January 16, 2018

The Honorable Seema Verma

Administrator

Centers for Medicare and Medicaid Services

7500 Security Blvd.

Baltimore, MD 21244

Comments submitted electronically via [http://www.regulations.gov](http://www.regulations.gov/)

**RE: Medicare Program; 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 (CMS-4182-P)**

Dear Administrator Verma:

The Blue Cross Blue Shield Association (“BCBSA”) appreciates the opportunity to provide comments on the Proposed Rule: “Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefits Programs, and the PACE Program” as issued in the Federal Register on November 28, 2017 (82Fed.Reg.56336).

BCBSA is the national federation of 36 independent, community-based, and locally operated Blue Cross and Blue Shield Plans (“Plans”) that collectively provide healthcare coverage for one in three Americans. Plans participate in Medicare Advantage, Medicare Part D, and many also contract with CMS as Medicare Administrative Contractors.

Overall, we support and are pleased to see CMS’ proposals in this Rule that streamline processes and administrative tasks to reduce burdens on plans and providers. We strongly encourage CMS to finalize many of these positive proposals and consider additional flexibility wherever possible. In particular, we would like to highlight the following issues:

We specifically support and thank CMS for:

* + proposals to provide significant new benefit flexibility for Medicare Advantage organizations (MAOs), including flexibility in benefit uniformity;
  + elimination of the meaningful difference requirement;
  + changes in the transition first fill policy;
  + expansion of electronic delivery of member materials; and
  + elimination of burdensome provider and prescriber enrollment requirements.

We believe these new flexibilities and elimination of problematic rules will allow plans to continue to provide high-quality care to beneficiaries with greater efficiency. We encourage CMS to finalize many of these provisions as proposed.

In response to CMS’ Request for Information (RFI) on Part D sponsors passing through a portion of manufacturer rebates and price concessions at the point of sale (POS), we strongly encourage CMS not to finalize any of the optionsdiscussed. POS rebates will increase costs to the government and to Part D beneficiaries by increasing premiums. These proposals do not get to the heart of the issue, which is the manufacturer’s price of a medication. In addition, the proposals pose substantial operational challenges, which we discuss in detail in our RFI response.

With implementation of the Comprehensive Addiction and Recovery Act of 2016 (CARA), we urge the agency to allow MA/PDs and Part D sponsors to restrict the first fill of short acting opioids to a seven day supply to help reduce the supply of opioids in the marketplace and attach a legal analysis concluding that CMS has the authority to limit these first fills. We also urge the agency to tighten the criteria and processes as to the ability of plans to identify at-risk beneficiaries.

Finally, we urge CMS to delink audit and enforcement actions from Star Ratings and use those actions for oversight but not for Stars. We also believe that measures extracted from surveys should be appropriately weighted and recommend the restoration of 4 star thresholds (cut points) announced in advance of the measurement year in the Star program.

Thank you for the opportunity to provide detailed comments and recommendations. We would be pleased to discuss our comments with you at your convenience. Questions regarding these comments may be directed to [Jane.Galvin@bcbsa.com](mailto:Jane.Galvin@bcbsa.com).

Sincerely,



Kris Haltmeyer

Vice President, Legislative & Regulatory Policy

Office of Policy & Representation

**BCBSA Detailed Comments and Recommendations on the Proposed Rule: “Medicare Program; 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 (CMS-4182-P)”**

**Section A: Supporting Innovative Approaches to Improving Quality, Accessibility, and Affordability**

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

The Comprehensive Addiction and Recovery Act of 2016 (CARA) provided new authority for the establishment of drug management programs in Medicare Part D for beneficiaries who are at-risk for prescription drug abuse. In this Rule, CMS proposes new regulations to implement this authority. We supported passage of this legislation and see it as a means to provide plans with mechanisms to identify at-risk beneficiaries and hopefully stem the use of opioids in Part D. BCBSA as an Association with our members Plans have been active with initiatives to combat the opioid epidemic facing the nation and we see implementation of these new measures in Part D as a step in the right direction.

We provide comments and recommendations below on several specific areas of this proposal.

**Establishment of Part D Drug Management Programs**

Proposal: CMS proposes to define opioids as frequently abused drugs for 2019 and proposes to use the following clinical guidelines to identify potential at-risk beneficiaries:

* Use of opioids with an average daily morphine milligram equivalent (MME) greater than or equal to 90 mg for any duration during the most recent 6 months **and either**:
* 4 or more opioid prescribers and 4 or more opioid dispensing pharmacies **OR**
* 4 or more opioid prescribers, regardless of the number of opioid dispensing pharmacies.

Issue: BCBSA believes that these clinical guidelines could be improved with stricter standards with respect to the MME level as well as the number of prescribers and dispensing pharmacies used to identify at- risk beneficiaries. Based on their clinical experience, Plans believe that identifying at-risk beneficiaries based on 4 or more prescribers and dispensing pharmacies alone will continue to allow pharmacy and doctor “shopping” that has contributed to the existing opioid crises. In addition, we believe that CMS should use the 50 MME daily dose as recommended by the CDC as a threshold for increased risk of opioid overdose.

Recommendation: BCBSA strongly recommend that CMS consider a proposal to include:

* Use of opioids with an average daily morphine milligram equivalent (MME) greater than or equal to 50 mg for any duration during the most recent 6 months **and either:**
* 4 or more opioid prescribers and 4 or more opioid dispensing pharmacies **OR**
* 4 or more opioid prescribers, regardless of the number of opioid dispensing pharmacies **OR**
* 4 or more emergency room visits for non-emergent pain in a six month period.

Over time CMS can evaluate these specifications and modify them accordingly in order to determine their effectiveness as to identifying those who need to be monitored closely.

Issue: We recognize that based on CMS’ own analysis in this Rule, such a change would dramatically increase the estimated number of potentially at-risk beneficiaries, from approximately 33,000 to more than 300,000. However, given the scale of the national crisis surrounding opioid addiction and, in particular, its impact on the Medicare population, BCBSA believes the criteria described above are appropriate. A recent OIG report found that in 2016 over 500,000 beneficiaries received high amounts of opioids through Part D (excluding beneficiaries with cancer or in hospice care) and almost 90,000 beneficiaries were at serious risk of opioid misuse or overdose.[[1]](#footnote-1) Therefore, in order to protect beneficiaries’ health and safety and provide plans with the ability to identify and take steps to mitigate opioid addiction earlier, we recommend narrowing the prescriber and pharmacy guidelines necessary to identify these beneficiaries. As part of this definition, we note that CMS refers to a specified level of opioid use “for any duration during the most recent 6 months”.

Recommendation: CMS should confirm that this language merely requires that the opioid use occurred during the most recent 6 months, and not that plan would need to wait for 6 months of consistent abuse prior to identifying the beneficiary as high-risk.

Issue: CMS has chosen to designate only opioids as frequently abused drugs.

Recommendation: BCBSA encourages CMS to consider expanding this definition to include other highly abused drugs, such as triple combination regimes or sedative-hypnotics (particularly benzodiazepines) in future rulemaking. We also ask CMS to clarify that methadone will be considered a frequently abused drug under the proposed drug management program. This would ensure that implementation of the new Part D drug management program under CARA is consistent with current policy of identifying non-opioid drugs for drug utilization review (DUR) and Overutilization Monitoring System (OMS) efforts.

Issue: Currently CMS does not allow Part D sponsors to limit the first fill of a short acting opioid to a seven day fill.

Recommendation: BCBSA would like to reiterate our request that CMS implement CDC guidelines limiting a Medicare beneficiary’s first fill for short-acting opioids to a seven day supply in Medicare Advantage and Part D. CMS should allow plans the flexibility to restrict opioid dispensing based on needs within their population and/or alignment with state law (e.g. a recent Michigan law restricts opioids for treatment of acute pain to a 7-day supply in a 7-day period).

We have included, as an attachment, a legal analysis (previously shared with CMS) showing that CMS has the authority to allow such an edit under current law. Plans strongly believe that limiting opioids on a first fill to a seven-day quantity limit would help reduce the supply of opioids in the marketplace and reduce potential risks for MA and Part D beneficiaries, while ensuring uniformity with CDC guidelines.

**Beneficiaries Exempted from the Part D Drug Management Program**

Proposal: CMS proposes to exempt from the drug management program Part D enrollees who are receiving hospice care, are residents in a long-term care (LTC) facility, or have a cancer diagnosis, and solicits comments on whether to exclude additional categories of beneficiaries, such as those receiving palliative and end-of-life (but not hospice) care, beneficiaries in assisted living, or beneficiaries in other facilities, such as group homes or adult day centers.

Issue: CMS should consider further tailoring the exemption list to be more specific about beneficiaries who have had a cancer diagnosis. We agree that drug management programs should not be able to interfere with a beneficiary’s pain control regime and agree that beneficiaries with certain stages of cancer should often be excluded from drug management programs because the benefit of their opioid use may outweigh their risk. However, we are concerned that CMS’ proposed exemption of a “cancer diagnosis” is too broad and encourage CMS to consider an approach that would exempt those beneficiaries with a current cancer diagnosis who are currently being treated for such cancer and have a clinical need for pain medication. Absent these more specific parameters, beneficiaries who no longer have active cancer but are at-risk for misusing frequently abused drugs could be inappropriately overlooked in drug management programs.

BCBSA also seeks clarity about the treatment of beneficiaries residing in LTC facilities. While they are statutorily excluded from drug management programs under CARA, it is unclear if they would also be exempt from retrospective drug utilization review (DUR) programs. We request clarification from CMS on this issue.

In addition to the exemptions proposed, we believe that it is appropriate to exempt beneficiaries receiving palliative and non-hospice end-of-life care, but would caution CMS against exempting beneficiaries based on the other proposed settings. It would be operationally difficult for plans to identify beneficiaries based on these other settings. BCBSA does not believe there are compelling clinical reasons that any beneficiary (absent their classification in one of the proposed clinical groups) in these settings should be exempt from the requirements described here.

Recommendation: We recommend that CMS tailor the exemption list to ensure that only beneficiaries with an active cancer diagnosis and treatment are exempt and consider additional exemptions based on palliative and non-hospice end of life care but not base exemptions on settings, such a group homes, etc.

**Limitations on Access to Coverage for Frequently Abused Drugs**

Proposal:CMS proposes that a Part D sponsor may establish a drug management program for at-risk beneficiaries to address overutilization of frequently abused drugs, which may include limitations on access to coverage through point-of-sale edits and/or limiting coverage to certain prescribers and/or pharmacies, subject to specified notice and timing requirements.

Issue: While we appreciate the new flexibility provided by CARA and proposed in this Rule, BCBSA is concerned that the protracted notice requirements and 6-month waiting period to implement a prescriber or pharmacy “lock-in” are overly restrictive and will prevent plans from implementing critical case management measures in a timely fashion.

Recommendation: BCBSA recommends that CMS revise this proposal to allow plans to implement necessary management techniques as soon as possible following notice requirements to identify a beneficiary as high-risk.

We note that, although CMS states that prescriber lock-in should be a “tool of last resort,” POS claim edits, pharmacy lock-in, and prescriber lock-in should be viewed as three equal mechanisms for limiting a beneficiary’s access to frequently abused drugs, and not viewed in a hierarchical manner. Because the effectiveness of each technique or process may differ depending on a beneficiary’s circumstances, plans should have sufficient latitude in deciding which tool to use for which beneficiary in an appropriate timeframe.

In addition, we recommend that CMS categorically exclude beneficiaries, who are subject to any lock-in, from certain Star measures, such as grievances/CTMs, voluntary disenrollment, and CAHPs/HOS measures. These beneficiaries are receiving potentially life-saving care management services, but may be temporarily unhappy with their plans, and could unfairly bias Star results for plans that take appropriate actions to address their medication issues.

**Termination of a Beneficiary’s Potential At-Risk or At-Risk Status**

Proposal: CMS proposes a maximum 12-month timeframe for both a lock-in period and also for the duration of a beneficiary-specific POS claim edit for frequently abused drugs.

Issue: A maximum 12-month period may be too limited to ensure appropriate case management for at-risk beneficiaries.

Recommendation: CMS should revise its proposal to allow plans to conduct an expedited review of a beneficiary’s lock-in and at-risk status at 12-months (without having to repeat the lengthy process for a new “at-risk” determination) and extend the lock-in and at-risk status with a possible termination after 24 months.

**Special Enrollment Period for LIS Beneficiaries with an At-Risk Status**

Proposal: CMS proposes that dual and LIS-eligible beneficiaries, who are identified as at-risk or potentially at-risk for prescription drug abuse under the drug management program, be unable to use the current special enrollment period (SEP) that allows month to month changes in plans.

