



January 16, 2018

Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-4182-P
PO Box 8013
Baltimore, MD 21244-8013

Via Regulations.gov Electronic Portal

RE: Comments on CMS-4182-P - 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

Dear CMS:

Thank you for the opportunity to provide comments on the CY2019 Proposed Changes to the Medicare Advantage and Part D programs released on November 16, 2017.

If you have questions with regard to our comments and recommendations, please contact Michael Husmann, Director of Regulatory Affairs, at (212) 453-4457 or mhusmann@healthfirst.org.

Best Regards,

A handwritten signature in blue ink, appearing to read "Pat Wang", with a stylized flourish at the end.

Pat Wang
CEO

Healthfirst Health Plan, Inc. – Contracts H3359 and H5441

Healthfirst Comments on 2019 Proposed Rule

Our comments focus on the following provisions contained in the Proposed Rule:

1. Revisions to Timing and Method of Disclosure Requirements
2. Meaningful Differences in Medicare Advantage Bid Submissions and Bid Review
3. Passive Enrollment Flexibilities to Protect Continuity of Integrated Care for Dually Eligible Beneficiaries
4. Establishing Limitations for the Part D Special Election Period (SEP) for Duals
5. Codification of the MA and Part D Star Ratings Program
6. Star Ratings Guiding Principles
7. Stakeholder Feedback on Specific Topics
8. Contract Ratings
9. Contract Consolidations
10. Adding, Updating and Removing Measures
11. Improvement Measures
12. Data Integrity
13. Measure Weights
14. Categorical Adjustment Index
15. Reviewing Appeals Decisions (Part D)
16. Coordination of Enrollment and Disenrollment Through MA Organizations and Effective Dates of Coverage and Change of Coverage
17. Restoration of the Medicare Advantage Open Enrollment Period
18. Medicare Advantage Coding Pattern Adjustment
19. Implementation of the Comprehensive Addiction and Recovery Act of 2016 (CARA) Provisions

1. Revisions to Timing and Method of Disclosure Requirements

We strongly support the proposal to revise the timing of certain disclosure materials as well as the updated method of delivery of various materials. These changes would reduce overall plan administrative burdens, unnecessary use of resources, and reduce time necessary to deliver materials, while catering to the changing needs and preferences of plan beneficiaries.

2. Meaningful Differences in Medicare Advantage Bid Submissions and Bid Review

We strongly support the proposal to eliminate the MA meaningful difference requirement. The current meaningful difference calculation does not take into consideration factors that are significant to the beneficiaries – such as plan premiums –while limiting the number of plans available in the market to address the needs of the population. Eliminating the meaningful difference requirement would allow for plans to make appropriate modifications to specific plans as needed without the need to forcibly change other plans to create preset differences in plan values.

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

We agree with the proposal to passively enroll full-benefit duals currently enrolled in an integrated DSNP into another integrated DSNP as necessary to minimize the disruption these beneficiaries may face. However, we recommend the following modification to the proposed language:

- The proposed rule would require plans to have a Star Rating of 3 stars or better to be eligible to receive passive enrollments. However, low-enrollment contracts or new plans without Star Ratings

would be exempt from this requirement. Given the high-risk nature of the population, passive enrollment should be limited to plans with the experience and size to meet their unique needs. The exemption for low-enrollment contracts and new plans should be removed.

- The proposed rule considers “limiting our exercise of this proposed new passive enrollment authority to those circumstances in which such exercise would not raise total cost to the Medicare and Medicaid programs.” Plan participation in these programs is based on the Medicare bid process and State-approved contractual Medicaid arrangement. We request additional clarity in how the total costs will be compared plan by plan; additionally, choosing plans for passive enrollment based on any artificial cost estimate would be inconsistent with the bid process and good faith contracting efforts. We would recommend against any rule that bases eligibility for passive enrollment on cost alone.

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

We support the proposal to limit the SEP rules for dually eligible beneficiaries to one annual opportunity as it would allow for improved continuity of care for this segment of population. However, we recommend the following modification to the proposed language:

- Beneficiaries who experience a change in Medicaid or LIS status should be given a one-time opportunity to change plans post status change without imposing a time-limit during the calendar year (i.e. remove the “switch within two months of the change or being notified of the change” language). The ability to successfully reach these members and educate them on the change of their status, versus simply notifying them of the change, has a much longer timeline and varies from member to member. Removing the time limit will allow plans to assist the beneficiary to make a fully-informed choice.
- Full-benefit duals eligible to enroll in an integrated DSNP, but currently not enrolled in an integrated DSNP should be given SEP to switch into an integrated DSNP throughout the year – even without a change in status (i.e. eligible, but currently not enrolled). Once the beneficiary enrolls in an integrated DSNP, SEP opportunity would be removed and the annual enrollment period to switch from integrated plan to another integrated plan would apply.
- We request that CMS provide additional detail regarding the federal vs. state authority over SEP for dually eligible beneficiaries

5. Codification of the MA and Part D Star Ratings Program

We support codification of the Star Ratings System in order to improve standardization and stability of program methodologies and policies and we also recommend that CMS maintains flexibility to quickly institute improvements to the way social risk factors are addressed in the Star Ratings (e.g., through a more meaningful CAI methodology). Additionally, we support a process in which stakeholders have advanced notice of any changes and updates to the Stars Rating Program and are given an opportunity to comment prior to the impacted measurement period.

6. Star Ratings Guiding Principles

We support CMS’s use of guiding principles for the Star Ratings program and we urge CMS to use these guiding principles to reassess the program that exists today. We are concerned about discrepancies from the guiding principles in the current Star Ratings program. These concerns and our recommendations to address them are itemized below:

- **Measures developed by consensus-based organizations are used as much as possible.** CMS-developed measures such as SNP Care Management and MTM Program Completion for CMR are not

evaluated as rigorously as Star measures developed by measure stewards like NCQA and PQA. For measures such as these, which are not developed or reported by measure stewards or similar third party organizations, we recommend that CMS provide certified software for plans to utilize as they calculate performance (as done for NCQA/PQA approved measures) in order to validate and standardize reporting requirements. This would also give plans the ability to assess year-over-year results when measure specification changes are made.

For 2018 Star Ratings, volatility in the SNP Care Management measure specification due to substantive and non-substantive changes announced before, during and after the measurement period, opened the measure to varying interpretations and resulted in non-standardized calculations of the measure rate by plans and data validation auditors. The use of certified software would have standardized the calculation of the measure and minimized performance differences due to varying interpretations of the measure specification.

