The Special Needs Plan Alliance (SNPA) is pleased to offer our comments on this Medicare Proposed Rule: File Code CMS-4182-9. The SNPA represents 24 organizations of special needs plans and Medicare/Medicaid plans serving 1.5 million enrollees. Because our focus is on SNPs and MMPs, we did not comment on the entirety of the Proposed Rule. Instead, we have identified our comment areas by section, and where appropriate, by §§ numbers.

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

2. Flexibility in the Medicare Advantage Uniformity Requirements

Summary of Changes: CMS is proposing to provide MA organizations the ability to reduce cost sharing for certain covered benefits, offer specific tailored supplemental benefits, and offer lower deductibles for enrollees that meet specific medical criteria related to health status or disease state, provided that similarly situated enrollees (that is, all enrollees who meet the identified criteria) are treated the same. CMS is requesting comments and/or questions from stakeholders about the implementation of this flexibility. Implementation is proposed for CY 2019.

SNP Alliance Comments and Recommendations:
The SNP Alliance greatly appreciates the additional benefit flexibility provided to MAOs and their inclusion of SNPs. We believe these supplemental benefit policies should also incorporate the following key considerations:

- While the SNP Alliance supports the additional benefit flexibility, we believe it is important for CMS to carefully consider how comparative information will be presented across plans, such as in Medicare Plan Finder, in order to give beneficiaries an objective and clear representation of the merits of different plan choices. These comparisons need to incorporate special programs offered by C-SNPs.

- We would also underscore the importance of transparency as a means to mitigate member confusion and facilitate appropriate enrollment decisions. It is critically important to make sure that enrollees are aware of these benefits as early as possible so that they can immediately take advantage of the improved benefits. This transparency will in turn, maximize the opportunity for improved outcomes.

- When CMS includes in the preamble of the final regulation and sub-regulatory guidance particular disease states or health statuses that are permissible groups to target benefits/cost sharing adjustments, we urge CMS to include an affirmation that C-SNPs would automatically be permitted to adjust benefits and cost sharing based on the eligibility groupings that CMS has approved for each C-SNP. Similarly, we request that CMS allow D-SNPs that have been approved to serve particular Medicaid eligibility categories to tailor benefits for each Medicaid eligibility benefit category.

- In addition, it would be helpful for CMS to clarify in the preamble how this provision impacts the current VBID demonstration and the planned inclusion in that demonstration of C-SNPs. We want to ensure that all SNPs are provided at least the same level of flexibility being provided to general MA plans, both inside and
outside of demonstration authority. Further, CMS should consider aligning program requirements for this general MA provision with applicable provisions being used in the VBID Demonstration. The VBID initiative could be utilized as a market based learning laboratory for designing, testing, and implementing new innovations, with best practices allowed to be implemented by other MA plans quickly and easily as soon as practicable, similar to the private sector.

- CMS should also provide clarification in the preamble on how the additional benefit flexibility as outlined in the Medicare Managed Care Manual Chapter 16b for highly integrated D-SNPs is retained and/or modified under these provisions. That flexibility originated in the April 2012 MA regulatory amendments to §422.202, which allowed fully integrated dual eligible SNPs that meet certain additional quality-related requirements certain flexibility in providing certain supplemental benefits that CMS concluded were a “means of furthering this goal of better integrating care for dual eligible beneficiaries.” Current provisions as outlined in Chapter 16b allow highly integrated D-SNPs to provide additional flexible benefits to dually eligible beneficiaries including those with IADL and ADL needs. We suggest that CMS state in the preamble that this provision is distinct from the proposed modification of the uniformity of benefits provision. We also request that as part of this rulemaking, CMS should revise current guidance implementing §422.202 in order to allow more flexibility in the specific services identified in Chapter 16b to assure that these benefits could include additional items not listed here, including those tailored to populations with defined needs for long term supports and services or other supports needed to maintain health status, many of which are too expensive to be practically included in bids as supplemental benefits and/or overlap current Medicaid services so cannot be offered except to those not otherwise eligible.

- As noted above, we recommend that, under the change to the uniformity of benefits interpretation, CMS allow D-SNPs to tailor supplemental benefits for defined population segments that are not driven by disease and should expand the current population segments (people with IADL and ADL needs). For example, this provision should be expanded to include subpopulations such as those with behavioral health problems or homelessness and partial versus full benefit dually populations. We are especially supportive of flexibility that would allow plans to provide certain supplemental benefits only to fully integrated dually eligible Special Needs Plan (FIDE-SNP) enrollees who do not meet nursing home level of care requirements that would otherwise make them eligible for home and community-based services under an HCBS waiver.

3. Segment Benefits Flexibility

**Summary of Changes:** CMS proposes to allow MA plans to vary supplemental benefits, in addition to premium and cost sharing, by segment, as long as the benefits, premium, and cost sharing are uniform within each segment of an MA plan’s service area.

**SNP Alliance Comments and Recommendations:**
The SNP Alliance appreciates this change. See comments above on item 2.

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

**Summary of Changes:** CMS proposes to eliminate the requirement for the evaluation of meaningful differences between products based on premium levels and CMS review. Meaningful difference is currently not applicable to D-SNPs, but currently may apply to I-SNPs and C-SNPs. CMS seeks comments and suggestions on making sure beneficiaries continue to have access to innovative plans that meet their unique needs.
The SNP Alliance supports this change, recognizing that it is needed in order to implement further benefit flexibility as proposed in Section 2 and 3 and may be less burdensome for certain I-SNPs and C-SNPs. See comments above on item 2 for suggestions on how to ensure beneficiaries access to innovative plans that meet their unique needs.

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

**Summary of Changes:** CMS proposes codifying requirements for seamless default enrollments upon conversion to Medicare for dual eligible special needs plans (D-SNPs) offered by the same parent organization as their existing Medicaid plan, subject to five substantive conditions including approval from states. CMS requests comment whether authority to rescind approval should be broader and whether a time limit on the approval (such as 2 to 5 years) would be appropriate so that CMS would have to revisit the processes and procedures used by an MA organization in order to assure that the requirements are still being followed.

CMS also proposes sub-regulatory guidance to create a new and simplified positive (that is, “opt in”) election process that would be available to all MA organizations for the MA enrollments of their commercial, Medicaid or other non-Medicare plan members to provide individuals the option to remain with the organization that offers their non-Medicare coverage.

CMS requests comment on these proposals as follows:

- Permit default MA enrollments for dually-eligible beneficiaries who are newly eligible for Medicare under certain conditions and
- Permit simplified elections for seamless continuations of coverage for other newly-eligible beneficiaries who are in non-Medicare health coverage offered by the same parent organization that offers the MA plan.
- The form and manner in which these enrollments may occur, and whether the CMS authority to rescind approval of an organization’s request to conduct default enrollment should be broader or limited to a specific time frame.

CMS also requests comment on these alternatives:

- Codify the existing parameters for this type of seamless conversion default enrollment such that all MA organizations would be able to use this default enrollment process for newly eligible and newly enrolled Medicare beneficiaries in the MA organization’s non-Medicare coverage.
- Codify the existing parameters for this type of seamless conversion default enrollment, as described previously, but allow that use of default enrollment be limited to only the aged population.

**SNP Alliance Comments and Recommendations:**

The SNP Alliance greatly appreciates CMS’ thoughtful approach to this long standing issue and generally supports this provision. We recommend that the seamless conversion option be extended only to D-SNPs and MMPs at this time. We also suggest that CMS consider extension to other SNPs who hold Medicaid contracts such as those designed for people with HIV and AIDS, as mutually agreed upon by the state and the SNP.

We also suggest that CMS review the current process and guidance used for states and D-SNPs and MMPs to participate in seamless conversions, to reduce the complexity of the process and assure that the
requirements do not deter state interest and ability to work with interested qualified plans to provide this option to beneficiaries.

In order to successfully implement this policy, it will be important to ensure that states have clear guidance regarding when they must approve use of this default enrollment process, as well as what type of information they must share with the Medicare Advantage Organization (MAO), and in what timeframe. To make this process truly seamless, we ask CMS to provide guidance that details the respective roles of plans, states and CMS in the process, including when paperwork must be filed, and when decisions must be made. Ensuring timely and open communication between all parties will ensure the best experience for the member. In developing this guidance, CMS must pay particular attention to issues around the timing of Medicare eligibility data from the state via the Medicare Modernization Act (MMA) file because if not received in the month prior to the effective date, retro-activity becomes an issue for enrollment and CMS acceptance of that enrollment. Delays in receipt and incorrect data will cause member abrasion where benefits may not activate on the correct date or notices may not be delivered to eligible beneficiaries within CMS guidelines. If incorrect information is received, determination of the enrollment may be difficult. Thus, we urge CMS to set standards for the timeliness, completeness, and accuracy of the data included in the MMA file.

Further, because CMS will require a commitment from a MAO to implement the default enrollment—along with Agency and State approval to do so—we note that it would be helpful if CMS provided model boilerplate requirements to ensure a reasonable playing field—much like what it did as part of the MMP demonstrations. In addition, we request additional clarity on CMS’ approach to identifying/determining at any time whether or not to suspend/rescind approval of the default enrollment capability if the MAO is not in compliance. While we agree with the intent of the requirement, it is important for sponsors to have clear insight into the intended structure or approach for this review.