Issue: CMS’ proposedSEP limitation is an important tool to reduce the opportunities for duals and LIS-eligible beneficiaries designated as at-risk to switch plans and ultimately avoid a drug management program. BCBSA agrees that limiting the SEP in this manner will help ensure that especially vulnerable at-risk beneficiaries receive needed care coordination to manage their potential or actual overutilization of frequently abused drugs.

Recommendation: BCBSA supports CMS’ proposal to limit this specific SEP for subsidy-eligible at-risk beneficiaries and recommends that CMS finalize these provisions as proposed.

**Other Operational Considerations**

In response to CMS’ proposals to operationalize program requirements under CARA, Plans also suggest a number of operational issues for CMS to consider:

* When implementing drug management program requirements under CARA, CMS should consider how federal regulations and guidance for drug management programs at the national level will interact with state-level prescription drug monitoring programs (PDMPs). According to the Centers for Disease Control and Prevention (CDC), these PDMPs “continue to be among the most promising state-level interventions to improve opioid prescribing, inform clinical practice, and protect patients at risk.”[[2]](#footnote-2) However, although the majority of states operate PDMPs that collect all dispensing data, including opioid prescriptions paid for with insurance and with cash, we understand only a handful of those states provide Part D plan sponsors access to these data. We strongly encourage CMS to consider how issues, such as Part D enrollees who pay cash for their prescriptions, may limit the effectiveness of a drug management program under Part D, and determine steps that could be taken to mitigate these challenges;
* While Plans do not have concerns with CMS’ proposal that prescribers with a shared TIN and pharmacy locations that share real-time electronic data be considered as only one prescriber/pharmacy, we note that CMS will need to provide additional instructions to ensure seamless implementation;
* CMS also proposes that in order for a plan sponsor to place a beneficiary in a drug management program, the sponsor must first obtain the agreement of the health care professional who prescribed the frequently abused drug to the beneficiary. Plans have some concerns about this requirement and its feasibility, and request CMS provide additional detail on how this interaction would have to be documented and what options plans would have if the prescriber does not agree to a pharmacy lock-in;
* The CARA legislation requires that the initial notice provided to an at-risk beneficiary provide information describing all State and Federal public health resources designed to address prescription drug abuse to which the beneficiary has access, including mental health services and other counseling services. In the proposed rule, CMS notes that it intends to develop language for this initial notice. We would like to take this opportunity to request that CMS provide templates for comment as soon as possible, and request that CMS also clarify whether MA-PD plans will be allowed to provide beneficiaries with information about mental health benefits and treatment options specific to their plan (in addition to State and Federal resources); and
* We also ask for clarity on the issue of patient consent in the sharing of the patient personal health information related to implementation of these provisions. We have concerns whether patient consent to sharing personal health information could be a stumbling block to implementation of CARA.

1. **Flexibility in Medicare Advantage Uniformity Requirements (§422.100(d))**

Proposal: CMS proposes to permit Medicare Advantage Organizations (MAOs) the ability to offer disease-tailored benefit designs, including the ability to reduce cost sharing for certain covered benefits, offer specific tailored supplemental benefits, and offer lower deductibles for their enrollees that meet specific medical criteria, provided that “similarly situated” individuals are all treated the same. For contract year 2019, CMS is considering issuing guidance clarifying the flexibility MA plans have to offer targeted supplemental benefits for their most medically vulnerable enrollees, and notes that this benefit and cost sharing flexibility applies to Part C benefits, but not Part D benefits.

Issue: This new flexibility, which builds on practices that are currently only allowed under the CMMI Value-Based Insurance Design (VBID) demonstration, is greatly appreciated and will contribute to more efficient delivery of care and increased beneficiary satisfaction with their coverage.

We have identified several areas where we request the agency to issue additional clarifications, either in the Final Rule or subsequent guidance:

* BCBSA requests that the agency issue guidance outlining in more detail the specific flexibilities that will be allowed for CY 2019;
* We also urge the agency to issue a memo that reinforces for plans what practices are allowed today as plans make their decisions in the coming months for CY 2019;
* Under the current VBID demonstration, plans are specifically prohibited from citing their participation in the demonstration or referencing specific benefits available in any pre-enrollment marketing materials. BCBSA strongly encourages CMS not to apply this same prohibition to the new flexibility proposed under §422.100(d). We believe in order to maximize the impact of this flexibility on improving beneficiaries’ health status, potential enrollees should be aware of any additional benefits or programs when selecting a plan;
* CMS states that in identifying eligible enrollees, an MA plan must use medical criteria that are “objective and measurable, and the enrollee must be diagnosed by a plan provider or have their existing diagnosis certified or affirmed by a plan provider.” We ask CMS to clarify whether these criteria would preclude a plan from using social determinants of health as a criterion for a tailored benefit. An example would be a beneficiary with a specified health condition who also lives alone or is low-income;
* CMS refers to “reducing” cost sharing for certain covered benefits and/or offering “lower” deductibles for enrollees that meet certain criteria. We request that CMS clarify whether plans would be allowed to fully eliminate (make $0) the plan level deductible and cost sharing, or would this flexibility be allowed only for reductions to a non-zero level; and
* Under the proposed flexibility, we request CMS confirm that a plan may reduce cost-sharing only for a subset of high-quality network providers as long as all members with the specified medical conditions receive the same lower cost sharing for using these providers.

Recommendation: BCBSA supports this proposal and recommends that CMS finalize provisions as proposed with the additional clarifications described above. In addition, in CY 2020, BCBSA recommends that CMS consider extending benefit flexibility to Part D as well as Part C. Benefit flexibility in both Part C and D can have a meaningful impact on improving beneficiaries’ health. We understand more flexibility is allowed under the CMMI VBID demonstrations for Part D, but these demonstrations often come with significant reporting and design limitations. Therefore we recommend parity for Part D with Part C in regulatory flexibility as to benefits.

1. **Segment Benefits Flexibility (§422.262(c)(2))**

Proposal: CMS proposes to allow MA plan segments to vary supplemental benefits, in addition to premium and cost sharing, as long as the benefits, premiums, and cost sharing are uniform within each segment (county-level portion) of a plan’s service area.

Issue: BCBSA appreciates this added flexibility which will promote efficient plan designs. As part of their commitment to high-quality care, many Plans are entering into risk or incentive arrangements with providers who are willing to fully focus on Plan members to help manage their medical conditions. Plans need flexibility to be able to drive members to high-quality provider partners through medical and supplemental benefit designs. Therefore, we encourage CMS to clarify whether this segmentation could be available from a sub-set of network providers. We believe that being able to offer lower cost-sharing to support these provider arrangements would benefit beneficiaries and contribute to CMS’ goal of constraining costs in the Medicare program.

Recommendation: BCBSA supports this proposal and recommends that CMS finalize these provisions with the additional clarifications around provider segmentation as described above.

1. **Maximum Out-of-Pocket Limits for Medicare Parts A and B Services (§§422.100 and 422.101)**

Proposal: CMS proposes to continue using the 85th and 95th percentiles of projected out-of-pocket (OOP) spending for the immediate future to set MA Maximum OOP (MOOP) limits, but proposes to amend current regulations to incorporate several new authorities primarily related to data and the applicable methodology. CMS also solicited comments on whether to include the use of MA encounter data to inform its decision-making on MOOP limits and whether additional regulation is needed to achieve CMS’ goals of setting and announcing annual presumptively discriminatory levels of cost sharing.

Issue: BCBSA would like to caution CMS against using encounter data to inform any policy making related to MOOP limits before the data are validated as being as accurate and complete as possible. Plans feel that the use of encounter data is a work in progress where some continued refinements might be necessary before such data can be seen as accurate and complete.

Recommendation: BCBSA generally supports this proposal with the caution noted above on the appropriate use of encounter data in setting MOOP limits for CY 2019.

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

Proposal: CMS proposes to amend §§422.100(f)(6) to clarify that the agency may use Medicare FFS data to establish appropriate cost sharing limits. CMS also notes they intend to use MA encounter data to inform patient utilization scenarios (for the purposes of identifying thresholds and standards that are not discriminatory) and solicits comment on whether to codify that use of MA encounter data.

Issue: Similar to our comment related to MOOP, BCBSA urges caution to as to using encounter data to inform any policy making related to cost sharing limits before the data are validated as accurate and complete as possible. There are current concerns with some aspects of using encounter data for this purpose.

Recommendation: BCBSA generally supports this proposal with the caution noted above and recommends additional discussion of this issue in the upcoming CY 2019 Call Letter and Rate Announcements which will allow for an additional comment period.

1. **Meaningful Differences in MA Bid Submission and Bid Review (§§422.254 and 422.256)**

Proposal: CMS proposes to eliminate the meaningful difference requirement for MA organizations (§§422.254(a)(4) and 422.256(b)(4)) beginning in CY 2019.

Issue: Under current regulations, benefit packages offered in the same area by the same organization must differ with respect to key plan characteristics such as premiums, cost-sharing, or benefits. This methodology forces MA organizations to design benefit packages to meet CMS standards rather than beneficiary needs. BCBSA agrees with CMS that removal of the current meaningful difference requirement will increase competition, innovation in benefit offerings, and provide beneficiaries with affordable plans tailored to their unique health care needs and financial situations.

Recommendation: BCBSA strongly recommends that CMS finalize the provisions as proposed.

In the future, if CMS considers establishing restrictions on the number of plans offered by each MAO in the same area in place of the meaningful difference requirement, we offer two suggestions. First, CMS should treat the availability of full-provider networks separately from plans that offer more limited network providers. Second, any limits should be imposed at the parent organization level rather than the marketing name level in order to avoid unfair competitive advantages by national plans that may be able to offer similar offerings under different company names.

1. **Coordination of Enrollment and Disenrollment through MA Organizations and Effective Dates of Coverage and Change of Coverage (§§422.66 and 422.68)**

CMS proposes requirements for multiple types of seamless or default enrollments related to conversion to Medicare. We address each of these enrollment issues separately:

**Default Enrollment for Dual Eligibles**

Proposal: CMS proposes to allow a parent company that operates a Medicaid managed care plan to automatically enroll Medicaid managed care enrollees newly eligible for Medicare into that company’s dual eligible Special Needs Plans (D-SNPs). This default enrollment would be subject to certain conditions, including state approval of the default enrollment process, ability of the individual to opt-out, sending required notices, and CMS approval.

Issue: BCBSA agrees with CMS that providing a seamless conversion for those transitioning from Medicaid managed care into a specialized MA plan can promote a smooth transition and continuity of care for complex beneficiaries. In light of the wide variation in the needs of this population, we request that CMS consider expanding the proposal to also allow default enrollment within the same parent company into Chronic Condition SNPs (C-SNPs) and Institutional SNPs (I-SNPs).

Furthermore, to ensure that seamless enrollment is truly seamless, BCBSA asks CMS to ensure that plans and states (as well as CMS itself) have clear guidance detailing their respective roles in the process, including when states must approve the process and what information will be shared. Timely and open communication between all parties will ensure that best experience for the member. In particular, the timing and accuracy of Medicare eligibility data from the state via the Medicare Modernization Act (MMA) file will be important to activate benefits and deliver notices on the correct dates.

Recommendation: BCBSA recommends that CMS finalize this provision and consider modifications to allow maximum flexibility for parent companies to identify the most appropriate SNP for newly eligible dual beneficiaries.

**Optional Simplified Election for Non-Medicare Members into MA**

Proposal: CMS proposes to establish a new and simplified opt-in election process, beginning in contract year 2019, which would be available to all MAOs for the MA enrollment of their commercial, Medicaid, or other non-Medicare plan members.

Issue: BCBSA appreciates CMS’ commitment to offering options to make enrollment in MA easier for the beneficiary to complete and for the MAO to process. However, we disagree that an opt-in process is the best mechanism. We acknowledge that CMS wants to preserve beneficiary choice. However, we believe that an opt-out proposal, with additional requirements and consumer protections, would be adequate while also promoting simplified enrollment for both beneficiaries and plans. Specifically, we would support an opt-out proposal that required:

* A minimum 3-Star rating for an MA plan to be eligible for this type of enrollment;
* Demonstration that a plan’s MA network is closely aligned with their commercial network in order to promote continuity of care; and
* Additional notification requirements to beneficiaries to ensure they are aware of their choices.

Recommendation: We recommend that CMS modify its proposal in order to continue to allow opt-out seamless conversion from commercial, Medicaid, or other non-Medicare plans subject to certain quality, network, and notification requirements. Plans have had favorable experiences in this area, as have their members, and we recommend that CMS continue to allow the current processes to remain in place with additional notice requirements and consumer protections.