- **Ratings treat contracts fairly and equally.**

Performance differences on a number of measures in the Star Ratings program are driven by individual member characteristics instead of plan quality, which runs counter to the guiding principle of treating contracts fairly and equally. These measures include the MTM Program Completion Rate for CMR (Part D), SNP-specific measures (Care for Older Adults and SNP Care Management), and Voluntary Disenrollment.

- Performance on the MTM Program Completion Rate for CMR (Part D) is heavily influenced by the plan's proportion of MTM-eligible members, which is influenced by the clinical complexity of the plan's members. Healthfirst has the most stringent eligibility criteria in accordance with CMS regulations for enrollment in the MTM program (at least 3 chronic conditions and 8 Part D drugs), but even with these eligibility criteria, 40,000 Medicare members (one-third of the plan's membership) qualify for the MTM program, demonstrating the disease complexity of Healthfirst Medicare members.

Tremendous resources are required for Healthfirst to achieve ever-higher CMR rates due to our high proportion of eligible members, high proportion of non-English speaking members, and greater clinical complexity of our MTM-eligible members. Compounding these challenges is the difficulty reaching a mostly low-income subsidy/dual-eligible population who are disproportionately transient, with frequent address and phone number changes.

We recommend that CMS move the MTM measure to the display page while CMS explores modifying the measure specifications to take into account the variation in MTM eligibility across plans (i.e., high proportion MTM-eligible vs. low proportion MTM-eligible plans). Additionally, we support CMS's exploration of options to standardize eligibility criteria across plans based on plan population (i.e. demographics, low-income subsidy population, etc.).

Furthermore, we ask that CMS provide flexibility to MA plans to participate in the Enhanced MTM program (currently available for PDPs), which allows for significant regulatory flexibilities, including:

- The ability to offer different MTM services to individual enrollees based on their level of medication-related risk, with interventions tailored to those enrollees' specific barriers to improvement;

- The ability to offer a more expansive set of MTM-related items and services, as well as cost sharing reductions to financially needy beneficiaries;
 - The flexibility to experiment with alternative communication strategies to improve beneficiary, pharmacist, and medical provider coordination and engagement;
 - A plan-specific prospective payment to support more extensive MTM interventions that will be outside of a plan's annual Part D bid and will therefore not impact plan premiums
- Performance on SNP-specific measures (Care for Older Adults, SNP Care Management) also varies widely based on type of SNP. Within Healthfirst plans, our Institutional and FIDE-SNP plans have nearly 100% compliance across all Care for Older Adults measures and the SNP Care Management measure. The plan is able to achieve this because we know where these members are, and are actively facilitating care related to their place of residence, and have access to members in that location in order to facilitate completion of functional assessments, medication reviews, etc. Our Dual-SNP plan, however, includes members who are much more challenging to reach, as noted above and below. While Healthfirst works actively with these members and their providers to ensure these assessments and screenings are completed each year, unsurprisingly, we have a lower success rate. When Healthfirst has reviewed data across other plans, it appears performance on these measures is heavily biased related to type of SNP plan, rather than indicative of plan quality.
- Performance on the Members Choosing to Leave the Health Plan Star measure currently does not account for the proportion of members with a continuous Special Election Period (SEP). LIS-eligible and dual-eligible beneficiaries are granted SEPs throughout the year and can choose to enroll and disenroll from plans as many times as they'd like; as a result, the measurement creates a bias against plans like Healthfirst with a disproportionately large LIS and dual-eligible population (approximately 65% for Healthfirst) who may choose to disenroll from the plan only to return within a short period of time.

For example: a LIS-beneficiary who unexpectedly needs comprehensive dental work can take advantage of their SEP to enroll in another plan with richer dental benefits, consume those benefits in the new plan, and return to their original plan for the reasons they chose it in the first place. A non-LIS beneficiary does not have this opportunity; therefore plans with a higher proportion of non-LIS beneficiaries are not subject to this consumer behavior. This creates an unfair comparison among plans on this measure based on their membership with access to SEPs.

- **Improvement on measures is under the control of the health or drug plan.**

Performance on several Star measures is driven primarily by member outreach (e.g., SNP Care Management, MTM). As such, plans like ours with a large dual-eligible population are disproportionately negatively impacted by members who are more transient, with frequent address and phone number changes that directly result in fewer successful contacts and lower engagement. For outreach-driven measures, we urge CMS to exclude members who were unreachable after a justifiable number of documented good faith attempts.

- **Process of developing methodology that is transparent and allows for multi-stakeholder input.** We request that CMS provide full transparency into the methodology used for calculating cut point thresholds. We ask that CMS release national performance data during Second Plan Preview so that plans are able to validate established cut point thresholds and identify any calculation errors nationally.

Additionally, we strongly urge CMS to continue with their process in the past of providing plans with notice of any proposed updates and changes to the Stars Rating program and methodology prior to the measurement period and release of the Draft Call Letter. It is imperative that plans are given adequate time to assess and provide meaningful input to CMS on how changes may impact plans and the beneficiaries they serve. This approach not only promotes transparency among stakeholders, but also allows ample time for CMS to evaluate suggestions by commenters prior to the Draft Call Letter.

7. Stakeholder Feedback on Specific Topics

- **Improving measures to reflect outcomes.** We request that CMS prioritize working with consensus-building entities such as NCQA and PQA to push for a long-term solution to address social risk factors impacting quality performance through risk-adjustment at the measure-level. According to the ASPE report released to congress on December 2016, “beneficiaries with social risk factors had worse outcomes on quality measures, regardless of the providers they saw, and dual enrollment status was the most powerful predictor of poor outcomes...” While we support and applaud CMS for instituting an interim solution to address performance disparities among plans (i.e., CAI adjustment), risk-adjustment at the measure-level will be able to reflect a more accurate picture of member outcomes.
- **Establishing Cut Points.** Plans make significant investments in member programs to improve health outcomes, member experience and retention. Large increases in measure cut points year-over-year remains problematic. To support health plans in their quality improvement activities, we request that CMS place a cap on cut point increases (i.e. no more than 3% over the previous year), minimizing the volatility of the Star Ratings program.
- **Adjustments to account for unique geographic and provider market characteristics.** We strongly urge CMS to address and adjust for performance disparities due to unique geographic and provider market characteristics. For example, New York City members experience different environmental and social risk factors compared to other MA markets. We ask that CMS take into account important factors such as Health Professional Shortage Areas (HSPAs), urban setting, and population density to distinguish and identify varying geographic / provider market characteristics that impact the socio-economic determinants of health and health care utilization patterns of Medicare beneficiaries.
- **Including measures based on physician experience surveys.** We do not support the inclusion of measures based on provider feedback in the Star Ratings program as 1) these measures are not targeted to the member experience of care and 2) would only add noise to the program by introducing variability of physician responses for different health plans.