The SNP Alliance suggests that this provision be available to both aged and disabled members, however states and plans should have the ability to mutually determine the feasibility of application to those populations and should be able to choose to apply this feature to both or either population depending on their determinations of feasibility.

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

**Summary of Changes:** CMS proposes to add authority to long standing existing passive enrollment provisions to passively enroll full-benefit dually eligible beneficiaries who are currently enrolled in an integrated D-SNP into another integrated D-SNP under certain circumstances to preserve continuity of integrated care. CMS anticipates that these proposed regulations would permit passive enrollments only when all the following conditions are met:
- When necessary to promote integrated care and continuity of care;
- Where such action is taken in consultation with the state Medicaid agency;
- Where the D-SNP receiving passive enrollment contracts with the state Medicaid agency to provide Medicaid services; and
- Where D-SNPs meet certain other conditions to promote continuity and quality of care.

In addition to the proposed minimum quality standards and other requirements for a D-SNP to receive passive enrollments, CMS requests comments on whether to limit this proposed new passive enrollment authority to those circumstances in which such exercise would not raise total cost to the Medicare and Medicaid programs.
All individuals would be provided with a special election period (which, as established in sub-regulatory guidance, lasts for 2 months), as described in § 422.62(b)(4), provided they are not otherwise eligible for another SEP (for example, under proposed §423.38(c)(4)(ii)). CMS is not modifying current requirements for beneficiary notices but solicits comment on alternatives regarding beneficiary notices, including comments about the content and timing of such notices. CMS also notes that such restrictions would also apply to the Part C SEP.

**SNP Alliance Comments and Recommendations:**
The SNP Alliance is very appreciative of CMS’ recognition of the need for Medicare mechanisms for enrollment alignment and the benefits of integrated plan options in the limited situations covered by this proposal. We encourage CMS to require two notices for impacted beneficiaries and possible telephonic outreach for beneficiaries from whom the notices were returned, as well as for beneficiaries who do not speak English as a primary language.

The SNP Alliance does not support CMS’ suggestion that they might limit this proposed new passive enrollment authority to those circumstances in which such exercise would not raise total cost to the Medicare and Medicaid programs for several reasons. We would be concerned that this might create obstacles to states and plans that would further restrict their ability to align enrollment and preserve continuity of care. We believe this would be very difficult to implement and raises questions about how CMS would be able to make distinctions that would appropriately balance costs with quality considerations. Would plans that receive higher quality bonuses or have higher risk scores due to serving higher proportions of costly populations be disqualified?

We also want to point out that many other beneficiaries outside of these limited situations may be enrolled under two different plan sponsors, creating risk of conflicting care management incentives that may pose an enrollment alignment problem which is even more inefficient and potentially harmful to the beneficiary than the loss of an integrated plan option in the situations noted.

The SNP Alliance proposes that CMS expand this provision to allow passive enrollment into a D-SNP or MMP offered by the same parent organization as their existing Medicaid plan, when a state Medicaid agency is passively enrolling members into a mandatory Medicaid LTSS plan, allowing for both an opt out process and a special election period as proposed here, consistent with most Medicaid procedures.

The SNP Alliance also recommends that CMS clarify in the preamble how this provision is impacted by the reductions in access to a SEP for dually eligible beneficiaries. We request that CMS provide an exception to the proposed SEP restriction in § 423.38 for these passive enrollment purposes even when related to enrollment in an integrated plan.

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

**Summary of Changes:** CMS is proposing to revise Part D regulations to remove the reference to the use of a SEP by LIS and FBDE beneficiaries “at any time” and to limit SEPs for these beneficiaries as follows: limit the SEP for LIS and FBDE beneficiaries identified as at risk or potential at risk under proposed §423.100 to one per calendar year provided they are not limited under CARA provisions, to include duals in
a one-time annual SEP for all individuals under §422.62, to allow a SEP for members assigned to a plan to be used prior to the election effective date or within 2 months of enrollment, and to allow members who have a change in Medicaid or LIS status a SEP to make an election within two months of the change or being notified by the change:

CMS also seeks input on the following areas:
- Are there other limited circumstances where the dual SEP should be available?
- Are there special considerations CMS should keep in mind if we finalize this policy?
- Are there other alternative approaches CMS should consider in lieu of narrowing the scope of the SEP?
- In addition to CMS outreach materials, what are the best ways to educate the affected population and other stakeholders of the new proposed SEP parameters?

SNP Alliance Comments and Recommendations:
The SNP Alliance does not support the proposal to limit the continuous SEP for LIS/dually eligible beneficiaries as proposed. CMS should modify its proposal to prevent a disincentive for dual eligible beneficiaries from enrolling in integrated MA-PD plans. At a minimum we request that CMS continue to extend a continuous SEP to duals for the purpose of moving to an integrated plan option including highly integrated and FIDE SNPs and MMPs or for the purpose of moving to any D-SNP to align enrollment with a corresponding Medicaid plan offered by the same plan sponsor. Otherwise, this proposal could create severe new barriers that will seriously set back aligned enrollment in integrated options.

While the SNP Alliance appreciates that CMS has provided data on the use of assignment versus initial choices into Part D plans for this group of beneficiaries, and we recognize that a small proportion of the population changes plans frequently, we cannot overemphasize how important the current continuous SEP for dually eligible individuals has been as a tool for enrollment in integrated aligned plans. Under this provision, it appears that many dual eligible members could be locked into a Part D plan after the OEP (except for the few limited exceptions as noted) and may not be able to choose a matching integrated plan option at the time they most need it. We believe having duals enrolled in two unaligned plans can lead to conflicting financial and clinical incentives, and thus result in negative impacts on the care and wellbeing of dually eligible beneficiaries. The current continuous SEP is in the best interest of the majority of dually eligible beneficiaries as well as important to joint marketing strategies, viable enrollment levels, alignment of Medicare Medicaid enrollment under one plan sponsor, and consumer choice in states where integrated care options through D-SNPs and MMPs are being promoted.

To explain further, most dually eligible beneficiaries are already enrolled in a Part D plan at the time they become dually eligible. As CMS points out, newly dually eligible beneficiaries who do not choose a plan can be initially assigned to a Part D stand-alone plan by CMS when they reach 65 to assure access to Part D coverage unless they choose a plan. This initial assignment provision also applies to the bulk of people with disabilities under age 65 who become dually eligible. At the same time, the majority of seniors are already enrolled in a PDP or MA-PD by the time they need Medicaid services and become dually eligible, and are then also eligible for enrollment in an integrated plan option such as a D-SNP or MMP. Many of these beneficiaries may have already used an annual SEP by the time they learn about integrated plans options that may be available to them.

Specifically, we are concerned front-end Medicaid enrollment procedures may take too long for those dually eligible to make meaningful use of the proposed SEP exception related to auto-assignments. It takes time to identify people with eligibility changes and send the appropriate mailing materials describing choice of health plans and programs. Beneficiaries and their families need sufficient time to consider their choices and submit the appropriate forms. By then, auto assignment by CMS into another Part D plan may have
occurred, generating another two month option to enroll into an integrated product, another set of notice materials to confuse beneficiaries, and another deadline that may be missed.

Furthermore, consumers are often fearful of any change of plans. Once they are already enrolled in a drug plan it is harder to get dually eligible beneficiaries to switch plans to enroll in an integrated D-SNP or MMP even though there are benefits to enrollment in the integrated programs. We believe further restriction of the continuous SEP provision will inhibit the movement from PDPs to D-SNPs and/or MMPs designed specifically to serve dually eligible beneficiaries.

Currently many D-SNPs and MMPs rely on the continuous SEP to obtain enrollees, including their primary targeted enrollment population consisting of those who are already enrolled in their corresponding Medicaid MLTSS plan. Marketing to these individuals requires considerable effort and immediate action when the time is right for them, or when the person has made up his/her mind. It appears this provision would restrict a dually eligible beneficiary’s choice to enroll in an integrated D-SNP or an MMP at a time when they may need such specialized care the most because of their medical and end-of-life care needs. Many of these enrollees cannot wait for another year to access another annual SEP for enrollment and indeed, may not live long enough to be able to utilize the annual SEP, thus denying them the enhanced care coordination that D-SNPs and MMPs provide.

In addition, because state enrollment in a managed care plan may lag initial assignment to a PDP by 2-4 months, the loss of this SEP will exacerbate this already difficult barrier to enrollment in integrated plan options. Beneficiaries already assigned to a PDP who later will need to choose a Medicaid plan may not be able to choose an integrated plan option (DSNP or MMP) that is sponsored by the same entity as their Medicaid plan because they may already be locked into a Part D plan. Further complications will ensue for members who temporarily lose Medicaid eligibility and currently may have up to 90 days to be reinstated and reenrolled in the Medicaid plan. Restriction of this election type could result in difficulties re-enrolling beneficiaries in the integrated programs. In many cases these temporary losses of Medicaid are related to paper work issues that may be out of the beneficiary’s control, and large numbers of reinstatements are common each month. It is also not clear whether CMS’ system will see these cases as new enrollees and auto assign them to an unaffiliated Part D plan in the meantime further disrupting their continuity of care.