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

Proposal: CMS is proposing a limited expansion of passive enrollment for full-dually eligible beneficiaries who are currently enrolled in an integrated D-SNP into another integrated D-SNP under certain circumstances when integrated care coverage would otherwise be disrupted.

Issue: BCBSA appreciates CMS’ proposal and intent to promote continuity of integrated coverage for dually eligible beneficiaries. However, we are concerned that this flexibility is too limited as proposed, especially given that the existence of highly integrated D-SNPs or FIDE SNPs are so limited today.

Recommendation: BCBSA supports CMS’ proposal and recommends finalizing it as proposed with the additional clarifications requested above. We recommend that CMS broaden eligibility to include all D-SNPs that have minimum quality standards and can demonstrate appropriate levels of integrated benefits. In addition, we request that CMS provide additional details on the proposed requirement at §422.60(g)(2)(ii) that in order to receive passive enrollment, a plan must have “substantially similar provider and facility networks” as the plan (or plans) from which the beneficiaries are passively enrolled. We ask CMS to share additional information on how it will assess whether networks are “substantially similar,” such as whether a percentage overlap will be required, and if so, what the percentage will be.

1. **Part D Tiering Exemptions (§§423.560, 423.578(a) and (c))**

Proposal: CMS seeks to clarify that eligibility for Part D tiering exceptions should be based on the lowest applicable cost sharing for the tier containing the alternative drug for treatment of an enrollees’ health condition in relation to the cost sharing of the requested, higher-cost drug.

Specifically, CMS proposes:

* To specify that a Part D plan sponsor would not be required to offer a tiering exception for a brand name drug to a preferred cost-sharing level that applies only to generic alternatives. However, 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, including when the preferred alternative is on a tier that includes only generic drugs or when the lower tier(s) contain a mix of brand and generic alternatives; and
* A plan 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.

Issue: BCBSA supports CMS’ efforts to clarify the tiering exceptions process and encourages CMS to continue to provide plan sponsors with clear and specific guidelines and examples to govern this process.

However, we are concerned with CMS’ proposal at §423.578(c)(ii) that tiering exceptions permit enrollees to access drugs at the lowest applicable cost sharing for the tier containing the preferred alternative drugs(s). This policy is inconsistent with existing guidance in Section 30.2.1 of Chapter 18 of the Prescription Drug Benefit Manual, which states that:

*If a plan utilizes a tiered cost-sharing structure to manage its Part D drug benefits, it must establish and maintain reasonable and complete exceptions procedures that permit enrollees to obtain a non-preferred drug in a higher cost-sharing tier at the more favorable cost-sharing terms applicable to drugs in a* lower *cost-sharing tier. (Emphasis added)*

We believe this change from “lower” to “lowest” represents a significant policy change that could have serious cost implications and the potential to eviscerate the entire tiering structure. It is clearly not required by statute at 1860D-4(g)(2), which simply specifies that a beneficiary enrolled in a Part D plan offering a tiered formulary may request an exception to the tier cost-sharing structure, but does not mention the right to access a drug at the lowest cost-sharing tier.

We have previously asked CMS to provide clarity on the meaning of “alternative drugs” for purposes of tiering exceptions. While we appreciate CMS’ clarification in this Rule, we believe it is important for CMS to further clarify that tiering exceptions for a preferred or formulary drug “for treatment of the same condition” should be limited to drugs within the same drug class for the same medically accepted indication. We have provided a specific example of this below, in which two drugs share an FDA approved indication for diabetes, but cannot be substituted for one another.

|  |  |  |  |
| --- | --- | --- | --- |
| Drug Name | FDA approved indication | Price | USP 7.0 |
| Metformin (immediate release tablets) | Management of Type 2 diabetes | $8.40/30 days (average maintenance dose) | Antidiabetic agent (oral) |
| Lantus vial | Management of Type 1 and Type 2 diabetes | $307/28 days (minimum dose) | Insulin |

In this example, the way the tiering exception language is currently written, a member could request and receive a significantly higher cost medication at the same cost-sharing as much lower cost drug. We do not believe this reflects statutory intent and would unnecessarily raise costs to Medicare.

Recommendation: We recommend that CMS revise its current proposal to: (1) allow plans to permit enrollees to access drugs at a lower tier, rather than the lowest, through the tiering exceptions process; and (2) clarify that tiering exceptions for a preferred or formulary drug “for treatment of the same condition” should be limited to drugs within the same drug class for the same medically accepted indication.

BCBSA also requests that CMS continue to provide clear and specific guidance on this complex process. In order to provide transparency to our beneficiaries, we request that CMS define the tier reductions that can be permitted in a grid based on the formulary tier design.

Finally, while not related to the tiering exceptions process discussed here, BCBSA would like to take this opportunity to reiterate our request for CMS to permit plan sponsors to offer a preferred and non-preferred specialty tier. As we noted in our April 2017 response to CMS’ Request for Information (RFI), this recommendation was endorsed by MedPAC in its June 2016 Report to Congress, could reduce the need for non-formulary exceptions, and could encourage beneficiaries to substitute lower-cost biosimilar products, resulting in more affordable care for Part D beneficiaries and lower costs to the Part D program.

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

Proposal: Under current regulations, all subsidy eligible beneficiaries (LIS and dual eligible) can make Part D enrollment changes throughout the year, unlike other Part D enrollees who generally may only switch plans during the annual enrollment period (AEP) each fall or if they qualify for an SEP. CMS has identified the significant unintended consequences with this continuous SEP and resulting plan movement, and proposes to amend §423.38(c)(4) to make the SEP for full-benefit dual eligible (FBDE) and other subsidy-eligible individuals available only in certain circumstances.

Issue: BCBSA agrees with the rationale discussed by CMS that a continuous SEP presents obstacles to efficient delivery of care as a continuous changing of plans can interfere with treatments and coordination of care among providers, health plans and states. It also hinders the ability of beneficiaries to benefit from case management and disease management, and diminishes incentives for plans to innovate and invest in serving potentially high-cost members.

Recommendation: BCBSA supports CMS’ proposal to establish limits on the number of SEPs a dual or subsidy-eligible may have and recommends that CMS finalize these provisions as proposed. Narrowing the scope of SEPs will positively impact beneficiaries, states, and plans.

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

There are a number of proposals related to the Star rating program in MA. We take this opportunity to discuss various components of the rating system in order to capture all issues, concerns and recommendations.

**Basis, Purpose, and General Applicability of the Quality Star Ratings System**

Proposal:CMS proposes to codify the current Part C and D Star Ratings system uses, methodology, measures, and data collection beginning with the measurement periods in CY 2019, which result in the 2021 Star Ratings and 2022 Quality Bonus Payments (QBPs). The current Star Ratings system and the procedures for revising measures would generally remain in place for the 2019 and 2020 Star Ratings, subject to changes made during the annual Call Letter process.

Issue:BCBSA has long advocated for the use of the formal federal notice and comment rulemaking process to propose and finalize changes to the Star Ratings system. We thank CMS for responding to this feedback and support the proposed policy to codify Star Ratings measures and methodology beginning with the 2019 measurement periods. BCBSA agrees that having codified regulations to govern the Star Ratings fosters the transparency and predictability needed to support continued investment in quality improvement activities and, more importantly, ensures beneficiaries can rely upon the Star Ratings as a true measure of quality and performance when selecting a plan.

Recommendation:BCBSA applauds CMS for moving towards a formal regulatory process for updating Star Ratings measurements and its methodology and recommends CMS finalize its proposed approach as proposed.

**Guiding Principles**

Proposal: CMS details a set of principles for enhancements to the MA and Part D Star Ratings. Many of these principles were incorporated into BCBSA’s RFI response on MA and Part D in 2017. These principles emphasize, among other things, alignment with the CMS Quality Strategy, provide for stability, accuracy and reliability, transparency, and fair and equal treatment of contracts.

Issue: BCBSA recognizes CMS’ efforts to increase transparency and expanded dialogue with plans and other stakeholders to ensure the Star Ratings system helps beneficiaries, families, and caregivers make informed choices; incentivizes quality improvement; provides information to oversee and monitor quality; and accurately measures and calculates scores and Stars to reflect true performance. The guiding principles CMS articulates will serve an important role in ensuring that the Star Ratings system continues to encourage improved health outcomes of beneficiaries in an efficient, person-centered, equitable, and high-quality manner.

Recommendation*:*  BCBSA agrees that the guiding principles outlined by CMS are most welcomed and appropriate to the program. We encourage CMS to rely on these guiding principles to ensure that any future changes to the Star Ratings create meaningful quality improvement incentives and differentiate options based on quality.

**Contract Ratings**

Proposal: CMS proposes to continue calculating overall and summary Star Ratings at the contract level, but requests comments on whether data reporting of ratings should be at a different level, such as at the plan benefit package (PBP) level, parent organization level, state level, etc. Some contracts have options located in different states or multiple types of options all under a single contract, leading MedPAC and others to raise questions about the best level to assign Star Ratings.

Issue:CMS notes that, because beneficiaries select a plan, rather than a contract, it has considered whether data should be collected and measures scored at the plan or PBP level. BCBSA appreciates this question, but notes that there are pros and cons associated with collecting data and measuring scores at the plan level. Both the positive and negative consequences of doing so must first be thoroughly evaluated. We recommend that CMS continue to calculate Star Ratings at the contract level at this time.

However, as CMS continues assessing data reporting at the PBP or other level, BCBSA recommends that plan-level quality reporting should be examined for *all* SNP types (not just D-SNPs), and each group of SNPs (I-SNP, D-SNP, and C-SNP) should have separate cut points for the measures. This would be similar to what CMS does today for cut points for MA-PDs and PDPs.

CMS should also provide simulation data—similar to what they have done in the past for the Categorical Adjustment Index, for example—that illustrates how the PBPs would perform if quality were reported at the plan level with separate cut points. It is critical to evaluate this data in order to provide comprehensive input on the most appropriate approach to PBP-level ratings.

Recommendation*:* CMS should continue the practice of calculating Star Ratings at the contract level for CY 2019 and 2020 but continue the discussion as to whether other levels are more appropriate for the beneficiary and the program overall. We know there have been discussions as to whether Stars should be assigned at the organizational level, the state level or other platforms.  BCBSA offers a unique perspective on this issue since many Blue Plans are single state organizations while others are national players. As a result, we strongly believe that this issue deserves additional study and any design must prioritize the assignment of Star Ratings in a way that is fair and equitable to all sponsors.

**Contract Consolidations**

Proposal*:* CMS proposes a new set of rules for the calculation of Star Ratings for consolidated contracts. In most cases, the Star Ratings for the first and second years following the consolidation would be an enrollment-weighted mean of the scores at the measure level for all contracts (that is, consumed and surviving contracts). For the QBP rating for the first year following the consolidation, CMS proposes to use the enrollment-weighted mean of the QBP rating of the surviving and consumed contracts (which would be the overall or summary rating depending on the plan type) rather than averaging measure scores. In subsequent years after the consolidation, CMS would determine QBP status based on the consolidated entity’s Star Ratings displayed on the Medicare Plan Finder (MPF).

Issue: BCBSA appreciates the steps CMS proposes to take to ensure the Star Ratings provide beneficiaries with accurate and reliable information for enrollment decisions, and that the system truly rewards higher quality contracts. The new methodology CMS proposes to calculate a consolidated contract’s Star Ratings, which will be effective for the 2019 measurement year, appears to be a well thought out change to today’s practices and will adequately address differences in how data are collected and submitted for certain measures during different periods.

Recommendation*:* BCBSA recommends that CMS finalize the approach as proposed, effective for the 2019 measurement year. The proposal seems fair and equitable to all stakeholders and we thank CMS for addressing this issue in a favorable manner.

**Data Sources**

Proposal: Currently, Star Ratings measures encompass data submitted directly by MAOs and Part D sponsors to CMS, surveys of MA and Part D enrollees, data collected by CMS contractors, and CMS administrative data. CMS proposes to establish authority to collect quality data and require sponsors to submit data that can be reliably used to calculate ratings and measure plan performance. CMS also asks whether it should include survey measures of physicians’ experiences in the Star Ratings.