Instead, we recommend CMS to implement a standardized provider rating system that is aligned with the Medicare Advantage Star Ratings program, one that is based both on subjective patient experience metrics and objective quality measures that are tightly aligned with existing MA plan measures. Currently, members have transparency and access to MA plan quality ratings, and this same transparency should be put in place for health care providers (e.g., primary care doctor,

specialist). This allows for a standardized approach for identifying and improving the quality of care and health outcomes for Medicare beneficiaries. Provider ratings should be publicly available to Medicare beneficiaries and could be posted on the CMS website. This information could also be used by MA plans for display purposes (e.g., provider directory) and/or operational processes and programs (e.g., pay for performance programs). Additionally, we urge CMS to consider implementing a standardized set of access to care guidelines for all MA providers as provider expectations for appointment availability and waiting room times vary regionally. For example, the CAHPS Getting Appointments and Care Quickly measure asks members if they are seen within 15 minutes in the waiting room, while New York State guidelines state that patients should be seen within (1) hour upon arrival. Additionally, this same question is just a supplemental question on the CAHPS Clinician & Group Survey – providers themselves are not held accountable on this measure.

8. Contract Ratings

We support the reporting data at the market-level to account for differences in the composition of enrollees and performance disparities.

9. Contract Consolidations

We strongly support CMS's efforts to develop a new set of rules for the calculation of Star Ratings for consolidated contracts as the lack of an appropriate policy is:

1. Inflationary to the Medicare program because it awards Star bonuses to contracts that are performing below 4 stars (i.e., it was reported that in 2017 alone, 1.4 M beneficiaries in consumed contracts will be moved from contracts below four stars to a contract in a bonus status, 4+ star contract)
2. Misleading to beneficiaries enrolled in consumed contracts as they are not accessing care from a 4-Star plan, defeating a core principle objective of the Stars program since its inception – accurate information to inform beneficiary choice and
3. Providing an unwarranted and inappropriate competitive advantage to consumed contracts that would not have earned the Stars bonus on their own because it provides them with additional funding to invest in plan benefits and services to attract new members. This particularly disadvantages regional plans and others who do not engage in contract consolidations.

CMS proposes to determine Star Ratings based on the enrollment-weighted average of the measure scores of the surviving and consumed contracts. While this may be the easiest policy to implement in the short term, we would like to raise two concerns with this approach: (1) it does not eliminate inaccurate public quality ratings for consolidations that don't share exactly the same local market area and (2) it continues to incentivize gaming of the system as there are still enrollment-weighted average combinations that would result in unwarranted bonus payments (e.g., consolidation of two contracts with the same enrollment size, but with star ratings of 4.5 and 3.5 would likely earn a 4-star rating on the consolidated contract, resulting in a quality bonus payment for the entire membership).

As CMS finalizes the policy for contract consolidations effective January 2019, we ask that in the interim CMS reports pre-consolidation contract performance on Medicare Plan Finder for contract consolidations effective 1/1/2018 so that Medicare beneficiaries are provided with accurate plan rating information during open enrollment for CY 2019.

Furthermore, we recommend that CMS considers the following policy option for assigning Star Ratings to merged contracts:

- Determine quality bonus payments based on pre-consolidation contract performance for when the contracts were not consolidated for the entire measurement period. For example, for a

consolidation effective January 2019, both the consumed and surviving contracts should continue to report separately and receive separate quality bonus payments through the 2020 Star Ratings period because the 2020 Star Ratings uses HEDIS performance from the 2018 measurement year.

- For Star Ratings based on measurement periods when the contracts were consolidated for the entire measurement period:
 - Plans in different health care market area geographies continue to report quality separately and receive a separate star rating
 - Plans in the same health care market area report consolidated quality results and receive a single star rating for the contract

This policy recommendation is consistent with MedPAC's recommendation for reporting quality and determining quality ratings and bonus payments by local market area. It also requires the establishment of geographic areas for MA quality reporting that are accurate reflections of health care market areas. We ask that CMS engage stakeholders in this process and hold a public comment period.

We recognize that quality reporting at the local market area is a sizeable change from current practice and may not be feasible for several years. We encourage CMS to work towards this more accurate end-state policy and, in the interim, to implement policies (e.g., CMS's proposed enrollment-weighted average approach) to minimize current gaming of the Star Ratings system that masks low quality plans under higher rated surviving contracts and results in awarding unwarranted quality bonus payments.

10. Adding, Updating and Removing Measures

We request that any changes made by CMS to the Star Measure specifications and/or Part C/D Plan Reporting Requirements Technical Specifications Document are accurately and clearly communicated in advance of the measurement period so that plans are given an opportunity to comment on any proposed changes prior to implementation. For example, changes to the Technical Specifications for the SNP Care Management measure have been made during the measurement period for the last two years. Although the specification changes may appear to be minor, they had significant impact to the coding and process of the SNP Care Management measure. Therefore, we recommend that any specification changes (substantive and non-substantive) for any of the Star Rating measures (including CMS-developed measures) be announced prior the measurement period. Furthermore, if new clinical guidelines are released during the measurement period, we recommend that CMS elicit stakeholder feedback on whether to include or exclude the impacted measure from the program year.

11. Improvement Measures

We support the hold harmless provision in the calculation of the improvement measure for contracts that achieve 5 stars at the measure level, and recommend that CMS considers extending the hold harmless to measures to plans that maintain at least 4 stars. The stated intent of the hold harmless provision is to "prevent the measure from lowering a contract's improvement measure when the contract still demonstrates high performance." Since 4 star performance is considered high quality, the extension of the hold harmless to measures for which a plan maintains at least 4 stars is aligned with the original intent of the provision.