We are also concerned that the proposed changes in annual open enrollment time frames actually increase the need to retain the existing Part D SEP because it may no longer coincide with the Medicaid open enrollment dates and education (usually the last quarter of the year). It is our understanding that this time period is used by many states and employer group policies. This change will create communication difficulties for beneficiaries, making it difficult for them to understand when their annual open enrollment period runs. Potentially, an enrollee could be faced with even more requests to complete forms to enroll in an integrated program. We suggest that CMS allow states with integrated MAO/Medicaid programs to retain their existing open enrollment period.

We strongly request that CMS revise this provision to continue to allow the current continuous SEP for dually eligible beneficiaries (those not subject to the CARA restrictions) in order to avoid a serious new barriers to expansion of integrate care caused by this proposed limitation to the continuous SEP for dually eligible beneficiaries. If CMS must make a change we would support the option of use of the continuous SEP for the purpose of enrollment into a FIDE or highly-integrated D-SNP and for alignment with a Medicaid managed care plan.

We also note that we found the multiple sections and discussions related to these SEP changes and possible interactions between them somewhat confusing and difficult to navigate. It was difficult to determine how
many SEP plan changes were allowed, and what timelines for those changes would ultimately be available to LIS/Dually eligible beneficiaries. We were also unclear as to how they ultimately relate to AEP and OEP changes. If we have this difficulty we are sure that most beneficiaries will also be challenged to understand the changes. We request that CMS provide additional clarification in the preamble.

Therefore we do not believe explaining the SEP to beneficiaries using a SEP for enrollment into an integrated plan option or the ability to continue to have the current continuous SEP will be any more confusing that it will be to have to explain to these members that they are now locked into a plan and cannot move to an integrated option that could be clearly beneficial to them. Finally, we suggest that any outreach to communicate changes to the SEP must go beyond mailed English-only materials. There must be community-based outreach in multiple languages to ensure that those dually eligible of all communities are aware of the availability of this choice.

10. Medicare Advantage and Part D Prescription Drug Program Quality Rating System

**Summary of Rule Language:** CMS is proposing to codify the existing Stars measures and the Quality Management System, and solicits feedback from stakeholders on how well the existing Stars measures create meaningful quality improvement incentives and differentiate plans based on quality. [Relevant statutes and regulations: §§ 422.160, §§ 422.164, §§ 422.166 §§ 423.180, §§ 423.184 §§ 423.186; propose to add to part 422 subpart D and part 423 subpart D]

**SNP Alliance Comments and Recommendations**

In terms of our overall response, we hope that CMS will consider alternatives for special needs and Medicare/Medicaid populations and/or make substantive modifications to the current measures, methods, factors for adjustments, cut point methods, scoring, rating, and reporting toward the stated goals for the quality management system and the Stars Ratings as part of this rule codification, or through subsequent action in the near term.

The SNP Alliance appreciates the goals set forth by CMS for the Stars Ratings and quality management system under Medicare. The Proposed Rule describes these goals in several places within the rule as follows (from Introduction):

- To display quality information on Medicare Plan Finder for public accountability and to help beneficiaries, families, and caregivers make informed choices by being able to consider a plan’s quality, cost, and coverage
- To incentivize quality improvement
- To provide information to oversee and monitor quality
- To accurately measure and calculate scores and stars to reflect true performance.

And furthermore, CMS notes an additional goal:

- To recognize the challenges of serving high risk, high needs populations, while continuing the focus on improving health care for these important groups.

The SNP Alliance supports these goals and is committed to working with CMS and other stakeholders to help CMS achieve them. In our comments, the SNP Alliance focuses particular attention on the Part C Star measures and methods and would like to offer recommendations to enable CMS to more accurately measure and reflect the true performance of plans specializing in care of Medicare beneficiaries with multiple,
complex and ongoing care needs and/or persons who are also eligible for Medicaid benefits and services (the dually eligible). It is well-known that this population represents a vulnerable and high need group of beneficiaries. This is a high cost population with complex medical/physical, behavioral health, and social support needs.

Based on our analysis of the Stars Rating and Quality Management System (QMS), we are concerned that the current system does not yet achieve the goals stated in an equitable way. This concern derives from the fact that the current system represents a “one size fits all” approach with modest adjustments for some types of beneficiaries or in certain circumstances. While we recognize and appreciate the foundational work done thus far toward the goals, the current Star measures and QMS does not provide for adequate tailoring for special needs populations; has methodological biases, does not adequately accommodate and adjust for beneficiaries with social risk factors, linguistic and ethnic diversity, or cognitive, complexity status, and does not provide enough meaningful information for beneficiaries to make relevant comparisons across plan products, nor for plans to pinpoint targeted quality improvement in focus areas that are most relevant for special needs populations.

We appreciate the initial interim steps that CMS has taken to begin to address these limitations, such as the initial and interim adjustments on six Star measures under the Categorical Adjustment Index method. However, more is needed to make the system more equitable and accurate toward the stated goals. The quality measures, scoring, rating, and reporting must be based on sound instruments, equitable and complete data collection, sound methods, accurate and complete adjustment, and relevant comparisons.

There are at least two approaches to address current limitations: (1) continue to make targeted and substantive adjustments to the current Star measures, instruments, methods, measure and plan adjustment, analysis, and reporting—so that scoring, payment, and reporting is improved, or (2) create/design and test a tailored measurement and management system that is specific to special needs Medicare/Medicaid populations and compare results to the current system.

We believe CMS has the statutory authority to consider accommodation and tailoring of quality measures and the quality management system for special needs populations—as evidenced by the legislation enacting this particular form of Medicare Advantage Organization, and by the recognition through subsequent legislative action. Congress has repeatedly recognized the importance of focusing on chronic, complex care populations and of addressing social determinants of health (SDOH). These characteristics are recognized as impacting segments of the population covered under government programs. To better understand and account for these issues, Congress has authorized studies and regulatory modifications toward addressing the impact of these factors. Recent legislation and Senate bills directing changes and studies on these issues include provisions in the Patient Protection and Affordable Care Act, the 21st Century CURES Act, the IMPACT Act and the Chronic Care Act. As mentioned, section 1832(b) authorizes CMS to establish and annually modify the Star Ratings System, because the system “is an integral part of the policies governing Part C payment.”
The special needs population is characterized by a high degree of chronic physical and mental health conditions and disability, as well as substantial presence of social risk issues including low socioeconomic status. These factors have a significant impact on a person’s ability to achieve optimal health outcomes. The evidence is compelling that these issues must be taken into account when providing and evaluating care. Recent reports by the Assistant Secretary for Planning and Evaluation and the National Academies of Sciences, Engineering and Medicine support this conclusion.

In their service to beneficiaries, providers and plans are expected to re-design and adapt structures, processes, and services in order to address these issues in the special needs populations. Logically, the quality management system must also be expected to be redesigned and adapted so that meaningful data elements, structures, and processes are utilized to accurately measure and report on quality of care and performance.

The SNP Alliance has indicated in previous comments where/how specific measures and methods used in the Star Ratings do not match with the special needs plans’ beneficiary characteristics and thus may not provide adequate information for discerning quality performance or how to affect change toward quality improvement. Data which is not complete may lead to inaccurate conclusions and therefore inaccurate reporting on performance. This is particularly problematic with self-report survey information collected from dually eligible persons who are non-English speaking, of low health literacy, of diverse backgrounds, with high social determinant risk issues (such as housing transience or without a reliable phone), or cognitive impairment.

CMS has asked for comments on how, or if, the Star measures provide relevant information for quality improvement. We conducted a survey of the member plans as well as several calls to explore these benefits and challenges. Revised measure specifications, having a core set of meaningful measures that better match the SNP and M/M population, alignment across plan and providers, and relevant comparison group cohorts are four areas for improving the current system.

There are some cases where health plans report that they have been able to use the Star measure results for quality assessment and improvement, for example in working in a few targeted clinical focus areas, such as working with providers and directly engaging members to improve individuals’ willingness to be screened for breast cancer or colon cancer. Additional specific clinical measures, such as on Diabetes, can be useful in showing trends over time and indicating progress related to specific clinical interventions implemented by provider groups in concert with the health plan.

In many areas, however, the data are too old, the sample inadequate, or the measurement specifications problematic, such that the resulting information is not useful for quality improvement. The longitudinal two-year look back design of HOS is especially challenging in populations with high rates of degenerative or progressive conditions coupled with pervasive low socioeconomic status and high social risk factors. Plans end up utilizing other methods and working to find other data sources to identify quality gaps and be aware of high performing providers or strategies. Because these alternate measures and methods are not national, the resulting challenge is having relevant benchmarks.
In addition to having a core set of more meaningful measures that align across plans and providers around special needs populations, health plans would sincerely like to compare themselves and their performance with other like plans that have similar enrollment populations—people with similar characteristics as their own. This would offer greater opportunity for action.

Plans point to limitations in the current quality measurement specifications, data collection, self-report instruments, sampling, lack of complete risk adjustment, ranking/scoring methods, unit of analysis, and aggregate reporting which can confound results and may fail to provide either plans or beneficiaries with accurate information. Furthermore, the resulting quality bonus payments (or lack thereof) may perpetuate disparities in terms of resource distribution.

We urge attention to these needed changes to address potential inaccuracies or biases in the measurement process and quality management system, particularly as pertain to high need/chronic and complex care beneficiaries who are dually-eligible for Medicare and Medicaid and enrolled in special needs plans prior to codifying the current system, or as an additional step.