Issue: While BCBSA agrees that providers are important stakeholders in the quality initiatives, we are very concerned with any CMS’ consideration for developing a survey to collect information on physicians’ experience with plans. As we have previously noted, the subjective nature of surveys means they may not be valid representations of value and performance. Physicians, and other health care providers, frequently state that they do not know the name or identify of the particular health plans in which their patients are enrolled, and would therefore be incapable of accurately and appropriately responding to such surveys. Furthermore, we note that providers may be employed by a health plan for which they must complete a survey, creating an un-level playing field across different plan types and different plan/provider employment arrangements. Physicians could also use such a survey tool to vent their personal opinions on their payment arrangements with a specific organization or their dissatisfaction with certain MA and Part D program requirements which could bias the survey results.

Recommendation*:* BCBSA strongly urges CMS to refrain from incorporating any physician surveys into the MA and Part D Star Ratings system.

**Adding, Updating, and Removing Measures**

Proposal:CMS proposes specific new rules and processes for adding, updating, and removing Star measures. New measures would be announced in advance of the measurement period through the annual Call Letter process, and then proposed through rulemaking. New measures would be kept on the display page for a minimum of 2 years.

Updates to existing measures would be based on whether the change was substantive or non-substantive. Substantive changes would be announced in advance of the measurement period and through the Call Letter process, and then proposed through rulemaking. The updated measure would be on the display page for a minimum of 2 years. Non-substantive changes would be announced through the Call Letter process.

Finally, removal of existing measures would be announced through the Call Letter process and in advance of the measurement period.

Issue*:* BCBSA has long recommended that CMS apply all modifications to the Star Ratings on a prospective basis, and that measures and their methodology be finalized prior to the start of the measurement period in order to give plans adequate notice. This transparency is critical for plans to meet the goals for performance that CMS expects and to ensure beneficiaries can rely upon the Star Ratings as a true measure of quality when selecting a plan.

Recommendation: BCBSA generally supports CMS’ rules for adding, updating, and removing measures and we are pleased with the recognition of the role of federal formal rulemaking. However, we recommend that CMS modify its approach for updating measures due to “non-substantive changes.” We recommend that all changes, even those labeled as “non-substantive” or “substantive” should also be subject to rulemaking.

**Weighting of Star Measures**

Proposal: CMS proposes to make patient experience measures triple weighted.

Issue: Patient experiences can be subjective and may not reflect the true performance of a plan.

Recommendation: BCBSA recommends that patient experience measures should be moved to a weight of 1 instead of 1.5. We do not believe that any survey measures should be triple weighted as scores can be skewed depending on the sample of beneficiaries in the surveys. HOS measures that are proposed to be triple weighted should also be reduced. Overall no patient reported measures should be weighted higher than 1.5. Patient reported data is not as reliable as claims, PDEs, charts and other data sources.

Proposal: CMS proposes to triple weight access measures.

Issue: Access measures can be seasonal and influenced by external factors and entail a number of operational areas and are not always able to be validated

Recommendation**:**  BCBSA recommends that access measures should continue to be weighted at a 1.5 level.

Proposal: BAPP measure should remain on the display page for two years as a revised measure.

Issue: Last year there was considerable discussion of this measure, and the need to remove audit and enforcement activities from it, and to have it be revised and on display for two years after revisions are completed.

Recommendation: BCBSA recommends that the BAPP measure be revised and displayed for two full years.

Proposal: CMS proposes to possibly add new measures that address the issue of new technologies, such a telemedicine and other areas.

Issue: “Use of new technologies” is not clearly defined and can span a number of technologies implemented across plans but not in a uniform manner or across all service areas.

Recommendation: BCBSA recommends that CMS continue to look at the use of new technologies as being incorporated into Star Measure but withhold any proposals for CY 2019 and CY 2020 until more formal proposals can be put forth for notice and comment prior to adoption.

**Improvement Measures**

Proposal*:* CMS currently calculates the improvement measures in determining a contract’s overall Star Rating, and follows a specific methodology for calculating the improvement measures themselves. While CMS proposes to continue the current methodology for calculating the improvement measures, which includes a hold harmless provision for 5-star contracts, CMS requests comments on the methodology.

Issue: The current approach can penalize high-performing plans as it does not separately consider the impact of improvement on the Part C rating and the Part D ratings. CMS should calculate plans’ Star Ratings separately for Part C and Part D with and without the improvement measures to first determine if the corresponding QI measure should be included in the overall Star Rating calculation. Currently, the “hold harmless” methodology accounts for both QI measures together. A more appropriate approach would follow the steps as outlined above. As an example:

*Example: Plan A (Current Policy)*

* Step 1: Overall rating with just Part C improvement measure = 3.683
* Step 2: Overall rating with just Part D improvement measure = 3.751
* Step 3: Overall rating without either improvement measure = 3.731
* Step 4: Overall rating with both improvement measures = 3.701
* Step 5: If an MA-PD contract in any steps 1 through 4 has four (3.75) or more Stars, CMS should use that overall rating – otherwise, CMS should use the overall rating from step 4. In this example, CMS would use the overall rating from Step 2 (include only the Part D improvement measure) = 3.751

CMS’ methodology for how QI measures are calculated should also be modified to include measures for which plans achieved and maintained at least 4 Stars in the “hold harmless” category. Though CMS compares year-over-year performance for all QI-eligible measures, the “hold harmless” provision only applies to those measures for which a plan scored 5 Stars for both years in the comparison (and is therefore deemed by CMS to be “not applicable” to the QI calculation). This deviates from the general rule CMS follows for “hold harmless,” where plans earning 4 Stars or higher are deemed “high performing.” Including measures with 4 Stars in both years would be a more appropriate approach.

Recommendation: BCBSA has several concerns with CMS’ current approach to the improvement measures, and recommends that CMS adopt changes in order to ensure that the measure rewards plans that improve their quality, while not adversely impacting consistently high-performing plans:

* CMS should either adjust its methodology by assigning “not applicable” when determining “Improvement, Decline, or No Change” (see Column U in the QI template) for measures that increased in Star Ratings for year two of the comparison, or add these measures to the “held harmless” provision. Because the “held harmless” provision is tied to raw rates, and does not consider the actual Star Rating earned (except in cases when a plan earned a 5 Star Rating in the prior year)—combined with the fact that CMS’ uses a clustering methodology for the cut points—a plan can improve its “earned” Star Rating while its raw rate declines year-over-year. This can lead to a “significant decline” in the QI calculation. For example: Plan A earned a 4 Star on the complaints measure (CTM) with a rate of 0.088 in 2017, and earned 5 Stars with a CTM rate of 0.142 in 2018. Because a lower score on this measure is preferable to a higher score, Plan A actually had a higher complaint rate in 2018, but earned a higher Star Rating. Since the QI calculation is based on raw rate performance, it results in a “significant decline.” We urge CMS to implement our recommended modification to this component of the methodology.
* Ensure that all MA plans that are subject to the improvement measure should be allowed to benefit from it. BCBSA does not support any proposal that would limit the application of the improvement measure to only those plans with Star Ratings greater than 2.5 Stars (or any other minimum threshold). Limiting the measure to only plans with more than 2.5 Stars goes against the objective of the improvement measure in encouraging and rewarding improvements in performance, particularly among lower-rated plans. This is important because plans with 2.5 Stars may have a disproportionate share of members who are low income, have low health literacy, or who are otherwise vulnerable and more difficult to reach. As a result, these plans may be struggling to make strides in the Star Ratings and should not be further disadvantaged by being excluded from the improvement measure.[[3]](#footnote-3)
* Remove CAHPS and HOS measures from the improvement factor calculation because survey data are based on respondents’ perceptions of their health status and thus are not a true reflection of plan performance or members’ outcomes. Plans should not be judged on perceptions, but rather on objective and clinically relevant outcomes. We also note that CMS has had challenges with its CAHPS vendor in recent years, particularly around sample selection, causing some plans to appeal their results as not statistically valid. If performed inconsistently, the improvement comparison will not be valid—further emphasizing the importance of excluding CAHPS and HOS measures from this calculation.
* Calculate MA plans’ Star Ratings separately for Part C and Part D with and without the improvement measures to first determine if the corresponding Quality Improvement (QI) measure should be included in the overall Star Rating calculation. We propose the following revision for Medicare Advantage Prescription Drug Plan (MA-PD) contracts:

1. Calculate the overall rating for MA-PD contracts with just the Part C improvement measure.
2. Calculate the overall rating for MA-PD contracts with just the Part D improvement measure.
3. Calculate the overall rating for MA-PD contracts *without* including either the Part C or the Part D improvement measures.
4. Calculate the overall rating for MA-PD contracts *with both* the Part C and Part D improvement measures.
5. If an MA-PD contract in any steps 1 through 4 has four or more Stars, CMS should use that overall rating—otherwise, CMS should use the overall rating from step 4.

* Modify the current methodology related to how QI measures are calculated to include measures for which plans achieved and maintained at least 4 Stars in the “held harmless” category.
* Ensure that MA plans that are subject to the improvement measure benefit from it.
* Remove the CAHPS survey and HOS measures from the improvement factor calculation given their subjectivity.

**Data Integrity**

Proposal*:* CMS proposes to codify existing rules for the reduction of measure ratings when CMS identifies incomplete, inaccurate, or biased data that have an impact on the accuracy, impartiality, or completeness of data used for the impacted measures. CMS also proposes a new rule for scaled reductions for appeals measures, based on the degree to which Independent Review Entity (IRE) data are missing.

Issue:BCBSA supports CMS’ high standard (95%) and agrees that it is appropriate to take reasonable steps to ensure data integrity in the Star Ratings. We continue to believe that distinguishing between generally well-functioning plans that may have an occasional data error versus plans that have significant, material errors due to major systemic issues is critical when assessing and rating plans based on the integrity of their data.

Recommendation:BCBSA supports CMS’ proposal to scale reductions for the appeals measures when there are data integrity issues. However, BCBSA urges CMS to provide additional information about how it will ensure equity between plans that are audited and plans that are not. We also recommend that CMS consider a proposal under which thresholds for errors in forwarding cases to the IRE are based on the number of errors relative to the enrollment level under a given contract. This would improve equity across plan sizes. For example, a contract with 100,000 may be allowed 50 IRE errors, but a contract with only 50,000 members may be allowed 25 IRE errors.

**Measure-Level Star Ratings**

Proposal:While CMS proposes a continuation of existing policy to establish cut points with use of clustering methodology for non-CAHPS measures and use of relative distribution and significance testing for CAHPS measures, CMS seeks comment on potential changes to the cut point methodology.

Issue:Given the significance of the Star Ratings on beneficiary enrollment decisions and plan payment, BCBSA continues to believe that sponsors need better information to benchmark performance and focus on improvement efforts. BCBSA commends CMS for seeking feedback on the most appropriate methods for determining the cut points.

Recommendation: BCBSA recommends that CMS reinstate predetermined four-Star thresholds. Removing the thresholds places undue emphasis on relative performance among plans, and not on whether a plan achieved the desired level of performance or quality. BCBSA would also recommend a methodology that minimizes year-to-year changes in the cut points by setting caps on the degree to which a measure’s cut point could change from one year to the next. Reinstating this kind of transparency and stability not only aligns with the guiding principles CMS describes for the Star Ratings, but facilitates plans’ collaboration efforts with provider networks by setting quality expectations and performance targets.

BCBSA strongly recommends that CMS restore the predetermined thresholds as they provide valuable stability, enable plans to track achievement, and demonstrate a sense of partnership with organizations.

**Categorical Adjustment Index (CAI)**

Proposal: CMS proposes to codify the current calculation and use of the CAI that adjusts for the average within-contract disparity in performance associated with the percentages of beneficiaries who receive a low-income subsidy (LIS) and/or are dual eligible and/or have disability status. CMS will continue to announce the set of measures for adjustment for determination of the CAI during the Call Letter process while measure stewards continue examining measure specifications and the Assistant Secretary for Planning and Evaluation (ASPE) completes its research and formalizes final recommendations.

Issue:BCBSA agrees that beneficiary-level characteristics have a meaningful impact on Star Ratings and that it is critical to allow plans that care for the program’s most vulnerable beneficiaries to compete on an equal playing field. However, in our experience, the CAI is insufficient to address this important problem. CMS has also acknowledged that the CAI has a very small impact on plan ratings.

Recommendation**:**BCBSA recommends that CMS continue to work with plans and other stakeholders to identify a meaningful, long-term solution to the impact of socioeconomic status (SES) and disability status on Star Ratings. While we appreciate CMS’ ongoing attention to and focus on the impact of beneficiary-level characteristics—specifically, dual status and socioeconomic factors—on plan performance, we understand that the CAI is a temporary solution. We strongly urge CMS to work quickly to evaluate the options recently proposed by Office of the Assistant Secretary for Planning and Evaluation (ASPE) and develop longer-term, meaningful adjustments.