12. Data Integrity

We support CMS's proposed new rule for scaled reductions for the Appeal measures. However, we ask that CMS consider the same approach across their entire policy on data integrity. CMS's current Data Integrity policy does not distinguish between the deliberate submission of inaccurate data and the unintentional occurrence of minor errors and mistakes. A new approach is needed to correct rates

within set standard timeframes when there is no finding of intended bias by the reporting entity. We propose the following approach to appropriately penalize plans for data validation audit failures:

- CMS should create a process to vet data submission rejection appeals based on a set of established criteria. This evaluation criteria should take into consideration the following important factors:
 - Beneficiary impact – Will beneficiaries be unduly harmed if data correction is not allowed?
 - Data Transparency – Will data correction materially improve transparency of quality information to beneficiaries?
 - Nature of Issue – What is the root cause of the issue? Were there extenuating circumstances (e.g., natural disaster)? Where does primary culpability lie?
 - Health Plan Activity – Did the plan exercise best practices in the regular submission process and in resolving the issue? Is the plan able to submit complete and accurate data?
 - History of Data Integrity issues – Does the plan have any findings of intended bias in the last 3 years?
 - Timing – Is it operationally feasible to incorporate corrected data in time for reporting purposes?
- We recommend that CMS use a third party such as NCQA, (funded by plans wishing to appeal) to review and evaluate the plan's data submission based on the criteria suggested above. The third party should be charged with making a fair and appropriate determination on the course of action.
- If the third party finds that the incorrect data submission was not intentional – the following set of actions can be administered by CMS:
 - Provide the plan a narrow window for resubmission of the corrected data (e.g. 2 weeks) or
 - Have the measure be non-reportable in the applicable Star Ratings Cycle and/or
 - Penalize plans in the form of a Notice of Non-Compliance instead of reducing a contract's measure rating to 1 Star
- If there is more than one data validation failure found that was intentional, CMS should penalize plans with a Civil Monetary Penalty

13. Measure Weights

CAHPS Star Measures: We have several concerns about the CAHPS measures and urge CMS to consider down-weighting them or, at a minimum, removing them from the calculation of the Part C and D Improvement Scores. Our concerns are the following:

- **CAHPS measures are case-mix adjusted for beneficiary-level characteristics, but do not account for macro-environmental factors like Health Professional Shortage Areas (HPSAs) and benchmark rates.** HPSAs are not included in the CAHPS case-mix adjustment methodology, despite the fact that several CAHPS measures are directly impacted by provider availability (Getting Appointments and Care Quickly, Getting Needed Care).
- **CAHPS Sample Size and Small Differences in Star Cut Points.** The CAHPS survey has a small sample size. Because of this, it is difficult to reliably distinguish performance between Star cut points. For example, In 2016 Healthfirst had 411 respondents to the CAHPS survey, which results in a 3.9% margin of error at a 95% level of confidence. CAHPS cut points are very close with most measures having a 1-3% difference between adjacent Star cut points; as such, most cut point differences (1-3%) are less than our 3.9% margin of error. A considerably larger sample (n=> 1000) is necessary to

reduce the margin of error such that performance at adjacent cut points can be reliably distinguished.

Additionally, we attribute a low response rate to the CAHPS survey to the long length of the survey – over 90 questions. We appreciate that CMS shortened the 2017 MA CAHPS survey by removing some questions that are not tied to current Star Rating measures. However, there are still opportunities by restricting the CAHPS survey to questions related to services and support provided directly by the plan (e.g., customer service, care management, etc.). Health plans are limited in the control of and visibility into provider office procedures that are needed to hold the provider network accountable to member preference. As such, the MA CAHPS survey is not the appropriate instrument to assess provider operations and processes.

- **Provider-driven CAHPS measures on the MA Survey have a significant impact on the overall star rating, but providers themselves aren't consistently and directly evaluated on these measures.**
 - Inconsistency in Importance – The MA CAHPS survey asks members, “In the last 6 months, how often did you see the provider within 15 minutes of your appointment time?” This question is counted toward the scoring for CAHPS in the Star Ratings. However, this same question is only a supplemental question on the CAHPS Clinician & Group Survey – as such, providers themselves are not being held accountable on this measure. We recommend that CMS remove this question from the CAHPS composite measure, Getting Appointments and Care Quickly, as questions regarding provider access and availability should be consistent among provider-driven measures on all CAHPS surveys.
 - Inconsistency in Interpretation – We have concerns about the wording of the CAHPS composites measures: Getting Needed Care and Getting Care Quickly. The issue is that the type of care that is being evaluated is not clearly defined; as such, there is a risk of members across the sample interpreting what is being asked in various and inconsistent ways. Furthermore, the current questions are not actionable to the plan, and make it difficult for us to hold our network accountable due to the vagueness of the questions.
 - Inconsistency in Methodology – CAHPS surveys such as CG CAHPS, tie the survey questions to a specific event (recent hospital stay, doctor visit, etc.). However, the current MA-PD CAHPS asks our members to evaluate their experience over a period of 6 months and is not specific enough to tie this back to a particular provider, visit, or event. Provider-driven CAHPS measures should be changed to reference the most recent visit by their PCP or specialist. It is imperative for quality improvement purposes to be able to understand / determine what provider, event, and/or barrier the member is referencing as the current CAHPS question are very broad, vague and are subject to recall bias.

Recommendation: The noise associated with the CAHPS measures makes them less reliable for quality measurement. We urge CMS to reduce the weight of CAHPS measures until these concerns are addressed. At a minimum, they should be removed from the calculation of the Part C and Part D Improvement Scores.

14. Categorical Adjustment Index

CMS's use of the Categorical Adjustment Index (CAI) for the Star Ratings was an important first step towards the aim of ensuring that the Star Ratings system fairly evaluates all plans, including those serving high proportions of members with social risk factors. With two years of experience with the CAI and with the release of the ASPE report (“Social Risk Factors and Performance Under Medicare’s Value-Based Purchasing Programs, December 2016), we ask that CMS consider progressing its approach for the

2020 Star Ratings so that it more accurately and adequately accounts for social risk of members. Specific comments and suggestions:

- **Develop an Equity Bonus.** ASPE notes that the CAI is a reasonable short-term strategy, but in the longer-term, a strategy like a targeted star adjustment should be considered. One way that ASPE suggests this could be done is by providing an “explicit star adjustment for achieving high performance for dual/LIS beneficiaries.” (ASPE Report, P. 209) The approach of constructing an “equity bonus” to reward contracts for achieving high performance for those beneficiaries with social risk factors is particularly compelling: “First, a weighted average of the ratios of each contract’s performance for dual/LIS beneficiaries on each of the 19 clinical measures versus the average performance for dual/LIS beneficiaries across all contracts in the respective clinical measure was created. A bonus of $0.5 \times (\text{proportion dual/LIS})$ was applied for all contracts for which this weighted ratio was greater than 1. For example, if a contract had an 80% pass rate for a particular measure for its dual/LIS beneficiaries, when the average was 75% pass rate, that contract would receive a ratio for that measure of $80/75$ or 1.07. This 1.07 ratio would be averaged in a weighted fashion (using the weights assigned under the Star Rating scheme) with similarly created ratios for the other 18 measures to create a final ratio. If that ratio is greater than 1, a $0.5 \times \text{proportion LIS/dual}$ bonus would be applied, such that if a contract had 100% dually-enrolled beneficiaries it would receive the full 0.5 star bonus. If it had 75% dually-enrolled beneficiaries it would receive 0.5×0.75 , or 0.44, stars.” (ASPE Report, P. 211)
- **Implement ASPE’s recommendation to scale the quality bonus payment so that it is not all-or-nothing.** While the Equity Bonus approach described above is not budget neutral, the ASPE report notes that scaling the Quality Bonus would allow money to be reallocated to contracts. It would also alleviate the immense financial pressure created by the current all-or-nothing methodology.
 - “Money to reward contracts that perform particularly well for beneficiaries with social risk factors could be reallocated from current Quality Bonus Payments by moving to a scaled Quality Bonus Payment system rather than an all-or-nothing 5% bonus at the 4- star threshold, which may have additional value in terms of the behavioral economics of incenting contracts to continually improve.”
- **If CMS continues to use the CAI adjustment for 2020 Stars instead of moving to a longer-term adjustment, we request that CMS updates the criteria for measure inclusion in the CAI.**
 - The current criteria are that (1) the median within-contract difference for LIS/Dual to non-LIS/non-Dual must be at least 5% or (2) LIS/DE members performed worse than non-LIS/DE members in all contracts.
 - The criterion that all contracts need to show that LIS/Dual-eligible members perform worse than non-LIS/DE members is excessively stringent. We suggest that this criterion be updated to 90% of contracts showing that LIS/DE members perform worse than non-LIS/DE. This would bring in Annual Flu Vaccine, Controlling Blood Pressure, Rheumatoid Arthritis Management, Medication Adherence Diabetes, and Medication Adherence Cholesterol to the CAI for 2018 Stars.
 - Instead of using a within-contract difference of 5% for all measures, use a number that is meaningful for each measure being considered. For example, a 1% difference in medication adherence is statistically significant for our plan, but the standard for inclusion in the CAI is much higher at 5%.

15. Reviewing Appeals Decisions (Part D)

The tight turnaround times for Part D standard and expedited coverage determination requests continually presents many challenges to plans that are trying to ensure their members get their prescribed medications.

While we recognize that plans have a responsibility to ensure their network providers are well informed with the need to respond to requests 24/7, we do not have influence to elicit responses from out-of-network providers. We also find that the short turnaround times are not conducive to receiving responses from providers in a hospital setting. When Emergency Room doctors or residents (who do rotations at multiple sites) write prescriptions for patients that require a prior authorization, it is very difficult to locate these providers to request medical necessity responses. These providers also are in a busy practice setting where they have limited time with a patient and looking up the plan's formulary prior to writing the prescription is unrealistic.

The result of a lack of response is a denial for the member, which delays their receipt of their prescribed medications. Holding plans accountable for situations for which they have limited control through the Appeals Upheld measure unfairly penalizes them. We request that CMS remove lack of response denials from the Appeals Upheld measure.

Additionally, a plan has 72 hours for an expedited case and 7 days for a standard appeal. While the IRE is generally held to the same adjudication timeframes as previously highlighted, if additional information is needed from a prescriber, the IRE is allowed to extend the adjudication timeframe to obtain this information. In our experience, the IRE is often able to obtain additional information from the prescriber because of this extended time frame. A plan, however, is not afforded this time extension and thus if a prescriber is unable to provide the information needed to render a decision within the adjudication timeframe, the plan must deny based on the information provided in order to prevent cases from being auto-forwarded to the IRE. We recommend that CMS revise the appeals measure to align the time frames and processes for plan sponsors and IREs so that there is a more equitable evaluation of plan sponsor decisions starting with 2017 dates of service (2019 Star Ratings).

Plans should also not be penalized for appeals that were overturned when providers provided "new" information to the IRE, which was not originally submitted by the provider at the time of the Plan's original coverage determination or redetermination and after reasonable efforts were made by the Plan to obtain missing information from the provider. We fully support the IRE making the most accurate and timely decision on behalf of the member based upon information available at the time of review. However, it is incongruous for the IRE decision to count against the plan Appeals Upheld measure if there was a change in clinical status or prescriber request after the plan's decision that would account for the IRE reaching a different outcome. CMS should measure the fairness of the plan's decision based upon the status of the case and the information provided to the plan at time of the plan's decision. For example, the IRE could render two decisions on the case: one decision would be for the member's appeal based upon the most current information the IRE has received; the other decision would be on the fairness of the plan's decision based upon the status of the case and information available to the plan at time of its decision. Only the second decision should be used to support the D03 measure.

Recommendation: We recommend that CMS adjust the appeals upheld measure by:

1. Removing lack of response denials from the Appeals Upheld measure.
2. Aligning the time frames and processes for plan sponsors and IREs so that there is a more equitable evaluation of plan sponsor decisions starting with 2017 dates of service (2019 Star Ratings).
3. Measuring the fairness of the plan's decision based upon the status of the case and the information provided to the plan at time of the plan's decision

CMS could also consider excluding these appeals from the Appeals Upheld measure starting with 2017 dates of service (2019 Star Ratings).

16. Seamless Conversion

We strongly support codification of seamless conversion for the dual population. However, plans have faced challenges successfully participating in seamless conversion programs in the past due to each State's data sharing limitations, challenges, and/or delays. We recommend CMS develop a secure data exchange process that directly and sufficiently supports plan sponsors' access to their enrolled Medicaid members' information that attain Medicare eligibility via age-in and disability in a timely manner.

17. Restoration of the Medicare Advantage Open Enrollment Period

We disagree with the restoration of the Medicare Advantage Open Enrollment Period to all beneficiaries. The Restoration of OEP would in essence create a new SEP period of 3 months for all MAPD beneficiaries, including those who currently do not have SEP throughout the year, and offer unlimited ability to switch within MA plans or disenroll from MA. The proposal goes against the proposed policy of establishing limitations for the Part D SEP for Duals, by broadening the SEP coverage.