We appreciate CMS’s interest in codifying sections of the current rules to provide stability in the system. We agree that transparency and predictability is important for organizations to anticipate measure elements and respond, invest, and learn from accurate quality measurement results. However, we hope that CMS will test alternatives and make substantive modifications to the current measures, methods, factors for adjustments, cut point methods, scoring, rating, and reporting as part of this rule codification, or through subsequent action in the near term.

Specifically, we would welcome a commitment to developing and pilot testing an alternate QMS with substitute Star measures and methods that are tailored to dual, special needs beneficiaries. SNP Star rating reporting would compare like plans to like plans (e.g., displaying plans by proportion of enrollment that is dually eligible and disabled) and provide greater accuracy and transparency for beneficiaries and benchmarking. The SNP Alliance fully commits to assisting in this effort—together with beneficiary groups and other stakeholders.

**Summary of Rule Language (Background):** The proposed rule discusses the requirement for health plans to report on quality improvement and quality assurance and to provide data which CMS can use to help beneficiaries compare plans. Use of specific instruments are described, including use of the Healthcare Effectiveness Data and Information Set (HEDIS) data, Health Outcomes Survey (HOS) and Consumer Assessment of Healthcare Providers and Systems (CAHPS) referring to §§ 422.152 and 423.153. The language describes how these surveys have been used for many years. CMS has selected specific data elements from the surveys and data sets to measure specific elements of care which make up the MA (Part C) and Part D Star Ratings system. The rule notes that the information included in the ratings is selected based on its relevance and importance, such that it can meet the data needs of beneficiaries using it to inform plan choice. ...The ratings focus on aspects of care that are within the control of the health plan and can spur quality improvement. The data used in the ratings must be complete, accurate, reliable and valid.

Through examination and use of selected data elements from the data sets listed, CMS calculates measure-specific and overall ratings for Medicare Advantage Organizations—with all MAOs in one cohort, using a
contract level unit of analysis. Quality ratings are based on a 5 star rating system (section 1852(e)) and are to be used in calculating payment and determining rebates (pertaining to sections 1853(o) and 1854(b)(1)(C)). As noted, this practice began in 2012, so there should be enough experience to identify limitations and strengths.

In addition, CMS requests response by stakeholders in many specific areas, including the following:

- **Additional opportunities to improve measures so that they further reflect the quality of health outcomes under the rated plans.**

- **Whether CMS’ current process for establishing the cut points for Star Rating can be simplified, and if the relative performance as reflected by the existing cut points accurately reflects plan quality.**

- **How CMS should measure overall improvement across the Star Ratings measures.** We are requesting input on additional improvement adjustments that could be implemented, and the effect that these adjustment could have on new entrants (that is new MA organizations and/or new plans offered by existing MA organizations).

- **Additional adjustments to the Star Ratings measures or methodology that could further account for unique geographic and provider market characteristics that affect performance (for example, rural geographies or monopolistic provider geographies), and the operational difficulties that plans could experience if such adjustments were adopted.**

- **In order to further encourage plan participation and new market entrants, whether CMS should consider implementing a demonstration to test alternative approaches for putting new entrants (that is, new MA organizations) on a level playing field with renewing plans from a Star Ratings perspective for a pre-determined period of time.**

- **Adding measures that evaluate quality from the perspective of adopting new technology (for example, the percent of beneficiaries enrolled through online brokers or the use of telemedicine) or improving the ease, simplicity, and satisfaction of the beneficiary experience in a plan.**

- **Including survey measures of physicians’ experiences. (Currently, we measure beneficiaries’ experiences with their health and drug plans through the CAHPS survey.)**

- **Physicians also interact with health and drug plans on a daily basis on behalf of their patients. We are considering developing a survey tool for collecting standardized information on physicians’ experiences with health and drug plans and their services, and we would welcome comments.**

**Specific Priority Actions and Recommendations**

The codification of all of the quality measures, methods, scoring, rating, and reporting represents significant action on the part of CMS and the request for comments is extensive. Sections where comments have been provided pertain the following sections in the proposed rule:

- Introduction
- Background
- Basis, Purpose and Applicability of the Quality Star Ratings System
- Contract Ratings
- Data Sources
• Adding, Updating, and Removing Measures
• Improvement Measures
• Data Integrity
• Measure-Level Star Ratings
• Hierarchical Structure of the Ratings
• Domain Star Ratings
• Part C and D Summary Ratings
• Overall Rating
• Measure Weights
• Application of the Improvement Measure Scores
• Categorical Adjustment Index

We tried to pare down our initial analysis and set of comments to a core set—however we do have additional information that may be helpful for future work with CMS and other stakeholders. We are very open to continuing the examination and discussion and would welcome the opportunity to be part of a larger effort toward an improved system.

We offer sixteen substantive priorities for action and set of recommendations. Items #1 through 8 relate to making modifications to the Star measures, methods, adjustment, and reporting to address the current QMS inequities or limitations that appear to disproportionately affect SNP and Medicare/Medicaid (MMP) populations. Items # 9 through 16 are in response to additional specific requests by CMS for comment.

1) **Modify or Replace the Health Outcomes Survey** – replace or modify the HOS instrument and methods to accommodate and reflect beneficiary diversity, and address design and method limitations, attribution issues, as well as reliability and validity concerns. The two measures which are particularly problematic focus on maintaining or improving physical or mental health. If kept, provide for additional exclusions for beneficiaries with characteristics that have been shown to restrict ability to maintain or improve health, independent of plan or provider action—examples could include those on palliative care, those with degenerative progressive conditions, those who have reached the maximum medical therapeutic regimen available to address the condition(s), and those with advanced cognitive impairment. Provide translation and instrument adaptation for additional languages and explore alternative methods for administration. Drop the two year look-back design. Change sampling methodology to oversample typically under-represented groups. Discontinue use of proxies for self-report items, as there is strong evidence indicating proxies’ responses are not equivalent to beneficiaries’ responses. Finally, the HOS questions that are included in the Star measures should be re-weighted as “1” until such time as the validity of the question in diverse special needs populations, the methodological limitations, and these other issues can be resolved.

As part of this re-examination we strongly recommend that CMS initiate a study to obtain diverse beneficiary insights on HOS and make a commitment to revise HOS based on the findings. A rigorous process that includes examination of the validity and reliability of the items in diverse populations is warranted. This would include scientific testing—at least of key items in the survey—as well as substantive and diverse beneficiary input and feedback on the HOS survey items. We suggest that examination of question wording, response options, prompts, and question order, data collection methods, sampling and
accommodation, adjustment, and scoring—are necessary. The examination should particularly solicit input and feedback from persons who: are disabled, low-income, dually-eligible, do not speak English, Spanish or Chinese, have housing and communication method instability, have degenerative life-limiting chronic conditions, or are non-White, ethnic, or foreign-born individuals. We urge CMS to also involve key stakeholders including a continuum of “safety net” primary care, behavioral health, and long-term services and support providers and the health plans that particularly focus on these beneficiary populations. For several years, this has been a top rated concern among SNP Alliance health plans regarding the Star ratings.

2) Set Minimum Standards for Measure Developers and Stewards – We appreciate CMS willingness to respond to the ASPE report and work by NQF on the need for recognizing the effects of social risk issues and care complexity in the LIS/DE, disabled, and high social risk factor populations. An important gap in guidance could be filled by CMS immediately by issuing minimum standards to measure developers and stewards. Currently there are no minimum standards guiding or requiring measure developers and stewards to conduct specific sampling, include specific variables, design or utilize specific methods, or test, adjust, and report findings with a level of defined scientific rigor.

It is difficult to know if measures have been adequately developed and tested with inclusion of special needs populations in the sample, and if adjustment for social determinant health risk factors is warranted, as results are often not fully reported. We note that an expert panel on disparities from the National Quality Forum recently examined this issue and issued a report (September 2017). They found that there was wide variation in the methods and rigor in how measure developers conducted this examination. We do not have publicly available information on specific results for dual populations, those with social determinant of health risk issues, those who do not speak English, those with multiple complex co-morbidities, cognitive impairment, etc.

The clinically-related preventive and guideline-derived measures in Stars have more evidence behind them in terms of relevancy and of testing in different subpopulations and are driven and affected more directly by provider action. However there are other measures within Stars which do not appear to have been tested with the same rigor among special needs populations. There is not a sufficient body of evidence publicly available to which we can refer. In addition, the self-report measures (which are by definition, subjective) may experience a much greater influence of factors independent of provider or plan action on the result. This makes it even more important to ensure adequate measure testing and how measures may need to be adjusted to reflect or accommodate beneficiary characteristics.

Without minimum standards guiding development and testing, questions about the validity, reliability, and accuracy of measures and measure results are raised. The use of these measures for assessing a specific aspect of quality for diverse populations and those with a high level of social risk factors becomes problematic. We urge CMS to issue minimum standards for measure development and testing and considerations for adjustment, and also require developers to publish their findings to promote and support the goal of transparency.
3) **Conduct a Modeling of the Effect of Stratifying Plans into Relevant Comparison Groups** – Two stated key goals of Star Ratings are for beneficiary comparisons and plan benchmarking. In the current rating and reporting process, all MAOs are included in one cohort and treated as the same in terms of unit of analysis by contract. This is clearly not the case. Contracts differ widely in enrollment characteristics. We request that CMS model methods to calculate and report Stars ratings based on stratified groups (cohorts) of health plans with similar enrollment profiles, e.g., quintile cohorts based on proportion dually-eligible, low-income, or disabled. This stratification is supported by the ASPE report evaluating effect of these characteristics on Star ratings. Additional value would be offered by showing the median, mean, and range of Star measure distribution, by measure, by plan cohort. Furthermore, such a model should test the value in utilizing these cohorts to establish the cut points for each measure to determine achievement of 3, 4, or 5 Stars. We look to CMS to model this approach as a step which builds off of the recommendations in the ASPE and NASEM reports. This would be an important step toward advancing the stated goals for Stars and the QMS.