**High and Low Performing Icons**

Proposal: CMS proposes to continue its current policy to identify high and low performing plans with an icon on the Medicare Plan finder and also to continue to disable the Plan finder online enrollment function for MA and Part D plans with the low performing icon and directed the beneficiary to contract the plan directly.

Issue: CMS asked the question: “Since CMS does allow low performing plans to continue in the program even with a 2.5 or lower Star rating, is the icon a good way to send a message to those “shopping for a plan.”

Recommendation: BCBSA believes that the low performing icon, along with other CMS policies related to enrollment in lower-rated plans, are sufficient for beneficiary information at this time.

**Plan Previews of Star Ratings**

Proposal: CMS attempts to codify in rule-making the current practice of allowing plans to have preview periods before each Star Rating release.

Issue: Previews are viewed as helpful opportunities for plans. BCBSA thanks the agency for this opportunity for plans to be able to review their Star ratings before their release.

Recommendation: BCBSA supports CMS’ proposals and urges its adoption as proposed in the final rule

1. **Any Willing Pharmacy Standards Terms and Conditions and Better Defining Pharmacy Types (§§423.100, 423.505)**

Proposal: CMS proposes to clarify (and modify) its interpretation of existing regulations to ensure that plan sponsors can continue to develop and maintain preferred pharmacy networks while fully complying with the any willing pharmacy requirement. Specifically, CMS clarifies that the any willing pharmacy requirement applies to all pharmacies, regardless of how they have organized one or more lines of pharmacy business; proposes to revise the definition of a retail pharmacy and add a definition of a mail-order pharmacy; clarifies regulatory requirements for what constitutes “reasonable and relevant” standard contract terms and conditions; and codifies existing guidance with respect to when a pharmacy must be provided with a plan sponsor’s standard terms and conditions.

Issue: With respect to the requirement that Part D sponsors have standard terms and conditions available for requesting pharmacies no later than September 15 of each year for the succeeding benefit year, we note that for many of Plans may have pharmacy network negotiations occur much earlier in the year, often by March or April for the following benefit year. We believe that CMS’ proposal to make terms and conditions available no later than September would therefore be acceptable and that most plans would provide these materials earlier than required.

BCBSA is concerned with the remaining provisions for a number of reasons. It is essential that Part D sponsors have the ability to put in place quality and other appropriate safeguards when developing networks of pharmacies to provide services to their members. CMS’ statements appear to be based on an inaccurate understanding of Part D network contracting, could interfere with plan and pharmacy negotiations, and attempt to establish new substantive standards. We believe that the current any willing pharmacy (AWP) rules and guidelines (dated August 13, 2015) provide the right balance between statutory requirements and flexibility for Part D sponsors. We disagree with CMS’ proposal to further define types of pharmacies, address accreditation, and define “similarly situated” pharmacies.

We note that, although many pharmacies share some of the same capabilities, some have higher performance levels (or different attributes) than others that drive contracting decisions. These include: availability and access for beneficiaries, availability of patient education, ability to perform medication assessments, tracking of adherence levels and meeting a certain volume threshold.

Specifically, CMS’ proposal would place retail pharmacy business interests above Medicare beneficiaries’ safety and comprise the ability of Part D plan sponsors to ensure that when Medicare beneficiaries choose to receive drugs delivered to their homes, they are receiving a consistent level of service, quality and safety regardless of which pharmacy fills and delivers their drugs. We are concerned by CMS’ suggestion that it is “inappropriate to classify pharmacies as ‘mail order pharmacies’ solely on the basis that they offer home delivery by mail”.

Dispensing and delivering drugs to an individuals’ home gives rise to unique quality, safety, privacy, and timeliness considerations as compared to retail dispensing. CMS explicitly recognized these considerations when it considered imposing its own timely delivery standards on mail order pharmacies. Timeliness of drug delivery is a critical factor for beneficiaries that rely on medications, and medication dispensing errors may be less easily identified without in-person pharmacy consultation. These factors make it imperative that a pharmacy offering home delivery has a closely monitored delivery mechanism and a comprehensive quality control process.

Large and highly automated mail order pharmacies that focus solely or primarily on this method of dispensing have designed processes to ensure that shipped drugs arrive timely and accurately, and have demonstrated substantially lower dispensing error rates than retail pharmacies. By comparison, retail pharmacies with a low volume of home delivery orders necessarily have a different focus than mail order pharmacies, and there is reason for caution in allowing them to experiment with this new business line with the Medicare population.  Because all mail order pharmacies deliver drugs to a member’s home and typically result in a uniform level of cost-sharing, there is not the same compelling interest in access to a wide variety of mail order pharmacies as there is with retail pharmacy access.  There is, however, a compelling interest in ensuring the safety and timeliness of drug delivery through the mail.

CMS’ Preamble statements regarding mail and retail pharmacy networks appear to be based on an assumption that Part D Plan Sponsors prohibit pharmacies from participating in their networks because they provide drugs through home delivery. This is not generally an accurate understanding of Part D pharmacy contracting practices.  Rather, it is more likely that a Part D Plan Sponsor would require a pharmacy that wants to receive payment for drugs delivered to a Medicare beneficiary’s home to meet certain terms and conditions relating to the quality, safety, and timeliness of such drug delivery as a condition of coverage of such drugs.

If a pharmacy is not able to meet such reasonable criteria, the pharmacy would typically only be able to receive payment for drugs delivered in the retail setting, but generally would not be entirely excluded from a Plan Sponsor’s entire pharmacy network.  It is well within Part D Plan Sponsor’s rights – and its obligations to Medicare beneficiaries and CMS – to impose these types of standards on network pharmacies seeking coverage for drugs dispensed to Medicare beneficiaries.

Section 1860D-4 of the Social Security Act permits Part D Plan Sponsors to establish “terms and conditions” as prerequisites for contracting with pharmacies and does not prohibit Sponsors from establishing different standards for mail and retail pharmacy services.  CMS requires that these terms and conditions must be “reasonable and relevant.”  CMS now suggests, in the Preamble to the Proposed Rule, that specific terms and conditions may not be permissible, without offering any specific basis for why they are not “reasonable and relevant.”

Regardless of a pharmacy’s primary line of business, it seems reasonable that if it is delivering drugs to a patient’s home, it would be required to meet the standards imposed by a Part D Plan Sponsor on other pharmacies that deliver drugs to patients’ homes, particularly when such standards relate to qualifications relevant to home delivery.  CMS’ preamble statements impermissibly seek to expand the statutory any willing pharmacy requirements beyond the agency’s statutory authority, in a way that inappropriately disincentives the imposition of high quality standards on drug delivery practices.

Recommendation: BCBSA recommends revising the timeframe under which Part D sponsors must make terms and conditions available to pharmacies to five business days rather than the proposed two-day timeframe. This proposed deadline is too limiting and will not allow for potential extenuating circumstances that might require additional time.

BCBSA also strongly recommends that CMS withdraw the remaining proposed changes to the AWP rules and guidelines to maintain the current well-functioning and competitive nature of the Part D program, which ensures that Part D sponsors can make pharmacy network decisions that best suit the needs of their members and plan operations.

1. **Changes to the Days’ Supply Required by the Part D Transition Process**

Proposal: Current regulations require that a Part D sponsor ensure certain enrollees have access to a temporary supply of their current medications within the first 90 days under a new plan by ensuring a temporary fill when an enrollee requests a fill of a non-formulary drug during that time period. In the outpatient setting, the supply must be for at least 30 days of medication, unless the prescription is written for less, and in the LTC setting, the supply must be for at least 91 and up to 98 days.

CMS proposes to make two changes to these regulations:

1. Shorten the required transition days’ supply in the LTC setting to the same supply currently required in the outpatient setting; and
2. Change the current required days’ transition supply in the outpatient setting from “30 days” to a month’s supply (this is in response to inquiries from plan sponsors regarding scenarios involving medications that do not easily add up to a 30 days’ supply when dispensed – e.g. drugs that are typically dispensed in 28-day packages)

Issue: BCBSA appreciates CMS’ proposal to shorten the transition day supply requirement in the LTC setting to align with the outpatient setting. With respect to the second proposal, Plans are concerned that requiring a “month’s” supply introduces more uncertainty for plans, since a calendar month can be greater than, equal to, or even less than 30 days. Therefore, we recommend that CMS clarify that a month would be considered 30 days unless packaging dictates otherwise. This would preserve a beneficiary’s ability to receive the full transition supply and prevent waste dispensing in the examples cited where drugs are typically dispensed in a 28-day package.

Recommendation: CMS should finalize the proposals with additional clarification regarding the definition of a month.

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

Proposal: CMS proposes to revise regulations to permit Part D sponsors to immediately remove or change the preferred or tiered cost-sharing of brand name drugs when the sponsor replaces the brand drug with (or adds to their formularies) therapeutically equivalent newly approved generics. CMS would permit these substitutions and changes to occur at any time without advance approval. CMS also proposes to decrease the number of days for enrollees’ notice and refill required when drug removal or changes in cost-sharing will affect enrollees.

Issue: BCBSA greatly appreciates the additional formulary flexibility that CMS proposes to offer Part D sponsors. However, some of our Plans would like CMS to consider removing the direct notice requirement to beneficiaries given that it repeats information already provided in the EOB. If CMS does ultimately require the provision of a direct notice, Plans ask CMS to reconsider the need to include information regarding how members can submit a coverage or tiering exception request. Plans believe that inclusion of this language could create unintended consequences, such as an expectation that a member would qualify for the exception without trying the generic.

Recommendation: BCBSA supports CMS’ proposals with the additional considerations described above.

1. **Treatment of Follow-on Biological Products as Generics for Non-LIS Catastrophic and LIS Cost Sharing**

Proposal: CMS proposes to revise the definition of generic drugs at §423.4 to include follow-on biological products approved under section 351(k) of the Public Health Service (PHS) Act solely for the purposes of non-LIS catastrophic and LIS cost sharing.

Issue: Currently, because biosimilar and interchangeable biological products do not meet CMS’ definition of a generic drug, they are subject the higher Part D maximum copayments for LIS beneficiaries and non-LIS enrollees in the catastrophic portion of the benefit. This creates a disincentive for beneficiaries to choose lower cost alternatives. Thus, CMS’ proposal will improve enrollee incentives to choose follow-on biological products over more expensive reference biological products, and will reduce costs to both Part D enrollees and the Part D program.

Recommendation: BCBSA supports CMS’ proposal and recommends finalizing these provisions as proposed.

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

Proposal: CMS proposes to eliminate the PDP Enhanced Alternative (EA) to EA meaningful difference requirement, while maintaining the clarification that enhanced plans be meaningfully different from the basic plan offered by a plan sponsor in the same service area. CMS also indicates 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.

Issue: In the past there have been restrictions on enhanced alternative plans that have kept innovation from the marketplace.

Recommendation: BCBSA supports CMS’ proposal and requests that the agency be transparent about, and allow sufficient stakeholder input on, any contemplated changes to the out-of-pocket cost (OOPC) method used to evaluate differences between basic and enhanced plans.

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

Proposal: BCBSA attaches a separate document that discusses our responses to the RFI regarding the application of manufacturer rebates and pharmacy price concessions at the point of sale (POS) in Part D.

Recommendation: BCBSA strongly recommends that CMS not move forward with adoption of these policies for a number of reasons outlined in our response. BCBSA opposes adoption of POS rebates. We thank the agency for the opportunity to comment and not have these issues as proposals in the Rule. We urge additional discussion on ways to reduce costs for medications for beneficiaries and the government.

**Section B: Improving the CMS Customer Experience**

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

Proposal: CMS proposes to codify the implementation of the new open enrollment period as required by the 21st Century Cures Act.

Issue: BCBSA opposed passage of this provision by the Congress as the current 45 day open enrollment period was sufficient but we understand the agency’s responsibility now to codify these provisions in rulemaking.

Recommendation: In the final rule BCBSA asks the agency to clarify in detail who is eligible to exercise their right to use this new and extended open enrollment period and how such a change in enrollment also affects a new enrollment in Part D if the beneficiary returns to FFS. Specifically, we request CMS clarify whether the OEP is open to all MA enrollees, including those who had an opportunity to make changes to their MA plan selection during the previous fall Annual Enrollment Period (AEP) and elected not to. We believe that allowing these beneficiaries to use a secondary open enrollment period for those already enrolled in an MA plan for the entire previous year could result in inappropriate “gaming” and urge CMS to consider a more narrow interpretation of the eligibility and/or mechanisms to monitor abuse of this provision.

