (2) contract number; (3) adjusted MLR; and (4) the remittance amount. Notwithstanding these streamlined reporting elements, organizations would remain obligated to retain records and documentation sufficient to support their reports and would remain subject to audit and sanctions.

The Proposed Rule also would make a handful of technical and conforming changes.

2. **Medicare Advantage Contract Provisions (§ 422.504)**

The Proposed Rule seeks to correct an inconsistency in the regulatory text that identifies the contract provisions deemed material to the performance of an MA contract. The proposed change to § 422.504 would provide that compliance with all contract terms listed in paragraph (a) of the section is material to performance of the contract.

3. **Late Contract Non-Renewal Notifications (§§ 422.506, 422.508, and 423.508)**

Under § 422.506(a)(2)(i) and § 423.507(a)(2)(i), contract non-renewals effective at the end of the 1-year contract term must be submitted to CMS in writing by the first Monday in June. There may be instances where CMS accepts a late non-renewal notice after the first Monday in June for an MA contract if the non-renewal is consistent with the effective and efficient administration of the contract under § 422.506(a)(3). MAO non-renewal requests after the first Monday in June are treated as a request for a mutual termination pursuant to § 422.508. CMS has received a number of late non-renewal requests and received questions from MAOs inquiring why their request was not treated as a contract non-renewal, but rather as a termination by mutual consent.

CMS proposes to modify § 422.506(a)(3) to remove language that indicates late nonrenewals may be permitted by CMS so that there would only be one process – mutual termination under §§ 422.508 – that is applicable if CMS is not taking action under § 422.506(b) or § 422.510. CMS also proposes to amend §§ 422.508 and 423.508 to clarify that organizations that request to non-renew a contract after the first Monday in June are in effect requesting that CMS agree to mutually terminate their contract.

4. **Contract Request for a Hearing (§§ 422.664(b) and 423.652(b))**

CMS proposes to address an inconsistency in regulations regarding the date by which an organization must receive a decision from CMS on an appeal of an application denial. Section 422.660(c) specifies that a notice of any appeal

decision favorable to the MAO must be issued by September 1 for the contract to be effective on January 1. However, § 422.664(b)(1) specifies that if a final decision is not reached by July 15, CMS will not enter into a contract with the applicant for the following year. There are similar inconsistencies in the Part D regulations.

The proposed changes would align with the September 1 date.

5. **Physician Incentive Plans - Update Stop-Loss Protection Requirements (§ 422.208)**

The Proposed Rule would update the stop-loss insurance protection requirements imposed on MAOs operating physician incentive plans (PIPs). With the Proposed Rule:

- CMS would update the current stop-loss insurance deductible requirements to account for changes in medical cost and utilization and be more narrowly tailored to the risk of substantial loss. Additionally, CMS would codify the methodology used to update stop-loss deductible limits for the future.
- In the panel size used to determine the deductible, physician groups would be able to consider non-risk patient equivalents, such as Medicare fee-for-service patients, who obtain some services from the physician. This change would account for the effect that the number of non-risk patients has on the overall financial risk of a physician group. The deductible for required stop-loss insurance would be the lesser of (1) the deductible for globally capitated patients plus up to \$100,000 or (2) the deductible calculated for globally capitated patients plus non-risk patient equivalents.
- CMS would permit MAOs to use other actuarially equivalent stop-loss protection arrangements.

6. **Changes to the Agent/Broker Compensation Requirements (§§ 422.2274 and 423.2274)**

In its May 23, 2014 file rule, CMS codified technical changes relating to agent/broker compensation, linking payment rates for renewal enrollments to current fair market value rates rather than the rate paid for the original (initial) enrollment. These changes also removed the 6-year cycle from the payment structure. CMS failed to remove the compensation language related to the original enrollment. CMS proposes to make a technical correction to remove the obsolete language.

7. **Changes to the Agent/Broker Requirements (§§ 422.2272(e) and 423.2272(e))**

MAOs and PDP sponsors are required to terminate any agent/broker who becomes unlicensed as well as to take other steps including notifying any beneficiaries enrolled by the unqualified agent/broker of that agent/broker's status. The regulation does not allow any latitude, such as where a license lapses and is immediately reinstated. CMS proposes to delete these requirements, but reminds MAOs and PDP sponsors that CMS may pursue compliance actions upon discovering that an MAO or PDP sponsor allowed unlicensed agents/brokers to continue selling their products in violation of §§ 422.2272(c) and 423.2272(c).

8. **Codification of Certain Medicare Premium Adjustments as Initial Determinations (§ 405.924)**

CMS proposes to codify its existing interpretation that certain Medicare premium adjustments, including Medicare Part A and Part B late enrollment and reenrollment premium increases, constitute initial determinations under the regulations, and can be appealed as such, because of their effect on individuals' entitlement to Medicare benefits. The proposed change would not affect Part D late enrollment and reenrollment penalties.

9. **Eliminate Use of the Term “Non-renewal” to Refer to a CMS-Initiated Termination (§§ 422.506, 422.510, 423.507, and 423.509)**

The Proposed Rule would eliminate CMS-initiated nonrenewal authority and modify the agency's existing termination authority to include the current nonrenewal authority provisions. The term “nonrenewal” would only describe decisions by sponsoring organizations to discontinue Medicare contracts. This change would align the regulations with how the term “nonrenewal” has effectively been used within CMS and among industry stakeholders, and it would eliminate overlap between CMS's May nonrenewal and termination authorities.

Additionally, some of the current nonrenewal authority notice requirements would be incorporated into the revised termination provision. The MAO would be required to notify enrollees of a contract termination no later than 90 days prior to the December 31 effective date of a contract termination, when CMS makes the determination on or before August 1 of the same year.

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