4) **Conduct a Modeling of Adjustment for Community Characteristics** – Thank you for recognizing that there are unique community/market characteristics that affect health outcomes and therefore can impact observed performance on Star measures. Similar to the need for considering Dual/LIS/Disabled factors among the enrolled population, is the need for considering community characteristics which can impact beneficiary outcomes. Given evidence of the influence of market and community characteristics on health, which may not be able to be overcome by actions at the individual level, we agree that CMS should examine key characteristics and model methods for a population-level geographic adjustment that is finer than at a county or zip-code unit level. This modeling could provide additional value to the field by analysis conducted at a neighborhood geographic unit, e.g., using 9-digit zip codes, and testing out effects. Community factors that have been linked to poorer health status in multiple studies include:

- Percentage of the population in the geographic area living below poverty
- Significantly older average age of the population (e.g., one or two standard deviations from national average)
- Percentage of the population who are homeowners (lower level indicates greater vulnerability)
- Designation as a primary care shortage area
- Designation as a low behavioral health/mental health service access area

These data are available nationally in various data sets, though not necessarily in publicly available files. They need to be brought together in a dataset that is organized around relevant and consistent small geographic units (e.g., beyond 5-digit zip code areas which are not standardized units/sizes). This information needs to be made available to the public. Such information would be valuable to both CMS and the field to move toward more complete population health strategies, measuring outcomes, and addressing vulnerable populations, particularly those with high social determinant of health risk characteristics. As CMS made the dataset available, it could also test methods for determining the relevant community areas by plan enrollment and then model various approaches for adjusting Star measure results for the variability that these characteristics introduce. That is, options could be explored that adjust for influence which is empirically demonstrated to be associated with these community characteristics. A goal would be to identify and promote effective strategies for health outcomes improvement at a community level. Incentives to
increase the level of resources and tailored approach for care and service to communities with high risk characteristics could be designed. This effort should involve key stakeholders such as plans, providers, beneficiaries, government, and community agencies in each relevant market area to affect greater change and promote a community-derived approach to addressing underlying disparity issues.

Regarding Star rating adjustment related to plans serving high at-risk communities, an interim solution could be tested around the feasibility and merits of providing an additional Star “bump” (e.g., 1/2 Star bonus prior to overall rating scores) to plans with a high proportion of enrollment residing in at-risk, high need communities, where improvement over two time periods has been demonstrated. The focus would be to support quality improvement in these high risk communities and advance important goals toward health equity.

5) **Improve the Categorical Adjustment Index** – The CAI is a method that was implemented following action requiring that socioeconomic status (SES) and other beneficiary characteristics that affect health outcomes independent of plan performance be taken into account. While we appreciate the initial and interim step, this has now been in use for two+ years, and it is clear that the method has not been effective in addressing this issue. Only 6 out of 47 Part C Star measures are included in the CAI formula. Unadjusted measures used in the Star ratings may be yielding inaccurate conclusions about providers and plans who serve a disproportionate number of individuals with these characteristics. These quality ratings can influence consumer behavior and are tied to payment. This may inadvertently negatively impact providers and plans serving the most vulnerable population subgroups. Options for improvement could include: (1) applying an additional population-level quality adjustment to plans achieving at least 3 Stars where their enrollment profile characteristics indicate high social determinant of health risk issues, and/or (2) adding more social risk adjustment factors to the CAI model, and/or (3) including more measures in the CAI.

6) **Level the Playing Field on Measurement Burden** – CMS notes that there are four additional measures applied to SNPs but not applied to all MAOs serving older adults. These include: Older Adult Care Management, Care of Older Adults-Medication Review, Functional Status, and Pain Assessment). We agree that these are useful and relevant measures. While challenging to collect and report, they can offer important information that is specific to older adult care management and priority focus areas. However, because they are only required by SNPs to collect and report and are not taken into account in the overall Star Ratings for plan comparisons, there is unequal burden on SNPs under the Star measurement process. The SNP Alliance recommends that the measurement burden made equal, particularly as the Star measures and rating system already have a number of limitations given SNP population characteristics which are not yet fully taken into account. Therefore, we recommend that these four measures either be applied to all MAOs serving older adults, or allow SNPs to voluntarily substitute these measures for other Star measures within that domain to be included in Star Ratings, so that SNPs do not have unequal administrative and reporting burden under the Stars QMS.

7) **Recognize Additional Operational Costs for Serving LIS/Dual/Disabled** – We appreciate the opportunity to comment on the issue of accounting for LIS/DE, disability, and social risk factor effects on quality measure results, administrative costs, and performing the care management functions—specifically how these differ
between caring for these beneficiaries as compared to beneficiaries who do not have these characteristics. Health plans that have both a general MAO plan product and a special needs plan product are likely most familiar with the cost differential in conducting the following processes and operational or administrative functions (listed below). As some special needs plans only provide special needs plan products and have 100% of their population with the vulnerability characteristics described, it is harder for these organizations to offer comparison information.

The processes and operational or administrative costs to serve the LIS/DE, disability, and high social risk factor beneficiary population are often higher in many areas. We offer examples:

- **Member intake** - The processes for intake and ongoing member (beneficiary support) often require multiple attempts, needing to investigate multiple potential addresses or phone numbers; additional time and information one-on-one is often needed to explain processes at time of enrollment; establishing and maintaining contact information including emergency contacts and the individual’s preferred clinic or primary care provider (which can change more frequently in this population) requires more time and monitoring; providing the member with needed member materials and health insurance card—simple sounding, but may involve multiple attempts (different addresses) and interpreter services as well.

- **Member engagement and call center response** – More time and translation services are often required to conduct and respond to member calls and to reach out proactively to encourage member/beneficiary participation in accessing their benefits including participating in wellness activities, care management processes, or prevention actions, such as getting a flu shot, or important annual screenings.

- **Care management and care coordination** – Conducting the health risk assessment can be challenging, both in terms of finding the individual, and in securing their permission to conduct the assessment—in person or over the phone. Spotty access to communication devices (e.g. the individual has several track phones that are shared with others, the phone runs out of minutes prior to the end of the month, etc.) complicate communication. This population has a higher refusal rate and unable-to-be-reached rate (three attempts at least annually) to health plan requests to conduct a health risk assessment. Individuals (beneficiaries) may not have a home or be uncomfortable in allowing the health plan care support personnel to enter the home to do the survey. Literacy issues, language, and difficulty hearing may be other reasons that the assessment cannot reasonably be completed over the phone. Assessment interviews and care manager visits may have to be conducted in a public space determined by the individual. Homeless and transient housing issues for assessment and care management follow up particularly challenging. Coordination with providers and support services involved in member’s care is also more challenging. The multiple needs and the social risk issues frequently involve behavioral health, physical/medical health, social services, community support, and other services or organizations with which the care management and interdisciplinary team of the health plan need to interact. Compared to individuals without these characteristics, members with multiple complex chronic conditions and social risk issues including behavioral and mental health (more prevalent among the LIS/DE, disability, and social risk populations) require significantly more health plan care management and administrative staff time to identify, communicate, coordinate, and respond.

- **Quality self-report and quality improvement projects** – As described, many of these members are hard to reach. There are many entities trying to reach them and trying to provide guidance in various aspects of their care. The multiple service providers involved in their care/support may be confusing to the individual. Moreover, each provider may have specific information needs, including quality initiatives.
This may proliferate the number of requests to these members to participate in surveys, visits, or other communication. Some of these surveys and visits may overlap in content and timing. Individuals can easily become overwhelmed and refuse to participate in any of them. Helping to differentiate the purpose and initiator of each request of the member and time needed to engage these individuals and encourage them to provide response to mailed or telephone surveys about their care and satisfaction with various aspects of the medical, behavioral health, or long term care, or about the access, ease, communication, or other components of their plan/benefits, as well as follow-up on care recommendations—all of this can be very labor intensive. In ethnically and linguistically diverse populations this will also involve interpreter services.

This information is illustrative to provide insight into the operational and administrative challenges. We are encouraged that CMS will continue to collect information and address issues raised. We appreciate the work undertaken to date.

8) **Provide Additional Measure Exceptions and Exclusions** – Some of the Part C measures do not currently exclude from the denominator individuals with the following characteristics where such exclusion would be warranted: those with advanced illness and in palliative care, those who have refused treatment, assessment, or the screening recommended (documented), and those who are unable to achieve the desired clinical threshold despite having reached the maximum medical therapy and self-care practices available for the condition. We recommend that these adjustments be made.