We also request CMS to issue guidance or amend the enrollment manual as soon as possible to detail the changes allowed under this provision as they relate to also disenrolling from an MA plan and returning to FFS and the subsequent ability to elect a Part D plan and the effective dates for such terminations and changes.  This would be helpful in implementation of this new provision. Finally, we request that CMS clarify how it proposes to prohibit “unsolicited marketing materials” during the new OEP.

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

Proposal: CMS proposes to reduce the federal compliance training requirements for certain provider and entities that contract with MA and Part D plans.

Issue: The current training and tracking of compliance training was a burden to plans and affected providers and entities in terms of tracking compliance.

Recommendation: BCBSA thanks the agency for this proposal and recommends that it be adopted as proposed.

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

Proposal: CMS proposes to eliminate the requirement to renew a three year waiver annually for those plans that have minimum enrollment.

Issue: The current process was burdensome to plans with an annual renewal process.

Recommendation: BCBSA thanks the agency for the re-evaluation of these requirements and recommends the provision be adopted as proposed.

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

Proposal: CMS proposes to change disclosure requirements related to the EOC and ANOC and provide more use of electronic delivery of documents.

Issue: Currently the timelines for mailing the ANOC and EOC to members need improvements to meet marketplace demands since the use of electronic delivery was limited. This proposed provision will increase administrative flexibility and save overall administrative costs.

Recommendation: BCBSA thanks CMS for these changes and recommends that the proposals be adopted as proposed.

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

Proposal: CMS proposes to narrow the definition of marketing, define communication materials and activities, and also asks for comments on marketing for those who have not yet been enrolled in plans during the OEP and might want to exercise their right to enroll in the new open enrollment period beginning in CY 2019.

Issue: Plans have always had concerns with the amount of regulation around the issue of marketing and communications related to materials and activities, how each was defined and what materials and activities needed CMS approval in advance.

Recommendation: BCBSA thanks CMS for defining these areas and the materials that need CMS approval and recommends that CMS adopt the provisions as proposed which will greatly streamline requirements for Plans. In the final rule, Plans would appreciate if CMS could provide additional clarification on the new terms through specific examples of activities that are described by each term. In light of these changes and the significant impact to 2019 materials, CMS should release the 2019 Marketing Guidelines no later than 4/1/2018.

With regards to the new open enrollment period created by Congress, we have concerns that certain parties might use the new open enrollment period solely as a means to secure new agent and broker commissions. BCBSA believes that CMS should put guardrails around the materials that can be used during this period and to whom they may be targeted. BCBSA recommends that marketing be targeted to avoid any confusion or disruption to the millions of current MA members who are happy with their plan section and are not interested in changing plans.

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

Proposal: CMS proposes to change the timeline for issuing decisions on payment redeterminations from 7 calendar days from the date the plan sponsor receives the request to 14 calendar days from the date the plan sponsor receives the request.

Issue: Plans have frequently advocated for more time to issue payment redeterminations and this change in timelines will allow Plans to have more time to process all information related these payment redeterminations. This in turn should allow for more informed decision-making and could also benefit the beneficiary as there will be more time to assess the specific redetermination.

Recommendation: BCBSA thanks CMS for this proposal and recommends it be adopted as proposed.

1. **Elimination of MA Plan Notice for Cases Sent to the IRE (§422.590)**

Proposal: CMS proposes to eliminate a plan notice to a beneficiary that duplicates a notice sent by the IRE as to the member’s case.

Issue: A notice from the IRE and the Plan was costly and duplicative and often confusing to the member.

Recommendation: BCBSA supports the elimination of the Plan’s notice and thanks CMS for elimination of this notice and recommends that CMS adopt the provision as proposed.

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

Proposal: CMS proposes to adopt updated e-prescribing standards.

Issue: There is a need for the industry to update e-prescribing standards.

Recommendation: BCBSA thanks CMS for recognizing the need to update standards and recommends that CMS adopt this provision as proposed**.**

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

Proposal: CMS proposes to reduce the past performance review period from 14 to 12 months.

Issue: In the past Plans believed that the 14-month look back period was not realistic.

Recommendation: BCBSA thanks CMS for this change and recommends that CMS adopt this provision as proposed.

1. **Part D Prescriber Preclusion List and Part C/Medicare Advantage Cost Plan and PACE Preclusion List**

Proposal: CMS proposes to eliminate the prescriber enrollment requirements, scheduled to take effect on January 1, 2019, and to replace those requirements with requirements for plan sponsors to reject claims for Part D drugs prescribed by providers on a preclusion list.

Similarly, CMS proposes to eliminate the provider enrollment requirement (also scheduled to take effect in 2019) and impose a preclusion list requirement. MA/PDs would be prohibited from making payments for an item or service furnished by an individual or entity on the preclusion list for both basic and supplemental benefits.

Issue: Given ongoing concerns about the burden associated with CMS’ enrollment requirements for affected providers and suppliers, as well as the potential for negative downstream implications for beneficiaries, we agree with CMS’ decision to eliminate those requirements. While the preclusion list should mitigate many stakeholders’ previous concerns, BCBSA requests that CMS develop, in consultation with plans, providers, and other stakeholders, more detailed guidance on how the preclusion list would actually work at the point of sale to avoid beneficiary disruptions. In addition, Plans request that CMS provide the list as soon as possible prior to implementation, and provide clarification on how this list differs from the sanctions list and how often it will be refreshed.

Recommendation: BCBSA also asks that CMS confirm that elimination of the federal provider enrollment requirement will not bar plans from requiring providers to be enrolled in Medicare as a requirement of our contracts with them if a plan decides to have such a policy.

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

Proposal: Current CMS regulations require MA organizations to have ongoing Quality Improvement Projects (QIPs) and a Chronic Care Improvement Project (CCIP) as part of their overall QIP. CMS proposes to eliminate the QIP requirement, but retain the CCIP requirement for MA organizations to address populations identified by CMS.

Issue: Based on evaluation of annual plan reported updates of the QIPs and CCIPs, CMS believes that the QIPs do not add significant value and are duplicative of other plan activities undertaken to meet requirements. Plans agree that this proposal will reduce redundant or duplicative requirements and allow MA organizations to remain focused on existing health improvement initiatives.

Recommendation: BCBSA supports this CMS’ proposal to eliminate the QIP requirement and recommends it be adopted as proposed in the final rule.

1. **Reducing Provider Burden – Comment Solicitation**

Proposal: CMS solicits feedback from the industry as to how to reduce provider burdens in the Medicare Advantage and Part D programs.

Issue: BCBSA believes that many providers do not always agree with some of the rules and regulations associated with participating in MA and Part D. These provider concerns can stem from plan requirements, such as requesting prior authorization for certain services, being asked to provide documents for risk adjustment audits or purposes, following coverage determinations and appeals processes, etc.

CMS is required by law to adjust payments to MA organizations for their enrollees’ risk factors, such as age, disability status, gender, institutional status, and health status. To this end, MA organizations are required in regulation to submit risk adjustment data to CMS to characterize the context and purposes of items and services provided to enrollees. Risk adjustment data that is submitted must be documented in the medical record, and upon request, MA organizations are required to submit medical records to validate the risk adjustment data. Thus, Plans may include in their contracts with providers, suppliers, physicians, and other practitioners, provisions that require submission of complete and accurate risk adjustment data as required by CMS. As CMS evaluates ways to reduce provider burden, BCBSA encourages CMS to hold up these laws and requirements to ensure a functional and accurate risk adjustment system.

In addition, BCBSA notes that 42 CFR 422. 310(e) states: “Validation of risk adjustment data. MA organizations and their providers and practitioners will be required to submit a sample of medical records for the validation of risk adjustment data, as required by CMS. There may be penalties for submission of false data.”

Recommendation: BCBSA requests that CMS revise this language, as follows (proposed revisions in italics), to support the risk adjustment data validation process:

“Validation of risk adjustment data. MA organizations and their providers and practitioners will be required to submit a sample of medical records for the validation of risk adjustment data, as required by CMS *or at the request of the MA organization*. There may be penalties for submission of false data. *Providers may seek reasonable reimbursement as determined by the Plan for the cost of these medical record request and shall respond to such request within thirty (30) calendar days*.”

Furthermore, to facilitate access to medical records, CMS should require providers to provide access to electronic medical records systems. Alternatively, CMS should allow Plans’ contracts with providers to include this requirement as a term of the contract. BCBSA notes that this may require coordination with other agencies to ensure such access is compliant with privacy and security rules. CMS could also consider a pilot year to evaluate traditional methods for collecting medical records compared to an EMR-only access pilot in order to compare results, process improvement, and provider burden.

Finally, while BCBSA supports CMS’ ongoing focus on ensuring provider directories are accurate for Medicare beneficiaries and their caregivers, plans continue to have significant concerns with the corresponding expectations and requirements put forth by CMS, including the burden they place on providers. We agree that timely dissemination of comprehensive and correct consumer information is important and thus we continually work to ensure a high-quality consumer experience. However, CMS’ current rules around the information required in MA plan directories, the timeframe for directory updates, and quarterly outreach to providers for validation are overly burdensome and duplicative, detrimentally impacting plans, providers, and beneficiaries. The outbound outreach in particular has caused significant process and operational work impacting our ability to focus on more proactive provider education/communication campaigns. In addition, since providers receive these inquiries not just from BCBS Plans but from other plans as well, this creates a significant administrative burden that leads to provider abrasion. CMS should adopt a goal of limiting duplicative transactions and streamline processes impacting providers. BCBSA believes a more efficient process would be for CMS to require providers to submit updates directly to CMS and to make this data available to MAOs and beneficiaries. Providers have a higher level of responsiveness to CMS and this centralized process would eliminate the need for duplication of administrative queries to providers.

**Section C: Implementing Other Changes**

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

Proposal: CMS proposes to allow MA and Part D plans to streamline their MLR reporting and also include fraud prevention activities and Medication Therapy Management (MTM) activities as eligible quality improvement activities included in the calculations of their MLR.

Issue: BCBSA is very pleased to see streamlined reporting as well as the expanded definition of quality improvements.

Recommendation: BCBSA fully supports the adoption of this provision as proposed in the final rule and thanks the agency for this change.

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

Proposal: CMS proposes technical changes to correct an inconsistency in current regulatory text.

Recommendation: BCBSA does not have any comments on this proposal.

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

Proposal: CMS proposes 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.

Recommendation: BCBSA does not have any comments on this proposal.

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

Proposal: CMS proposes technical changes to clarify inconsistencies in current regulatory text.

Recommendation: BCBSA does not have any comments on this proposal.

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

Proposal: CMS proposes change to regulatory requirements for MA plans that operate physician incentive plans (PIPs).

Recommendation: BCBSA does not have any comments on this proposal.

1. **Changes to Agent/Broker Compensation Requirements (§§422.2274 and 423.2274) and Changes to Agent/Broker Requirements ((§§422.2272(e) and 423.2272(e))**

Proposal: CMS proposes to delete rules that limit what MA organizations and Part D sponsors can do when they have discovered that a previously licensed agent/broker has become unlicensed. CMS also proposes several technical changes to align the agent/broker compensation requirements with the changes made in a 2014 final rule.

Recommendation: BCBSA does not have any comments on this proposal.

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

Proposal: CMS proposes to codify existing policy that premium adjustments count as initial determinations for appeals purposes, but Part D late enrollment penalties and re-enrollment penalties do not.

Recommendation: BCBSA does not have any comments on this proposal.

1. **Eliminate Use of Term “Non-renewal” to refer to a CMS-initiated termination (§§422.506, 422.510, 423.507, and 423.409)**

Proposal: CMS proposes to remove the term “CMS initiated non-renewal” and define the term “non-renewal” to include actions initiated by the plan sponsor (and not by CMS). Actions initiated by CMS would be referred to as terminations.

Issue: Some Plans would like to ask CMS to clarify if this change would prohibit MAOs from expanding or marketing other plans in the service area in which one of its plans was terminated or non-renewed. CMS should also clarify how this change would be displayed on Medicare.gov.

Recommendation: BCBSA supports adoption of this provision with requested clarifications as described above.

**Attachment I**

**BCBSA Response to the CMS Request for Information Regarding the Application of Manufacturer Rebates and Pharmacy Price Concessions to Drug Prices at the Point of Sale**

1. **Point of Sale Rebates**

**Background and Issue**

The Proposed Rule includes an RFI on the issue of point of sale (POS) rebates in Part D and the value or concerns with advancing a policy that pharmaceutical rebates would be passed on to the consumer at the point of sale.