We recommend CMS consider the following:

- Keep the current MADP permitting MA enrollees to leave MA and return to Original Medicare within the first 45 days of the year.
- Additionally offer OEP through March 31 of each year for dually-eligible beneficiaries only, in conjunction with the proposed policy to limit Part D SEP for Dual for the remainder of the year

18. Medicare Advantage Coding Pattern Adjustment

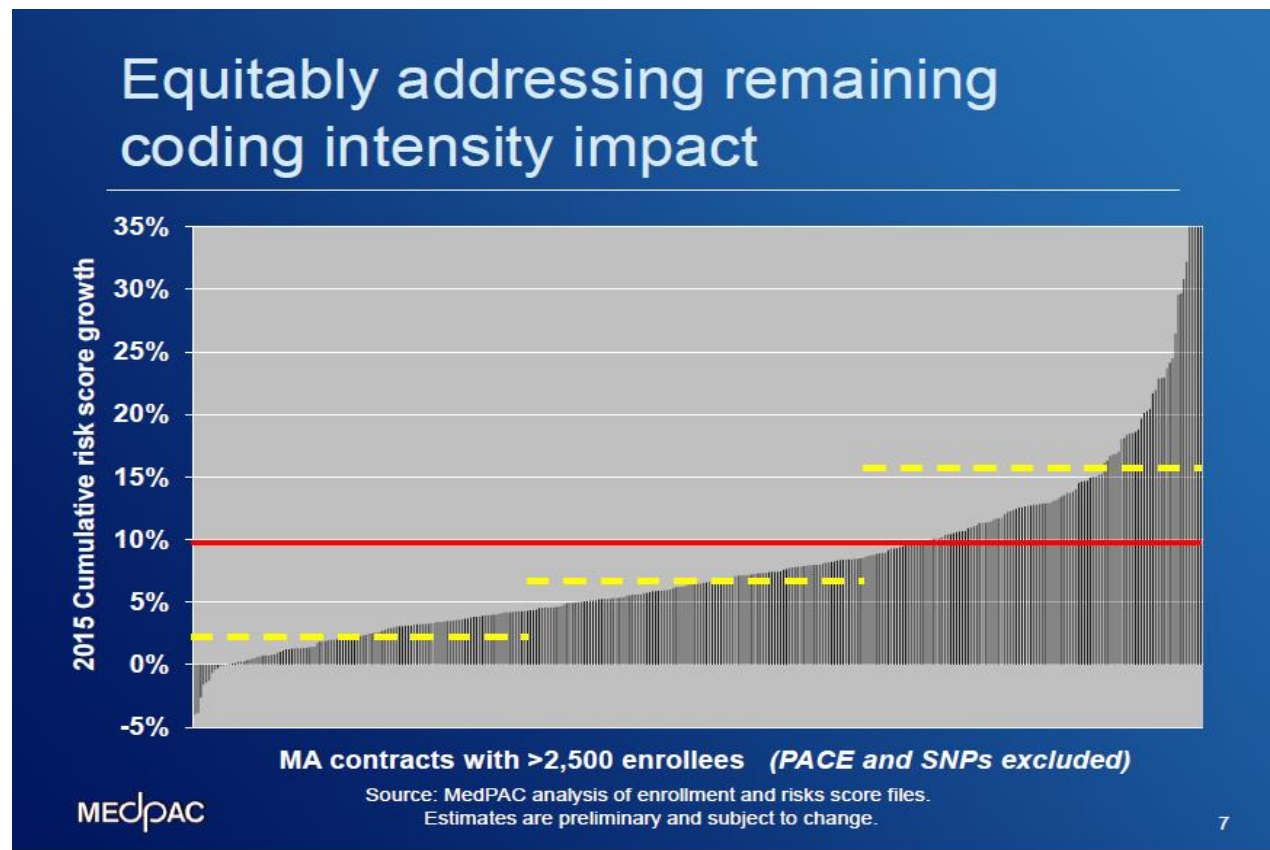
The summary of the 2019 proposed policy notes "...this proposed rule would revise the Medicare Advantage program (Part C) regulations... to address program integrity policies related to payments based on prescriber, provider and supplier status in Medicare Advantage... Specifically, this regulation meets the Administration's priorities to reduce burden and provide the regulatory framework to develop MA and Part D products that better meet the individual beneficiary's healthcare needs."

We strongly support many of the policies proposed and believe the updates promote CMS's goal of improving program integrity policies. However, policies contributing to the Medicare Advantage Coding Pattern Adjustment – a significant contributor for determining accuracy of payments for PA products – need to be further discussed for 2019.

A 2014 CMS study titled "Measuring Coding Intensity in the Medicare Advantage Program" supports the idea that coding patterns across the MAO landscape are very heterogeneous. Failure to recognize these differences across plans by applying a Coding Intensity Adjustment (CIA) based on average results is an inequitable outcome no matter what method is used to calculate the adjustment. In addition to failing to promote equity among plans, this approach rewards the most aggressive risk score maximization practices because the adjustment will by definition never be commensurate with increases above the average, a perverse incentive.

At its November, 2016 public meeting, MedPAC staff displayed the graph on the next page. The graph arrayed the 2015 cumulative MA plan coding intensity of contracts with more than 2500 enrollees (excluding PACE and SNPs). It also portrayed the effect of a hypothetical 10% CIA applied as an across the board coding intensity adjustment versus a hypothetical application in three tiers according to the relative coding intensity. The current across-the-board adjustment significantly favors the contracts at

the far right of the graph, i.e., those with the greatest coding intensity, while significantly disadvantaging those below the average by applying reductions in excess of their actual risk score growth.



We urge CMS to apply the CIA in a more equitable way. CMS should use a segmented approach to coding pattern adjustments that recognizes different levels of coding intensity among plans, with the aggregate value of the coding adjustment apportioned overall several tiers of plans that are grouped according to their actual coding intensity and scaled so that the lowest coding intensity factor is applied to the lowest coding intensity plans, and the highest factor to the highest intensity plans. The result will be a more equitable application of an adjustment aimed at closing the growing gap between FFS and MA risk scores. Anything else will continue to force some plans, with less coding intensity, to effectively subsidize those with greater coding intensity and to offset their reductions in risk scores with reduced benefits and increased costs shares for the members.

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

We support the integration of the prescriber and pharmacy lock provisions of CARA with the existing Part D opioid Drug Utilization Review (DUR) policies and the Overutilization Monitoring System (OMS).