9) **Allow for PBP to Contract Conversion and H# contracts to be split** – We appreciate the interest by CMS to ensure that the Star measurement be conducted using a meaningful unit of analysis—and CMS rightly discusses that unit of analysis should relate to how beneficiaries select plan products at the PBP level. Toward that end, we request that CMS discontinue the moratorium that does not allow for existing H# contracts to be split. Some H#s now include many PBPs that represent different products and beneficiary types. Allowing for a split will provide for more meaningful measurement and reporting. Allowing for smaller and more population-based units of analysis would provide better representation of the distinct enrollment, provider network, and care management approaches that health plans have developed to tailor their plan products and care models to specific beneficiary subgroup populations and needs. We request that CMS allow health plans to designate contracts to be split on a voluntary basis—at least for a defined window of time to address older contracts that may have developed new plan offerings over time—as regional markets opened up and beneficiary interest across population subgroups grew.

10) **Test PBP-level Quality Measurement and Reporting** – Similar to item #9, we support the exploration that CMS proposes, namely: to determine options and feasibility (conduct a pilot test) of PBP-level Star measurement, scoring, and reporting. This could be done with a sample of plans through voluntary participation. This would provide modeling and information to ascertain the value of PBP level vs. contract level reporting, including understanding administrative and operational burden as well as effect on accuracy and population subgroup relevance. Examination of the enrollment profile at a PBP level vs. contract level could reveal relevant plan cohorts or categories for comparison, e.g., based on size, geography, beneficiary characteristics, etc.
11) **Make Adjustments to Cut point Methodology or Return to Thresholds** – We appreciate the methodological challenges and statistical rigor required to ensure accurate and meaningful cut points in order to determine the Stars ratings such as is described in this proposed rule. We continue to be concerned that grouping all MA plans together does not take into account significant underlying differences in the enrolled populations. By adjusting cut points based on national data annually, as performance rises overall, the differential between scores and Stars becomes smaller and smaller. This is apparent with some measures already. Alternatively, if there is wide variation from year to year in cut points—that calls into question the validity of the data—unless there were significant changes in the number of plans, volume of enrollment, or change in characteristics of beneficiaries. What would explain wide variation? We agree that finding ways to ensure stability in the cut points year to year is very important. It is also important to group similar plans into cohorts for comparison purposes (such as based on proportion of enrollment Dual/LIS/Disabled). As the field moves toward greater population health strategies for given beneficiary subgroups and as value-based payment methods continue to take hold, it is very important to base analysis and comparisons of like populations.

Modifications to improve the stability and utility of the cut point methodology could include any or all of the following: removing outliers prior to applying the clustering logic, raising the denominator threshold from 30 to 100 to reduce the number of outliers based on small numbers, or limiting the year to year variation through adding an additional index that takes into account improvement (or decline) from the year prior by that contract. This could produce more meaningful differentiation within the cut points, particularly for measures where performance overall is generally high. Another option is to calculate cut points after grouping plans into relevant cohorts (stratification at the plan level on key population characteristics, such as proportion Dual/LIS/Disabled). In addition to current case mix adjustment, additional factors could also be added to recognize special needs populations and underlying effects of beneficiary characteristics known to affect health outcomes independent of plan action. CMS could also consider return to pre-determined thresholds—setting quality targets which remain stable for more than one year—with some index for performance improvement (or decline) added in to the threshold calculation. Key purposes for adjusting the methodology include: improve stability of targets across years, address ceiling effect where differentiation between Star level cut points is very small, recognize improvement consistently, and remove any unintended biases or harm to plans with small enrollment where variations are statistically much more likely from year to year. We request that CMS offer detailed information on various options modeled, including the additional proposed options, such as using moving averages across two to three years. Stakeholder input is critical in this modeling process.

12) **Add, Update or Remove Measures** – We agree that an advance announcement on any changes is appropriate and that new measures should be kept on the Display Page for a minimum of two years. We request that CMS consider using the stated criteria to assess each measure’s value and lean toward measures that are universally applicable across populations groups and could be useful across settings. Measure exclusions for specific populations may also help reduce measurement burden where the measure may not be very relevant anyway. In addition, we suggest that CMS consider a consistent rule, trigger, and process for how to handle measures where many contracts score very high (e.g. at 5 Stars) or very low (below 3
Stars)—or where there is great variation from one year to another in overall scores. These triggers may indicate various important information, such as: the field has achieved a sustainable high performance level in a given area (high performance is pervasive), the field does not have the necessary process capacity, or strategies to address the measure (pervasive low performance), or that there are underlying measure specification issues, or population variances or external factors which affect the measure result independent of plan action from year to year. Finally, we request that measure stewards provide data/publish findings on testing of measures for key factors or in various populations to ensure the continued validity and reliability in these populations. Some of the examples given of “non-substantive” changes may be significant in special populations and therefore signal substantive change, requiring experience and additional testing in the field—which means they should be moved to the Display Page. Over time, additional testing and adjustment may be needed given greater understanding of underlying factors affecting the measure results.

We urge CMS to establish additional oversight over this issue—the requested minimum guidelines for measure developers and stewards pertains here.

13) **Address Potential Inequity in Application of Improvement measures** and **Consider Additional Factor in Overall Summary Ratings**—There is potential disadvantage for SNPs and Medicare/Medicaid plans who serve special needs populations and that tend to have smaller plan enrollment in application of improvement measure calculations in Star ratings. This may particularly come into play when measure application requires sampling to gather data from a subset of the enrolled population (such as in HOS). Given the methodology used with these self-report surveys sampling (described in more detail in this letter) the sample sizes can be quite small and therefore the measure results are considered not statistically valid. This effectively reduces the number of measures available from that plan to be considered for improvement in the summary rating calculation. Thus, this methodological design favors larger plans. As the process is currently set, the improvement measure score is only calculated for contracts that have numeric measure scores for both years for at least half of the measures identified for use in the improvement measure. Furthermore, as CMS considers additional factors that affect plan performance using the Star measures and current methods for calculating summary ratings (such as in considering social determinant of health, community characteristics, and dual/LIS, and disabled proportions within the enrollment of plans—as factors affecting Star quality measure results)—we encourage the consideration of an additional index that recognizes high quality performance by these special needs plans.

14) **Align a small core set of measures across providers and plans**—In the proposed rule, CMS refers to measurement alignment under its discussion of processes to add, update, or remove measures. We request that CMS consider meaningful measurement, duplication, and gaps for specific populations—particularly the dually-eligible, disabled and low-income populations and those who have complex conditions and care needs across medical, behavioral health, and social support care systems. We particularly request CMS work towards at least a core set of measures which are meaningful, valid, reliable, and endorsed by NQF and that could be applied across a set of providers and plans in order to support cross-site and interdisciplinary efforts and commitment to quality improvement areas. Currently, only the all-cause readmission measure meets this criteria—and even that does not fully include long-term services and support providers. Therefore, we ask that CMS add an additional criterion when considering measure addition, replacement, or removal—to ascertain if that measure can be used to align practices for a given
beneficiary population across sites and settings. Even 3 or 4 measures that do this would advance quality improvement and integrated care practice goals.

15) **Patient experience measure weight increase** – We do not support increasing the weights of patient experience measures, primarily for the same reasons that other self-report survey items have been problematic. The measurement biases, methods, and analysis must first be corrected prior to increasing the effect on overall Star rating scores.

16) **Physician survey of health plans** – While health plans greatly value the input and their relationships with providers to examine and attend to quality improvement areas, a survey of physicians with regard to their experiences with each health plan that they interact with over the course of a year on behalf their patients is unlikely to produce much information of value for many reasons. Survey response rate, validity, measurement burden, accuracy, attribution, and potential conflicts of interest are some of the areas of concern. An alternate action by CMS could be to study best practices observed and reported by clinicians (e.g., physicians, therapists, care coordinators, etc. from various settings) on how health plans have supported effective care, the therapeutic relationship, and promoted self-care among beneficiaries/patients/clients. Then information on these effective strategies could be disseminated. This might go farther in advancing effective care and improving cross-continuum care management—where providers and plans are serving the same people in complementary ways.

If CMS decides to pursue this, there are a variety of challenges to overcome. Physicians and nurse practitioners may not know the name/identity of the particular health plans in which their patients are enrolled. Anecdotally we have been told that physicians and nurse practitioners prefer not to know the particular details of the patient’s insurance. They would rather practice based on the standards set for their profession—at the highest level possible—and focus on the needs of their patients, not the person’s health insurance. Moreover, patients may change health plans at least annually, and some change more frequently. Another issue related to provider survey of health plan actions would be the level of interaction with the health plan and the number of patients/members that the provider has in his/her panel of patients. Volume would be necessary to see patterns in processes performed by the health plan for reasonable feedback on experience. An additional potential bias or conflict of interest would be in integrated provider/health plan arrangements, where the clinician is also employed by the same organization (i.e., both a provider and plan). In these cases the provider is likely to know that the patient is covered by their own employer as a member of the health plan—this may provide an advantage, for example allowing for easier access to the health risk assessment collected by the plan at time of individual enrollment since the provider and plan have a shared information system or health exchange. Having clinicians rate their own employer compared to other health plan organizations in the area might be difficult, as concerns about conflicts of interest could be raised. Finally, measurement and survey burden on clinicians—already overwhelmed—may not be well advised. As mentioned, a focus on effective and best practice strategies might advance quality improvement goals more.
SNP Alliance Comments and Recommendations – Further Detail

We provide additional detail and analysis on one key priority action item (the Health Outcomes Survey) to clarify the issues involved, and to offer ways to address observed limitations. We provide this detail given the importance of this item in the Star ratings and as one of the key areas of concern as identified by almost all of the health plans participating in the SNP Alliance.