As stakeholders look to solutions to curb the rising costs of pharmaceuticals and its impact of beneficiaries, BCBSA believes that rebates need to be seen in the context of the Part D program overall and the role that rebates play in plan designs, premiums, and cost sharing. POS rebates must be viewed in the context of how PBMs work with manufacturers and the flow of dollars from one to the other and then to the consumer. POS rebates may sound like a simple solution to high costs to the beneficiary and the government, but one needs to peel back how the Part D program works to better understand the issues in play.

BCBSA was pleased to see CMS focus on this POS issues in an RFI rather than a proposed policy change. BCBSA was also pleased to see CMS continued to allow plan sponsors the option to use the price concessions they negotiate with manufacturers and pharmacies to reduce premiums and other operation/administrative costs. The proposed rule addresses both the point-of-sale rebates and direct and indirect remuneration (DIR) issues through a Request for Information (RFI) rather than a requirement.

According to CMS, requiring plans to estimate and apply manufacturer rebates at the point-of-sale would raise premiums by up to $28 billion (or nearly $44 per beneficiary per month) and taxpayer costs by up to $82 billion over the next decade. Such a requirement would also create a windfall for manufacturers, who would pay up to $29 billion less in “donut-hole” discounts.”

This CMS assessment points in the direction of concluding that POS rebates would lower costs for a few but overall translate into higher Part D premiums and higher costs to the government, both of which are negative factors in the POS rebate policy debate.

**BCBSA Recommendation**

BCBSA opposes point of sale rebates as a Part D policy because the projected impact on adoption of such a policy on beneficiaries and the government. Adopting a policy that is estimated to cost the government $82 billion and increase premiums by over $28 billion over the next decade is not a solution.

While posed as a simple solution to lowering costs, such a policy will increase costs overall and reduce the affordability of Part D options in the marketplace. Such a policy might benefit only some beneficiaries, raising equity issues. Also Part D is a competitive program and POS rebates could expose proprietary information on relationships between PBMs, sponsors, and/or manufacturers that would hinder the competitive nature of Part D, a program that is frequently called out as a “marketplace success” where consumer can find value based on choice and costs.

Finally, implementation of POS rebates would create serious operational challenges for all parties involved (plans, pharmaceutical manufacturers, and PBMs), none of whom have the current appropriate infrastructure. CMS would need to provide detailed guidance on significant, unaddressed issues that would materially impact sponsor IT systems, bids, reporting, contracting with manufacturers and pharmacies, beneficiary notices and other materials, and more. In addition, a POS rebate system could cause confusion for beneficiaries, who may experience month-to-month changes to their copays as a result of fluctuating contract terms.

1. **Pharmacy Price Concessions**

**Background on Indirect and Direct Remuneration (“DIR”) in Part D**

“DIR” stands for “direct and indirect remuneration” and is a term used by the Centers for Medicare and Medicaid Services (CMS) related to the Medicare Prescription Drug (Part D) benefit. DIR addresses price concessions (e.g. drug manufacturer rebates) that impact the gross prescription drug costs of Medicare Part D plans that are not captured at the point of sale. Plans/PBMs are required to submit an annual “DIR” report to CMS, which is used by CMS in tandem with Prescription Drug Event (PDE) data to “true up” what is paid to a Medicare Part D plan by CMS for a given plan year.

**“**DIR Fee” is also used to describe arrangements between Plans/PBMs and pharmacies – a “catch-all” term designed to encompass different types of “fees” including “pay to play” fees for pharmacy network participation as well as periodic reimbursement reconciliations. For example, Plans/PBMs have used the term “DIR Fee” to describe a “true-up” between a target reimbursement rate in a participating pharmacy agreement and the aggregated effective rate actually realized by a pharmacy as well as a “true up” between the aggregate MAC/adjudicated rate and the aggregate contracted rate. In addition, the term “DIR fee” is also used to refer to a payment mechanism to pharmacies for the fulfillment of various quality measures or alternately a fee assessed to pharmacies for non-compliance with quality measures. These fees are collected from pharmacies after claim adjudications.

As mentioned above, “DIR fee” is simply the terminology that Plans/PBMs are currently using to categorize certain pharmacy network participation fees and the reconciliation of certain contractual terms with actual reimbursement. When CMS defined DIR and mandated the annual reporting of DIR, the intent was mainly to capture rebates from pharmaceutical manufacturers to Plans/PBMs related to formulary positioning and other similar remuneration which impacts a Medicare Part D plan’s gross prescription drug cost that is not passed through at the point of sale.

“DIR fees” are now used to describe the types of fees charged by Plans/PBMs to pharmacies under this terminology. The fees themselves are legitimate; however, some in the pharmacy community argue that there does not seem to be adequate disclosure to the pharmacies or the contracting entities by the Plan/PBM as to exactly how these fees are calculated either at contract initiation or at the time these fees are assessed and reported to the pharmacy or contracting entity. The detail level of the disclosure of assessed DIR fees varies based on the information provided by the Plan/PBM. As such, affected pharmacies now call for more transparency around “DIR Fees”.

**As with POS rebates, CMS solicits comments on Pharmacy Price Concessions in the RFI:**

In the RFI CMS states that a growing proportion of Part D sponsors and their contracted PBMs have entered into payment arrangements with network pharmacies in which a pharmacy’s reimbursement for a covered Part D drug is adjusted after the POS based on the pharmacy’s performance on various measures defined by the sponsor or its PBM.

There are in general two forms of pharmacy payment adjustments:

* + Pharmacy price concessions: Plans and PBMs recouping sums from network pharmacies after the point of sale for “poor performance” relative to defined standards
  + Pharmacy incentive payments: Sums paid to network pharmacies after the point of sale for “high performance” relative to defined standards

In a 2014 final rule, CMS amended the definition of “negotiated prices” to require sponsors to include in the negotiated price at the point of sale all pharmacy price concessions, with an exception, which was intended to be narrow, allowing for contingent pharmacy payment adjustments that cannot reasonably be determined at the point of sale.

CMS is soliciting comment on how they might update the requirements governing the determination of negotiated prices to better reflect current pharmacy payment arrangements. They describe one potential approach for doing this, and seek comments on this approach as well as any alternatives:

* + Revising the definition of negotiated price at 423.100 to remove the reasonably determined exception and 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;
  + Requiring the negotiated price to reflect the lowest possible reimbursement that a network pharmacy could receive from a particular Part D sponsor for a covered Part D drug *(CMS believes this would provide a standardized way for plan sponsors to treat the unknown (final pharmacy performance) at the point of sale under a performance-based contract);* Alternatively, CMS is also considering requiring that all contingent incentive payments be excluded from the negotiated price in order to avoid a scenario where drug prices appear higher at a high performing pharmacy than a low performing one.

CMS notes in the impact tables in the proposed rule that price concessions would reduce total beneficiary costs by about $10 billion over 2019-2028 (by reducing cost sharing by $16 billion and increasing premiums by $5.7 billion), increase costs to the government by about $16 billion, and reduce manufacturer liability by about $5 billion.

**BCBSA Recommendation:** BCBSA is opposed to any policy that would require direct and indirect remuneration (DIR) payments to be paid at the point of sale. We believe this would be a step in the wrong direction that would impede a move towards performance-based payments to reward value with network pharmacies that add to quality in Part D through such initiatives as increasing generic dispensing, reducing inappropriate use, and improving medication management and adherence. Performance of a pharmacy is an “after the fact” used with quarterly or annually assessments. These assessments cannot be calculated at the point of sale as they stem from contracts acknowledged in advance by pharmacies in their negotiations with a Pharmacy Benefit Manager and are rewards, not at the point of sale, but after an assessment of their performance.

In closing, while we commend CMS for their outreach to the industry to assess changes in Part D policies, neither of these proposed policies will advance the goal we all share: to have lower costs of medications on the part of manufactures that can be passed on to Part D beneficiaries in a meaningful way. Stakeholders must work together to ensure patient access to safe, effective and affordable medications by reducing barriers that limit competition and consumer choice; promoting greater transparency and sharing of information regarding the pricing of medications; provide medical and health care professional with the tools they need to support patient education and adherence; and promote regulatory changes that help patients get the right medicine at the most affordable prices.

POS rebates and price concessions at the point of sale will not meet those goals, and in some cases, will harm beneficiaries with higher Part D premiums and higher costs to the government.

**Attachment II**

**Legal Opinion on Opioid Prescription Limits**

**MEMORANDUM**

December 11, 2017

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| --- | --- |
| TO: | Blue Cross Blue Shield Association |
|  |  |
| FROM: | Tammy Killion  Lisa Lowenstein  Groom Law Group |
|  |  |
| RE: | Opioid Prescription Limits for Medicare Part D Plan Sponsors |
|  |  |
|  |  |

You have asked whether the Centers for Medicare and Medicaid Services (“CMS”) has the authority to allow Medicare Part D plan sponsors to limit the first prescription for short-acting opioids to a 7-day supply. This policy would be implemented as a point-of-sale (“POS”) “edit,” would limit the first prescription fill to 7 days, would limit further fills to a 14-day supply per 30 days, and would not apply for cancer-related pain, terminal conditions, and beneficiaries receiving palliative/ end-of- life care. The plan that designed this policy based it on specifications from the Centers for Disease Control and Prevention (“CDC”) guidelines, and believes the design limit necessary to help stem the opioid overuse epidemic.

The CDC prescribing guidelines for opioids state that

When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed.[[4]](#footnote-4)

At the same time, states,[[5]](#footnote-5) Congress[[6]](#footnote-6) and stakeholders[[7]](#footnote-7) have also taken specific steps to combat the opioid abuse epidemic, including by limiting prescription fills of opioids to 7 days, except for certain populations (*e.g.*, cancer patients). However, CMS has indicated to one of your plans that it will not permit Medicare Part D plan sponsors to impose these types of quantity limits on initial opioid fills at POS.

We have identified no statutory provision that prohibits CMS from allowing Medicare Part D plan sponsors from imposing initial POS quantity limits for all beneficiaries across a Medicare Part D plan. Further, the current regulations and subregulatory guidance you provided[[8]](#footnote-8) suggest that such policies may already be permitted by CMS. As a result, we conclude that CMS has the authority to clarify its current guidance to explicitly provide that Part D plan sponsors may impose quantity limits on initial opioid fills, as long as the limits comply with other preexisting requirements (e.g., are nondiscriminatory, reasonable, and appropriate).

We detail our analysis below.

1. **Statutory Provisions**

Section 1860D-4(c) of the Social Security Act (the “Act”), as amended, establishes utilization management provisions for prescription drug plans offered by Medicare Part D plan sponsors (also known as prescription PDP sponsors). Specifically, the Act directs Part D plans sponsors to have

[a] cost-effective drug utilization management program … [q]uality assurance measures and systems to reduce medication errors and adverse drug interactions and improve medication use, [a] medication therapy management program … [a] program to control fraud, abuse, and waste … [and a] utilization management tool to prevent drug abuse …

Act § 1860D-4(c)(1).

On July 22, 2016, the Comprehensive Addiction and Recovery Act of 2016 (“CARA”) was signed into law and added additional provisions to the Act regarding opioid utilization management for PDP sponsors, which will go into effect for plan years beginning on or after January 1, 2019. Pub. L. 114-198. CARA section 704(b) added the requirement to the Act that a PDP sponsor shall have, in addition to other programs, “[a] utilization management tool to prevent drug abuse.” Act § 1860D-4(c)(1)(E). The tool is considered to be:

*any* of the following: (i) *A utilization tool designed to prevent the abuse of frequently abused drugs by individuals and to prevent the diversion of such drugs at pharmacies*. (ii) Retrospective utilization review to identify— (I) individuals that receive frequently abused drugs at a frequency or in amounts that are not clinically appropriate; and (II) providers of services or suppliers that may facilitate the abuse or diversion of frequently abused drugs by beneficiaries. (iii) Consultation with the contractor described in subparagraph (B) to verify if an individual enrolling in a prescription drug plan offered by a PDP sponsor has been previously identified by another PDP sponsor as an individual described in clause (ii)(I). . . .