Definition of “Frequently Abused Drugs”:

CMS proposes to limit the “frequently abused drugs” definition to only opioids for 2019. Limiting the reviews to only opioids for both the OMS beneficiary-specific POS edits as well as the lock-ins limits our ability to manage all potentially abused or misused controlled substances. While opioids are the focus of many national initiatives, we believe that it is important to review and manage all of the controlled substances a beneficiary may be taking in order to reduce risk of significant adverse events.

- **Recommendation:** We strongly encourage CMS to define Frequently Abused Drugs as any

controlled substance (DEA Schedule II-IV), and continue to allow plans the flexibility to implement beneficiary-specific POS edits on all drugs deemed necessary by the plan in consultation with the beneficiary's prescriber. We currently can and do intervene on these cases of multiple controlled substance overutilization, including implementing beneficiary-specific POS edits, and we feel it is important that we can continue to use this tool. Furthermore, we recommend that prescriber and pharmacy locks be permitted for any controlled substance, as appropriate.

Definition of “Clinical Guidelines” and “Program Size”:

While we support the use of the 2018 OMS opioid targeting for 2019, we request that CMS continue to allow us to have flexibility in our targeting criteria. We may use additional targeting criteria to identify potentially at-risk individuals that are not necessarily based on the OMS criteria, but are consistent with the CDC guidelines. For example, a beneficiary that has filled opioid prescriptions from 10 different prescribers in the last 6 months, but who has an average MME of < 90 mg/day would benefit from better coordination of care that could be achieved using a pharmacy or prescriber lock. These individuals would not be identified by CMS as part of the OMS.

- **Recommendation:** CMS should allow to continue to utilize additional targeting criteria to identify potentially at-risk beneficiaries. We should be allowed to implement beneficiary-specific POS edits and locks for beneficiaries who demonstrate prescriber or pharmacy shopping behavior, but stay below the average morphine milligram equivalent (MME) of 90 mg/day, or are on combinations of controlled substances that place the beneficiary at risk for an adverse event.

Definition of “Exempted Beneficiary”:

We support exempting beneficiaries who have elected hospice and those residing in long-term care facilities from the OMS interventions and prescriber/pharmacy lock. While we agree that individuals being treated for cancer-related pain should also be exempt from these limitations, we do not believe a cancer diagnosis in and of itself should be an exemption. There are many people who have a cancer diagnosis in their history who may be taking opioids for pain unrelated to their cancer diagnosis. For instance, a woman who was successfully treated for skin cancer 5 years ago with no sign of recurrence may be at-risk for opioid overutilization due to pain subsequent to a motor vehicle accident 2 years ago.

- **Recommendation:** Beneficiaries in hospice or residing in long-term care should be exempt from the OMS opioid limitations. Beneficiaries currently being treated for cancer-related pain should also be exempt. However, a history of cancer, in and of itself, should not be sufficient to exempt an individual from the OMS limitations. CMS should permit exempting beneficiaries with cancer-related pain from opioid limitations *after* consultation with the prescriber. We should not be prohibited from reviewing potential at-risk beneficiaries for opioid management because they are not identified on the OMS report because of a history of cancer.

Limitations on Access to Coverage for Frequently Abused Drugs

We would like for CMS to clarify that a beneficiary could have any combination of a beneficiary-specific POS edit, prescriber and/or pharmacy lock, and that these limitations do not have to be implemented at the same time. For example, a pharmacy lock is implemented for a beneficiary with a history of provider shopping. Six months later, the beneficiary is still showing excessive use of controlled substances (e.g., fewer prescribers, but higher quantities) and his/her primary prescriber has requested that a beneficiary-specific POS edit be added to the pharmacy lock to better manage the controlled substances.

Requirements for Limiting Access to Coverage for Frequently Abused Drugs

We agree that the plan should get prescriber agreement for any beneficiary-specific POS edits or prescriber lock for at-risk beneficiaries, unless the prescriber(s) is unresponsive. However, we do not support obtaining prescriber agreement for a pharmacy lock. Pharmacy lock is primarily used when the beneficiary has shown a clear pattern of provider shopping, including primarily utilizing emergency departments to obtain controlled substance prescriptions. This behavior indicates a lack of care coordination. It could be extremely difficult for the plan to gain agreement from all controlled substance prescribers, or even identify who would be the primary provider to implement the pharmacy lock.

Beneficiary Notices and Limitation of Special Enrollment Period

- **Initial Notice to Beneficiary and Sponsor Intent to Implement Limitation on Access to Coverage for Frequently Abused Drugs**

It is our understanding that CMS will be providing model letters for the first and second beneficiary notifications. We request that CMS clearly identify areas of variable text vs required text and indicate if plans will be able to modify these letters (other than the variable fields).

CMS proposes to require the initial notification to include "public health resources designed to address prescription drug abuse." Please confirm that CMS will be including this information in the model letter. If we must include the resources specific to our plan, we would need additional time to program plan-specific language. This would increase the time to implement letters to at least 6 months and will add new costs to the implementation of the letters.

- **Second Notice to Beneficiary and Sponsor Implementation of Limitation on Access to Coverage for Frequently Abused Drugs**

It is our understanding that CMS will be providing model letters for the first and second beneficiary notifications. All comments associated with the initial letter would also apply to the second notice.

- **Alternate Second Notice When Limit on Access Coverage for Frequently Abused Drugs by Sponsor Will Not Occur**

The most likely scenario where a limitation would not be implemented after the initial notice would be if the beneficiary or prescriber successfully appealed the restriction. Since CMS has indicated that these appeals would follow the same process as a redetermination, please confirm that the redetermination approval letter would be sufficient notification that the limitation will not occur, and that a separate letter would not be needed. CMS could provide language to be used in the redetermination approval letter that meets the intent of the alternate second notice.

- **Timing of Notices**

We understand that CMS will require the second notice to be sent to the at-risk beneficiary not less than 30 days after the initial notice, and that the second notice must include the effective date of the limitation. If the plan must wait 30 days after the second notice to implement the limitation, it will have been at least 60 days since the beneficiary was determined to be at-risk before any limitations can be initiated.

- **Recommendation:** For lock-in limitations, plans should be able to implement the lock within 30 days of the initial notification if the beneficiary provides his/her prescriber or pharmacy preferences. If the preferences are not provided within 30 days, the lock-in limitations should be able to be implemented within 14 days of the second notice. If the beneficiary changes his/her preferences, the new lock-in preferences are effective 14 days after the plan receives them. For

beneficiary-specific POS edits, where prescriber and/or pharmacy preferences are not required, the limitation should be effective 30 days after the initial notification. The second notification serves as a courtesy reminder.