Health Outcomes Survey – Clarifying Problem Areas

The Health Outcomes Survey (HOS) has drawbacks in design, methodology, administration, and reporting that we believe disproportionately affect SNPs who have high dual and high SDOH enrolled populations. Our overall recommendation is to re-examine and modify the HOS and its design and methods of administration and analysis, or replace the instrument with another method toward securing reliable and accurate beneficiary feedback and to specifically include diverse, low income, dually-eligible, disabled, non-English speaking persons and those with complex chronic conditions, cognitive impairment, and other special needs populations in the re-testing.

Design and Administration. The HOS instrument has a two-year look-back longitudinal design. Answers from a given beneficiary to the items in Time 1 are compared to answers by that same beneficiary in Time 2. Deterioration or decline is considered a negative outcome.

Sampling. Methods to administer include random sampling (random selection of beneficiaries in Time 1 who are enrolled in a particular plan) to arrive at a smaller group of people who are statistically representative of the whole enrolled population. To ensure accuracy in a longitudinal design, the method depends on stability of the enrolled population over time. In this case, the design comparing Time 1 to Time 2 for the exact same beneficiary requires not only stability overall but that each person in the random sample be present and able to participate in the survey two years later. This is a difficult bar to reach in persons with many health issues and other reasons affecting their ability to respond and their continuity of insurance with a given health plan.

Unfortunately, stability (being present and able to respond to a survey two years later) is much less certain among persons who are low-income, disabled, dually-eligible, with multiple chronic conditions or behavioral/mental health issues and who experience high social risk concerns. Reasons can include: housing and geographic transience (frequent moves), loss of Medicaid status which initiates loss of health insurance eligibility by the state and automatic removal from the plan enrollment, or non-response to plan communication (does not respond to request to yearly re-instate enrollment in the plan). This can be due to poor health, difficult living situations, lack of literacy, or other issues affecting communication on the part of the individual.

If the enrolled group changes substantially, or if the particular beneficiary surveyed in Time 1 is no longer available or enrolled in that plan in Time 2, then the two-year longitudinal design severely limits the ability to adequately capture beneficiary response. The resulting small pool of remaining individuals from the first survey may not be sufficient for statistical accuracy for a second survey. Without sufficient numbers or if response rate is poor, not enough information is collected or reported. Thus, the design itself impairs the purpose—to collect relevant beneficiary input.
Furthermore, the decision not to oversample groups of individuals (such as those with the characteristics described) in Time 1 almost ensures that these individuals will be underrepresented in Time 2. The drop-off, unable to reach, and other reasons which elevate non-response rates in these more vulnerable individuals mean the lack of oversampling also severely limits the ability to appropriately and adequately capture an adequate representative sample. This again means that the methods negatively impact the purpose.

In summary, the longitudinal design and the beneficiary self-report survey sampling methods do not appear to adequately create a representative sample that reflects the composition of the plan or that is large enough to support statistical analysis. Furthermore, small SNPs and SNPs that are part of larger contracts are especially vulnerable to this issue. Thus there may be little utility in the surveys conducted. This represents a burden without much return.

These design limitations could be addressed by two actions: (1) drop the two year look-back design and simply sample and report annually, and (2) oversample certain beneficiary subgroups where response rate is typically lower to ensure a representative sample that is as near as possible reflective of the current enrollment profile. We believe that, in combination with a thorough examination of the self-report items validity and reliability in diverse populations (discussed below), these two actions would begin to address some of the limitations of the HOS-derived Star measures.

Validity and Reliability. For each data element, the HOS requires understanding (via verbal or written information provided) of the intent/focus area of the item, comprehension of the response options offered and how they differ, and often requires effective recall from a previous time period. Beneficiary characteristics as described can affect response, including factors such as health literacy, health beliefs/ethnicity, and cultural norms. Even the question order, who is asking the question, and what other life challenges or situations the beneficiary is facing can affect how the beneficiary responds. There is not sufficient understanding of these issues or how to accommodate them to ensure a valid (true) and reliable (consistent response if similar items asked in a different way under different testing) result. This subjectivity and variability affects confidence in results. We do not have enough data from use of these specific items in surveys among diverse vulnerable groups. More is needed here.

Attribution. Response by the beneficiary is attributed to actions (or inaction) under control by the health plan. For example, key questions are:

“**Compared to one year ago**, how would you rate your **physical health** in general **now**?”

1. Much better  
2. Slightly better  
3. About the same  
4. Slightly worse  
5. Much worse

“**Compared to one year ago**, how would you rate your **emotional problems** (such as feeling anxious, depressed or irritable) in general **now**?”

1. Much better  
2. Slightly better  
3. About the same  
4. Slightly worse  
5. Much worse
It is implied that change in status—positive or negative—is attributed to the actions of the health plan. It does not further question the individual on why or what transpired in this time period that may have also affected their response, such as death of a spouse or loss of a family caregiver, job, or home. Response for this individual is compared to their response to this question two years prior as described. Negative changes (including the death of the respondent in the sample in Time 2 survey) result in a lower Star measure rating for the plan.

**Accommodation** Persons who have degenerative conditions, are housing transient, do not speak English, Spanish or Chinese, or who have different health beliefs, have limited health literacy or understanding of the health system and medical care, and or have deteriorating health given progressive and severe chronic conditions, are at a disadvantage in participating in the HOS survey (or other self-report surveys) given multiple barriers to their participation. For example this SNP and Medicare/Medicaid population--made up primarily of low-income persons with multiple care needs and social risk issues--more often experience frequent moves during the two years between testing periods, as compared to the populations that do not have these vulnerability characteristics. Some beneficiaries change addresses often and multiple attempts to reach them can fail. Plans report that beneficiaries may have five or more changes of address in one year. Thus, a Health Outcomes Survey mailed to the last known address is unlikely to reach the individual. A telephone survey can be equally problematic. Among low-income and language or ethnically-diverse populations, health plans find that many individuals have track phones which run out of minutes prior to the end of the month. These beneficiaries may share phones as well—across family and friend group—and they are careful on how and when to use their minutes. The HOS survey has 68 items (questions) on it with various response options per question that have to be enumerated. The lengthiness of the phone call alone would be a reason the beneficiary cannot participate—never mind possible survey fatigue given health conditions and other issues at home. This is also an issue with individuals who are frail.

An additional challenge is that the HOS is only available in three languages: English, Spanish, and Chinese. Health plans are not allowed to provide translation services to individuals who receive the survey in the mail or by phone and who want to participate or even understand more about the survey.

The use of a family member to translate is allowed (proxy), but the length of the survey, the ability of the family member, and other language and literacy issues involved in effective translation of this instrument may introduce many biases in generating the responses. In addition, there are studies showing that family members may respond in different ways and have different opinions on care and health status than participants. Proxies are not equivalent to the beneficiary, and comparing responses across two time periods using proxies or a combination of beneficiary and proxy response introduces further potential for bias.

These are some of the ways that the HOS survey methods do not accommodate the vulnerable beneficiaries with the characteristics described. The influence of these factors, and how to adapt the HOS questions or survey process to take them into account, needs to be much better understood and addressed more completely.

We have offered ideas to address some of the recognized limitations. Given the number and variety of issues raised with HOS, we are concerned that the most vulnerable and high risk beneficiaries are not well served by the HOS. Plans with a high proportion of persons with chronic, social risk, and other complexity characteristics are likely disadvantaged by the HOS related HEDIS measures and the current Star rating
system that weights these self-report items so heavily. Furthermore, by including every MAO in one cohort
for determining cut points and global rating and Stars levels—SNP plans (particularly those not in large H# contracts with general Medicare Advantage PBPs) are at a disadvantage when compared to plans enrolling healthier populations, as in the general Medicare Advantage plan products.

Though these self-report surveys are well-intended and were originally designed to reflect important areas of health status among the general Medicare population, the survey may not be effective in use as an outcome measurement tool—it may not be truly measuring what was intended or may be leaving out important beneficiary groups. By continuing to use this instrument in this way, the data results may not be meeting the purported standards of validity, reliability, utility, and accuracy. Until such time as the validity of the questions in diverse special needs populations, the methodological limitations, and these other issues can be resolved, we recommend that the HOS-derived HEDIS data that are included in the Star measures be re-weighted as “1.”

Thank you for considering our comments. We welcome the opportunity to examine and discuss any of these quality measurement, methods, rating, adjustment, and reporting issues in further detail at your convenience.

B. Improving the CMS Customer Experience

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

**Summary of Changes:** CMS proposes to revise the text in § 422.514(b) to provide that the waiver of the minimum enrollment requirement may be in effect for the first 3 years of the contract. Further, CMS proposes that they would only review and approve waiver requests during the contract application and removes the requirement for MA organizations to submit an additional minimum enrollment waiver annually for the second and third years of the contract.