Act § 1860D-4(c)(6)(A), as added by CARA § 704(b) (emphasis added).[[9]](#footnote-9)

1. **Regulations and Subregulatory Guidance**

The Medicare Part D program was established through the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (“MMA”), Pub. L. 108–173 (Dec. 8, 2003). Soon after the MMA passed, CMS finalized a rule establishing general drug utilization management requirements. Medicare Prescription Drug Benefit Final Rule, 70 Fed. Reg. 4193, 4277-78 (Jan. 28, 2005) (“Final Rule”). Specifically, the Final Rule[[10]](#footnote-10) established the current policy for drug utilization management, requiring that a Part D plan sponsor must have:

. . . a reasonable and appropriate drug utilization management program that address *all* of the following: (1) Includes incentives to reduce costs when medically appropriate. (2) *Maintains policies and systems to assist in preventing over-utilization and under-utilization of prescribed medications*. (3) Provides CMS with information concerning the procedures and performance of its drug utilization management program, according to guidelines specified by CMS. (4) [with some exceptions] . . . establishes a daily cost-sharing rate.

42 CFR § 423.153(b)(emphasis added).

In addition, the preamble to the Final Rule suggests that CMS intends for this regulatory provision to provide “flexibility to Part D sponsors in their design of drug utilization management.” Final Rule at 4277. CMS declined to adopt further utilization management specifications in the Final Rule, but it emphasized that “all drug utilization management techniques must be medically appropriate, and § 423.153(b) requires the utilization management program established by plans to be ‘reasonable and appropriate.’” While CMS has not changed the regulation text since this Final Rule was published in 2005, CMS has published guidance – both via call letters and otherwise – regarding utilization management programs for Medicare Part D plan sponsors.[[11]](#footnote-11)

In addition to its general drug utilization management requirements, CMS has required Part D plan sponsors to manage opioid overutilization in particular, within their prescription drug plans.[[12]](#footnote-12) For example, in the 2013 Call Letter,[[13]](#footnote-13) CMS said:

Part D sponsors either already have, or should have, the existing expertise to address significant patterns of overutilization, and we are setting forth in this section how sponsors can use that expertise in ways some may not have thought permissible, have not previously considered, or have not implemented adequately

CY 2013 Final Call Letter at p. 132.

CMS’s efforts to control opioid misuse and overuse continue. CMS’s Medicare Prescription Drug Benefit Manual includes information pertaining to opioid-specific safety edits, which was added in January 2016. The Manual states that Part D sponsors “*may apply [quantity limits] to opioids* even though there is no clearly defined FDA maximum dose in the approved labeling.” Medicare Prescription Drug Benefit Manual Chapter 6, Section 30.2.2.1 (emphasis added). CMS also “developed a comprehensive morphine equivalent dose (MED) approach to assist Part D sponsors in identifying high risk beneficiaries.” CMS, Analysis of Proposed Opioid Overutilization Criteria Modifications (Feb. 1, 2017). The Manual discusses POS edits in the context of MED across an opioid class, but suggests that these edits are *in addition to* any quantity limits imposed by the plan.[[14]](#footnote-14) Likewise, the Manual is silent regarding quantity limits on initial prescription fills.

CMS addressed the issue of edits based on MED further in 2017, but that guidance also does not address quantity day limits for initial fills. The CY 2018 Call Letter, finalized in April 2017, discusses formulary-level edits based on MED but makes these edits optional, as opposed to prohibiting them:

In the draft 2018 Call Letter, we proposed that all sponsors implement a formulary-level hard opioid safety edit based on a cumulative MED. . . . Based on [the] feedback, we are not finalizing the proposal for all sponsors to implement a hard edit. As in 2017, *we continue to expect sponsors to implement formulary-level soft and/or hard cumulative MED opioid safety edits for 2018, but hard edits are not required, and we reiterate past guidance*. . . . Based on the comments to the draft 2018 Call Letter, we are providing additional background and guidance on formulary-level soft and hard safety edits for opioids based on a cumulative MED. CMS expects Part D sponsors to implement a soft and/or hard edit but only as a safety edit. [[15]](#footnote-15)

Even more recent guidance clarifies CMS’s intent regarding edits based on MED: “We recommend that a soft edit threshold be set at levels no lower than 90 mg MED, and a hard edit threshold be set no lower than 200 mg MED to reduce initial beneficiary impact. *Plans may not use these thresholds as prescribing limits and they can only function as a threshold to trigger the edit indicating potentially unsafe opioid use*.”[[16]](#footnote-16) Thus, it appears that under the guidance, *dosing* thresholds cannot be a prescribing limit and can only function to trigger a safety edit. But there does not appear to be a prohibition on quantity limits for opioids that are reasonable and appropriate.

1. **Analysis**

As demonstrated by CMS’s continued emphasis, opioid misuse and overuse continue to be a critical component of CMS’s and Part D plan sponsors’ Medicare strategies. As recently as January of 2017, CMS said that “attacking this devastating epidemic” was a “top priority” and that it was “working with people with Medicare and Medicaid benefits, their physicians, health insurance plans, and states to improve how opioids are prescribed by physicians and used by patients, how opioid use disorder is identified, how patients are connected to treatment, and how alternative approaches to pain management could be promoted.” CMS, Opioid Misuse Strategy 2016, p. 2.[[17]](#footnote-17)

Health insurance issuers in the commercial and Medicaid markets have also been successfully addressing the opioid epidemic by placing controls on opioid prescriptions by placing quantity limits at the point of sale for all initial opioid fills. You have indicated that when a Part D plan sponsor attempted to adopt a similar design—limiting an initial opioid fill to 7 days—they were advised by staff at CMS that implement plan designs that such a limit was impermissible.

It appears that the Act, as amended by CARA, does not prohibit Medicare Part D plan sponsors from limiting prescription drug refills to any specific period of time. In fact, the Act, as amended by CARA *requires* Medicare Part D plan sponsors to have a utilization management tool in place, and explicitly states that the tool could be one that is designed to prevent the abuse of frequently abused drugs and to prevent the diversion of these drugs at pharmacies. Accordingly, we believe that the statute permits a Part D plan sponsor to meet the requirement to have a utilization tool by imposing quantity limits on initial fills of opioids at the POS.

Similarly, CMS’s regulatory requirements—particularly the requirement that a Part D plan sponsor have “a reasonable and appropriate drug utilization management program that … assist[s] in preventing over-utilization and under-utilization of prescribed medications”—support a conclusion that Part D plan sponsors should be permitted to impose day limits, including a 7-day limit on initial fills of opioids in Medicare. At a minimum, this language does not prohibit Part D plan sponsors from placing quantity limits on drugs, and CMS’s continued emphasis on combatting the opioid misuse epidemic suggests that non-discriminatory, reasonable, and appropriate limits should be permitted for Plan D plan sponsors. And because a 7-day initial fill quantity limit is based on CDC guidelines, it would seem that such a limit, if applied to all initial fills, would be non-discriminatory, reasonable, and appropriate.

As noted, the MED Opioid MED Safety Edit Memo states that the MED thresholds may not be used as prescribing limits, which may suggest that MED thresholds, and the safety edits those thresholds may trigger, are the preferred method by which Part D plan sponsors may manage opioid use. However, the memo does not say that MED thresholds are the exclusive method by which Part D plan sponsors may address opioid misuse, and the memo does not prohibit day limits on initial prescription fills. Therefore, it appears that CMS guidance does not prohibit plan sponsors from imposing day limits on initial opioid prescriptions, and based on the information you provided and the guidance we reviewed, it is unclear why CMS staff would prevent Part D plan sponsors from adopting such policies.

To avoid confusion, CMS should clarify that Part D plan sponsors may adopt non-discriminatory, reasonable, and appropriate limits on opioid prescription fills, including 7-day limits on initial fills.

1. HHS Office of the Inspector General Data Brief (OEI-02-17-00250) [↑](#footnote-ref-1)
2. https://www.cdc.gov/drugoverdose/pdmp/states.html [↑](#footnote-ref-2)
3. Office of the Assistant Secretary for Planning and Evaluation. “Report to Congress: Social Risk Factors and Performance Under Medicare’s Value-Based Payment Programs.” December 21, 2016. Available at: https://aspe.hhs.gov/pdf-report/reportcongress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs. Accessed on February 20, 2017. [↑](#footnote-ref-3)
4. <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm> (March 15, 2016). [↑](#footnote-ref-4)
5. ACP Internist, States Aim to Limit Opioid Prescriptions, October. 2016, available at <https://acpinternist.org/archives/2016/10/laws.htm> (In addition to Massachusetts, “[o]ther states that have passed laws with prescribing limits within the last year include Connecticut, Maine, New York, Rhode Island, and Vermont.”) [↑](#footnote-ref-5)
6. Congress has acted by enacted CARA, as well as through proposed legislation from Senators McCain and Gillibrand, the Opioid Addiction Prevention Act of 2017. [↑](#footnote-ref-6)
7. CNN, CVS will limit opioid prescriptions to 7 days, September 22, 2017, available at: <http://www.cnn.com/2017/09/22/health/cvs-prescription-restrictions-opioids-bn/index.html>. [↑](#footnote-ref-7)
8. We reviewed the following CMS subregulatory guidance that you provided:

   Memorandum re: Additional Guidance on CY 2017 Formulary-Level Cumulative Morphine Equivalent Dose Opioid Point-of-Sale Edit (July 7, 2017);

   Memorandum re: UPDATES - 2017 Medicare Part D Patient Safety and Overutilization Monitoring System Reports (April 7, 2017);

   CMS Opioid Misuse Strategy 2016 (Jan. 5, 2017);

   Memorandum re: CY 2017 Formulary-Level Cumulative Opioid Morphine Equivalent Dose Point-of-Sale Edit (July 21, 2016); and

   Memorandum re: Improving Drug Utilization Review Controls in Part D (Sept. 28, 2011).

   We also generally reviewed documents on the CMS web page entitled Improving Drug Utilization Review Controls in Part D, which includes: Memorandum re: Analysis of Proposed Opioid Overutilization Criteria Modifications in Medicare Part D (April 28, 2017); additional HPMS memoranda, and Drug Utilization Review excerpts from the 2013-2018 Call Letters. [↑](#footnote-ref-8)
9. CARA also added a section to the Act establishing a drug management program for at-risk beneficiaries. *See* the Act § 1860D–4(c)(5)(B)(i)(I), as added by CARA § 704(a). However, since this analysis addresses drug management programs for initial opioid fills for all beneficiaries, we do not address this section. [↑](#footnote-ref-9)
10. The most recent CMS proposed Part D rule does not propose changes to § 423.153(b). *See* 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 Proposed Rule, 82 Fed. Reg. 56336 (Nov. 28, 2017). [↑](#footnote-ref-10)
11. *See* CMS, Improving Drug Utilization Review Controls in Part D, a*vailable at:* <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html> (documents beginning in 2013); *see also* Medicare Prescription Drug Benefit Manual, Chapter 6, *available at:* <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf> (last updated Jan. 15, 2016). [↑](#footnote-ref-11)
12. CMS, Improving Drug Utilization Review Controls in Part D, *available at*: <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html>; *see also* 2013 Final Call Letter at p. 133 (“A recent Government Accountability Office (GAO) report highlighted evidence that effective concurrent DUR has not been fully implemented across the Part D program (GAO-11-699 September 2011 http://www.gao.gov/new.items/d11699.pdf ). This report summarized findings of egregious overutilization of medications by Part D beneficiaries who were obtaining medications from a minimum of five different prescribers and a maximum of fifty prescribers, with the vast majority of beneficiaries receiving medications from between five and ten providers. The medications most often identified as being potentially overprescribed were those opioid products containing hydrocodone followed distantly by oxycodone containing products. Therefore, we are focusing on addressing overutilization of opioids beginning CY 2013.”) [↑](#footnote-ref-12)
13. CY 2013 Call Letter, *available at* <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents-Items/2013Announcement.html?DLPage=2&DLEntries=10&DLSort=2&DLSortDir=descending> [↑](#footnote-ref-13)
14. Medicare Prescription Drug Benefit Manual Chapter 6, Section 30.2.2.1 (emphasis added):

    Sponsors may apply QLs to opioids even though there is no clearly defined FDA maximum dose in the approved labeling. Overutilization may trigger a plan-level POS edit, which is implemented by a plan after case management and advance written notice, in accordance with the opioid overutilization guidance ….

    Sponsors are *also* encouraged to implement plan-level POS edits based upon cumulative morphine equivalent dose (MED) across the opioid class. [↑](#footnote-ref-14)
15. CY 2018 Call Letter, *available at:* <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2018.pdf> (April 3, 2017) (emphasis added). [↑](#footnote-ref-15)
16. MED Opioid MED Safety Edit Memo, *available at:* <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html>, Medicare Part D Overutilization Control HPMS memos (July 7, 2017) (emphasis added). [↑](#footnote-ref-16)
17. *Available at* https://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/Prescription-Drug-Information-for-Partners-Items/CMS-Opioid-Misuse-Strategy-2016.html. [↑](#footnote-ref-17)