Special Requirement to Limit Access to Coverage of Frequently Abused Drugs to Selected Prescriber(s)

We do not agree with requiring to wait at least six months from the time a beneficiary was identified as being potentially at-risk before being allowed to pursue a prescriber lock if warranted. As described earlier, if a beneficiary is provider shopping, the beneficiary may not be exceeding the average MME per day, but clearly needs better care coordination. We request the flexibility to implement prescriber lock sooner than 6 months for the following reasons:

- If the overutilization continues to be egregious,
- If the prescriber requests the lock, or
- If helping the beneficiary obtain better coordination of care through a prescriber lock is an appropriate course of action.

Selection of Pharmacies and Prescribers.

We agree with the guidelines for honoring the beneficiary's preference for prescriber and/or pharmacy in a lock limitation. However, we do not agree that the beneficiary should be allowed to change their preferences as often as they wish. By allowing beneficiaries to make unlimited changes to their prescriber or pharmacy preferences, it will again be possible to avoid the implementation of the limitation by simply requesting a different prescriber or pharmacy.

- **Recommendation:** Beneficiaries should not be permitted to change their preferences more than two times in a plan year, unless they can provide good cause for requesting the change.

Examples of good cause would include moving beyond easy access to the prescriber or pharmacy; the prescriber has discharged the beneficiary from his/her practice; or the pharmacy is unable to provide the requested drugs. We should be able to implement the limitation 14 days after a change has been requested.

CARA states that for the purpose of limiting access to a specific pharmacy(s), if the pharmacy has multiple locations that share real-time electronic data, all such locations should be treated collectively as one pharmacy. We support the concept of treating a pharmacy with multiple locations as a single pharmacy if they share real-time data; however, we may not always know which pharmacies have this connectivity. In addition, some pharmacy chains have been known to limit shared data by geographic region. If a beneficiary is locked into a pharmacy chain, one cannot assume that all locations will have visibility to all claims.

- **Recommendation:** We ask that CMS allow some flexibility when locking beneficiaries into a pharmacy with multiple locations - especially if we are unable to verify that all locations share real-time data. In this circumstance, we may need to limit the member to a specific pharmacy or a specific region.

Regarding the proposed requirement to treat all providers in a group practice as a single provider for a lock-in limitation, plans and PBMs do not have the ability to identify all practitioners in the same practice in real-time at point-of-service, especially as group practices add practitioners or practitioners change location. The prescriber's tax identification number (TIN) is not part of the claim transaction data. We would have to get agreement from each provider to participate in the lock, and set up the lock for multiple providers.

- **Recommendation:** We should not be required to treat all prescribers in the same practice as a single prescriber at POS for the purposes of a prescriber lock. We should be able to provide reject overrides when it is determined that the prescriber is in the same practice as the locked-in prescriber.

Drug Management Program Appeals.

Please confirm that when a beneficiary "appeals" their controlled substance limitation, that the request should be processed as a redetermination and not a coverage determination. Also please confirm whether or not the beneficiary should be provided with CMS-10147 - Prescription Drug Coverage and Your Rights, if they have a claim reject due to a controlled substance limitation.

Appeal requests for opioid/controlled substance limitations under CARA do not currently fit any Part D utilization management criteria (e.g., exception criteria are not really appropriate in this circumstance. If a beneficiary appeals the limitation beyond the plan (i.e., Independent Review Entity, Administrative Law Judge, etc.), will these higher appeal authorities know to evaluate these appeals based on the at-risk determination of the plan and not based on exception criteria.

There may be instances where a beneficiary needs a temporary change in his/her opioid/controlled substance limitation. For example, the beneficiary may be undergoing a surgical procedure that requires a temporary increase in the amount of opioids allowed under a beneficiary-specific POS edit. Per Chapter 18, exception requests must be approved through the end of the plan year. This may not be appropriate for a beneficiary at-risk for substance use disorder. Will CMS allow plans to implement temporary exceptions to limitations that are not through the end of the plan year if done so in consultation with the beneficiary's prescriber?

- **Recommendation:** We do not recommend providing beneficiaries with CMS-10147 when a claim rejects due to a beneficiary-specific POS edit, prescriber or pharmacy lock. This form could cause confusion as it refers to a coverage determination and lists the turnaround times for a coverage determination, rather than for a redetermination. We recommend that CMS provide additional guidance to plans and higher appeal authorities on how to assess appeals for opioid/controlled substance limitations initiated under the CARA rules, and how to differentiate these appeals from other coverage determination appeals. We also recommend that CMS provide guidance to allow plans to temporarily change a limitation for a specific timeframe without requiring the plan to approve the exception through the end of the plan year.

Termination of a Beneficiary's Potential At-Risk or At-Risk Status.

CMS has proposed a 12-month duration limit on beneficiary-specific POS edits and prescriber/pharmacy locks. We do not feel that a 12 month limit is appropriate as these limits were implemented because other interventions were not effective. The beneficiary and prescriber can appeal the limitations at any time, which would allow for changes in therapy, or discontinuation of a lock/beneficiary-specific POS edit.

- **Recommendation:** Require the plan to reassess the limits every 12 months to ascertain whether the beneficiary is still taking the controlled substances and to reconfirm with the prescriber that the limits are appropriate. As noted above, the beneficiary or prescriber can request the limits be lifted at any time (appeal). If we must terminate the limit after 12 months, allow us to reinstate the limits as soon as at-risk behavior is noted without waiting for the beneficiary to be identified in the OMS report. Allow to reinstate the limits utilizing only the second notice in order to prevent unsafe utilization.

Data Disclosure and Sharing of Information for Subsequent Sponsor Enrollments.

We agree with using the same data disclosure and information sharing processes that are in place for the OMS. Please confirm that CMS will be providing new response codes for prescriber and pharmacy locks. Since CMS is going to require plans to review all cases identified in the OMS report, the OMS response code of BSC (Beneficiary did not meet the sponsor's internal criteria) would no longer be valid. Please confirm whether or not we should continue to submit Sponsor-Identified Potential Overutilization Issues (SPIs) cases that they identified using our own criteria and were not identified on the OMS report. This would include those instances of provider shopping where the beneficiary was getting prescriptions from multiple prescribers but did not exceed the average MME per day.

- **Recommendation:** CMS will provide new response codes for prescriber and pharmacy locks for the OMS reporting. CMS should continue to allow plans to implement and submit SPI cases to CMS that did not meet (or did not meet yet) the CMS targeting criteria.