**SNP Alliance Comments and Recommendations:**
We request that CMS provide an opportunity for SNPs serving smaller specialized populations to reapply for the waiver or ask for extensions. While we understand that this is applied at the contract level, we are concerned that it will not be possible for some unique free standing small SNPs to meet the minimum enrollment criteria due to factors out of their control, and that beneficiaries may lose access to viable specialty care options under this provision. For example, I-SNPs by definition generally serve a smaller more targeted group of beneficiaries than typical MAOs, D-SNPs are bound by contracts with states which control their service areas, and some C-SNPs specialize in HIV-AIDs or behavioral health, a smaller subset population. We ask CMS to continue to recognize that there may be circumstances in which low enrollment is out of the SNP’s control, for example, related to the small number of institutionalized beneficiaries (I-SNPs) in a service area, a small number of dually eligible beneficiaries in a state designated service area (D-SNPs), continued start up issues pending state activity such as delays in implementation of corresponding state enrollment activities for dually eligible beneficiaries (D-SNPs), or the value of C-SNPs that focusing on a small target population (such as a HIV-AIDs or homeless populations) or other factors not directly within a SNP’s control.
4. Revisions to Timing and Method of Disclosure Requirements (§§ 422.111 and 423.128)

Summary of Changes: CMS proposes to revise timelines for certain member materials to require MA plans and Part D Sponsors to provide the EOC, formulary, provider directory, and pharmacy directory by the first day of the annual enrollment period, rather than 15 days prior, along with additional flexibilities including posting the EOC, Summary of Benefits and provider network information through websites or electronic delivery, with hard copies provided upon request.

SNP Alliance Comments and Recommendations:
The SNP Alliance commends CMS for these changes which should reduce administrative burden and consumer confusion related to receipt of large packages of paper documents and assist in aligning Part D requirements further with Part C. We recommend that CMS expand on the underlying objectives of these changes by considering how additional changes could assist states utilizing integrated materials and/or wishing to further integrate and streamline such materials through simplification of language describing both Medicare and Medicaid services and issuance of merged documents where state timelines or requirements may differ from these CMS requirements. We also suggest that for FIDE and highly integrated SNPs, CMS should consider allowing development and use of a model Member Handbook in place of the current EOC as tested and found successful under the FAI for MMPs and the Minnesota D-SNP administrative alignment demonstration. CMS should consider further methods for provision of this information to hard to reach beneficiaries including beneficiaries who are homeless or have other communications and language barriers.

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

Summary of Changes: CMS proposes several changes to communications and marketing provisions in Subpart V of the part 422 and 423 regulations in four areas of focus: (1) including new definitions for “communications” and “communication materials;” (2) amending §§ 422.2260 and 423.2260 to add (at a new paragraph (b)) a definition of “marketing” in place of the current definition of “marketing materials” and to provide lists identifying marketing materials and non-marketing materials; (3) adding new regulation text to prohibit marketing during the Open Enrollment Period proposed in section III.B.1 of this proposed rule; (4) technical changes to other regulatory provisions as a result of the changes to Subpart V.

Marketing and marketing materials would be subject to the more stringent requirements, including the need for submission to and review by CMS. Materials that are not considered marketing, per the proposed definition of marketing, would fall under the less stringent communication requirements and grievance and appeals notices and materials would also be handled separately. CMS proposes to exclude materials that do not include information about the plan’s benefit structure or cost-sharing or from the definition of marketing materials such as factual information that is not intended to influence the enrollee’s decision to make a plan choice or stay enrolled in their current plan such as monthly newsletters which remind them of preventive services a $0 cost sharing, or other certain post enrollment materials. The use of measuring or ranking standards such as CMS star Ratings would be included in marketing.

CMS also makes revisions related to translated materials in certain areas where there is a significant non-English speaking population to clarify that translation applies to all communications materials, not just marketing materials and that sponsoring organizations must provide translated materials, as defined by CMS, unless in the language of these individuals.

CMS welcomes comment on proposed distinctions between these types of prohibitions and whether certain standards or prohibitions from current §§ 422.2268 and 423.2268 should apply more narrowly or broadly than proposed. In addition, CMS requests comments related to the Cures Act which prohibits marketing to
individuals eligible for the new OEP during the OEP. CMS solicits comment on how a sponsoring organization could appropriately control who would or should be marketed to during the new OEP, such as through as mailing campaigns aimed at a more general audience.

**SNP Alliance Comments and Recommendations:**
Overall, this proposal appears to reflect a more realistic and less burdensome approach to member materials. The SNP Alliance is generally supportive of this concept though we would like clarification in the preamble about how it will impact FIDE-SNPs and D-SNPs that have integrated some of these materials, how it will align with state marketing requirements and thus impact joint marketing efforts with states, and how the OEP marketing restrictions will impact access for dually eligible members who want to move during that time to a FIDE or other highly integrated D-SNP. We request that CMS review both Medicare and Medicaid marketing requirements and provide guidance to states and plans for further alignment including examples of specific approvable marketing methods. CMS should also allow marketing to dually eligible beneficiaries for integrated FIDE and D-SNPs during the OEP.

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

**Summary of Changes:** Currently, MA plans are required to notify enrollees upon forwarding cases to the IRE, as set forth at § 422.590(f). The IRE also is required to notify the enrollee of receipt of the case. Under this proposal, the IRE would be responsible for notifying enrollees upon forwarding all cases – including both standard and expedited cases. This proposal is meant to reduce duplication by requiring one notice.

**SNP Alliance Comment and Recommendations:**
The SNP Alliance commends CMS for this proposal to reduce administrative burden for MAOs and duplicative notices for beneficiaries. However, CMS may want to consider that some plans would prefer to notify their members of their action as soon as possible and are concerned that such notice would be delayed if left to the IRE notice only, which could then cause other administrative burdens such as additional calls to the plan. In these cases CMS could allow plans to continue to provide notices to members on an options basis.

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

**Summary of Changes:** CMS conduct past performance reviews in accordance with a methodology published each year used to score each applicant's performance by assigning weights based on the severity of its non-compliance in several performance categories. Under the annual contract qualification application submission and review process, organizations must submit their application by a date, usually in mid-February, announced by CMS. CMS now proposes to reduce the past performance review period from 14 months to 12 months.

**SNP Alliance Comment and Recommendations:**
We support this change and appreciate CMS’ recognition of the unintended negative effects of the previous 14-month period, which should now be addressed.

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

**Summary of Changes:** CMS proposes to delete §§ 422.152(a)(3) and 422.152(d), which outline the QIP requirements.
SNP Alliance Comment and Recommendations:
We agree with CMS’ analysis of the issues with QIP requirements and support these changes, given that there has not been sufficient integration of QIPs between federal and state agencies, resulting in duplicative, overlapping, or conflicting efforts, particularly for those serving the dually-eligible.

13. Reducing Provider Burden – Comment Solicitation

Summary of Changes: CMS proposes to address concerns from providers about requests from MA organizations for their patients’ medical record documentation and solicits comment from stakeholders to more fully understand the issue and for ideas to accomplish reductions in provider burden.

SNP Alliance Comment and Recommendations:
With regard to the discussion on provider burden, we point to the various reasons for provider reporting burden related to medical record documentation. Some of this burden arises from state and federal governments—with regard to certification, billing, health information standards, quality reporting requirements—others arise from practice/discipline standards, quality and accreditation and measurement bodies, internal health system and QI requirements set by employers, some from risk management, and some from health plans. The proliferation of measures and reporting—applied to both providers and plans—and the move to value-based and alternative payment models, are additional forces driving this increasing measurement and reporting burden. Many of these reporting requirements that involve medical record information, including specifications, transmission processes, and data integrity standards—accuracy, completeness, timeliness—are driven by entities or standards not under the control of the health plan.

It is important to note that health plans have the contractual authority and obligation for a variety of purposes to require access to medical records, including claims auditing, ensuring data integrity, and determining performance on various metrics. We strongly urge caution on rules that restrict access. Convening a diverse stakeholder group to discuss data collection and reporting burden across providers, plans and beneficiaries may offer better insight and potential solutions that address issues that all stakeholders currently face with the proliferation of measures, measurement requirements, and reporting expectations that involve medical records and other data sources that involve the practitioner. The SNP Alliance would welcome the opportunity to participate in stakeholder and expert discussions on strategies, studies, and solutions. We propose that the analysis start with the dually eligible, disabled, low-income and population with high social determinant of health needs—the highest cost, most complex population of beneficiaries—and go from there. Otherwise, the analysis on the scope of the problem and the forces at play—could be too narrow and inadequate.

C. Implementing Other Changes

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

Proposed Regulatory Changes to the Calculation of the Medical Loss Ratio (§§ 422.2420,
**Summary of Changes:** CMS proposes to revise the MA and Part D regulations by removing the current exclusion of fraud prevention activities from QIA, to expand the definition of QIA to include all fraud reduction activities, including fraud prevention, fraud detection, and fraud recovery and to no longer include in incurred claims the amount of claims payments recovered through fraud reduction efforts, up to the amount of fraud reduction expenses. Instead, all expenditures for fraud reduction activities would be included in the MLR numerator as QIA, even if such expenditures exceed the amount recovered through fraud reduction efforts. Costs of compliant MTM programs would also be considered part of QIA for MLR numerator purposes. CMS also proposes to reduce duplication of MLR reporting elements to align with commercial MLR requirements.

**SNP Alliance Comment and Recommendations:**
The SNP Alliance supports these changes, and commends CMS for recognizing how current provisions may curtail incentives for expanding fraud prevention and valuable MTM activities.

**Conclusion**
The SNP Alliance, again, appreciates the opportunity to provide comments. We appreciate and applaud the work and commitment by CMS to address these many important issues to improve access and care for the beneficiaries served. We are happy to answer any questions and to provide additional information, if needed.

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