



A National Nonprofit Leadership Organization

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To: Seema Verma, Administrator
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Department of Health and Human Services,
Attention: CMS-4185-P,
P.O. Box 8013,
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Re: CMS-4185-P

**SNP Alliance Medicare Rule Comments NPRM 11-1-2018
(Selected Provisions)**

42 CFR Parts 422, 423, 438, and 498 Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021

**1. Requirements for MA Plans Offering Additional Telehealth Benefits
(§§422.100, 422.135, 422.252, 422.254, and 422.264)**

CMS proposes to allow additional telehealth covered benefits as part of Medicare basic benefits as well as continuation of supplemental benefits with an option for beneficiary choice of in-person or telehealth. Such services would be financed via inclusion in capitated payments. Capital and infrastructure costs continue to be excluded.

SNP Alliance Comments:

The SNP Alliance commends CMS for making this long-requested change. We appreciate that the CMS proposal allows plans to determine the clinical appropriateness of telehealth services and to also offer additional telehealth benefits as supplemental benefits. We support inclusion of these benefits in the EOC and consideration of which services should be included on an annual basis.

We also appreciate the broad definitions utilized in the rule which allow for evolution of future technology advancements and the opportunities provided for alignment with clinical best practices and discretion of the clinical provider. We would recommend against limitations on specific services allowed to be provided through telehealth, especially because service access can be highly variable, and limiting services might curtail additional choices for access.

Telehealth encounters are now an important source of information for diagnostic, treatment, evaluation and management of chronic conditions. We recommend that CMS recognize this by incorporating this data into the HCCs for risk adjustment purposes.

While we are not prepared to address it in depth at this time, we note that inclusion of these additional telehealth benefits will give rise to further discussion of how telehealth can supplement current network standards for time and distance and how they could provide additional flexibilities to meet needs for vulnerable members, especially with respect to hard to find behavioral health services. We look forward to those discussions.

We also concur with members who urge CMS to ensure that providers are given clear guidance on new requirements used to identify providers who offer telehealth services to streamline current processes for ensuring provider directory accuracy and to work toward harmonizing different state licensure rules around delivery of care and issuing of prescriptions via telehealth which may impede development of telehealth options for physicians.

2. Dual Eligible Special Needs Plans (P. 54992)

a. Integration Requirements for Dual Eligible Special Needs Plans (§§ 422.2, 422.60, 422.102, 422.107, 422.111, and 422.752)

Summary of SNP Alliance Comments on Additional Incentives, Integration and grievance and appeals:

The SNP Alliance commends CMS for its consideration and balancing of so many complex federal, state and market dynamics in developing these provisions. The SNP Alliance supports most of the provisions of this proposed rule with some questions, caveats and recommendations outlined in more detail in the corresponding rule sections following this summary.

Additional Incentives Needed for Integration

The SNP Alliance believes that CMS must take steps beyond these proposed regulations to provide additional meaningful incentives for D-SNPs and states in order to move them forward on the integration continuum. While the value to dually eligible beneficiaries of enrollment in an integrated program is gaining broader credibility through additional evaluation and congressional and policy support, many states continue to lack understanding of Medicare and its influence on their Medicaid LTSS costs, and many plans lack business incentives or face state specific market challenges that make change difficult. Both states and plans question the value of the additional investment required to reach higher levels of integration such as FIDE and HIDE SNP status. States still question the value of building state capacities to support integration without some ability to share in savings that may result. Further, there are too many remaining complex and/or misaligned administrative and operational processes that create disincentives for states and plans to change the integration status quo. The SNP Alliance recommends that CMS address additional alignment policies and incentives through the following actions:

- CMS should advance integration using all available statutory authorities, including seeking clarity from Congress regarding their intent in passing provisions contained in the BBA giving MMCO additional authority to address administrative alignment issues. CMS should examine all new and existing authorities and seek additional authority where it believes it is necessary to fully align Medicare and Medicaid requirements and oversight for FIDE and HIDE-SNPs. For example, CMS should renew its requests for authority to allow joint reviews of member materials for integrated programs and to allow a SEP for duals to enroll in an integrated program, as well as seek broader authority that allows them to make exceptions to statutory or regulatory provisions that impede application of program alignments allowed under the FAI demonstrations integration to FIDE or HIDE SNPs.
- CMS should fully utilize these authorities to create administrative and policy incentives that reward plans and states for moving further toward alignment including toward FIDE and HIDE SNP status. These could include:
 - Expanding passive enrollment options for transitioning dual eligible members to corresponding FIDE/HIDE SNPs beyond the current rule for transitioning members when integrated programs close.
 - Further promotion to enable “aligned enrollment” through expansion and broader adoption of default enrollment (for example, expand the current default enrollment processes to include Medicaid plan enrollees with previous dual status to more easily opt in to a corresponding D-SNP.
 - Updating additional supplemental benefit flexibilities outlined in Chapter 16b for FIDE/HIDE SNPs to address social determinants of health and other flexibilities beyond those for regular MA plans
 - Allowing FIDE/HIDE SNPs a higher percentage of rebate dollars
 - Increase access to the frailty adjustment by:

- Educating states about how to assist to facilitate separate coordinated PBPs for MLTSS and non MLTSS populations under the same FIDE-SNP
- Addressing the timing issue for the frailty factor (which is calculated too late to be considered in conjunction with supplemental benefits and bids)
- Revising the frailty determination methodology, with application at the individual level using available data on members that qualify for the nursing facility level of care to provide a more accurate comparison to frailty levels of PACE enrollees
- Allowing states enhanced Medicaid match under existing mechanisms (i.e. at the current clinical level of 75% for care coordination activities, and the enhanced IT level for data functions) for administrative functions related to sharing of data and other care coordination related activities needed to implement these rule provisions as well as to establish and maintain integrated Medicare Medicaid programs for dual beneficiaries
- Addressing Stars methodologies that disadvantage D-SNPs in quality bonus payments
- Reduced administrative reporting burdens designed to reward high performing and integrated D-SNPs
- Offering joint communication teams to additional states
- Developing template options for states for promotion of joint state/D-SNP marketing strategies
- Working toward alignment of state and federal contracting cycles for corresponding D-SNPs and Medicaid plans (such as allowed under PACE) in order to increase opportunities for alignment
- CMS should also conduct a comprehensive review of basic operational processes to determine where Medicare and Medicaid functions and features could be further aligned to enhance care delivery and quality and to reduce burdens on plans, providers and beneficiaries. At minimum CMS should be able to accomplish this administrative task to conduct such a review under current and additional BBA authorities provided to the MMCO. CMS could use this analysis to create simplified administrative and operational processes, options and incentives based on MMP and D-SNP demonstration experience and tailored for states and plans in different situations such as state plan preprints and integration “package options” to make it easier to move D-SNPs further along on the integration continuum such as toward FIDE and HIDE status.
- In addition, for FIDE or HIDE SNP plans and/or D-SNPs that already have significant enrollment alignment, CMS should extend application of flexible features already tested under the FAI and MN D-SNP demonstrations, including the use of the member handbook format, streamlined/integrated member materials, coordinated

enrollment processes and timelines, joint marketing with the state, coordinated CMS/State communications processes or teams, integrated MOCs, dual population specific network adequacy requirements, and streamlined reporting and oversight processes and options for unified state/CMS reporting at the PBP level for FIDE and HIDE SNPs.

- States' choices hold the key to pathways that allow D-SNPs to advance integration such as enrollment alignment and administrative coordination. CMS should continue and expand efforts to educate and encourage States to whatever degree possible to adopt policies and incentives that assist D-SNPs to move toward higher levels of integration (including FIDE or HIDE SNP status with better aligned enrollments) for dually eligible beneficiaries. CMS should engage NAMD and NASUAD or other state related organizations in discussions about how best to conduct specific outreach to states in which D-SNPs operate where states have not been involved with integration and design and implement efforts to educate them about the value of integrated programs, resources available to states them and assist them to build the capacity needed to support these new rule requirements.
- The SNP Alliance is committed to integration, quality and transparency. We believe that if CMS is to make these proposed integration requirements meaningful for people with dual eligibility and fair to D-SNPs that comply with existing and additional standards to meet the special needs of those dually eligible, CMS, plans and states must further address complex market factors that are arising and undermining integration. As a result of these market factors, MA plans that are not required to meet these additional standards are tailoring products to attract dually eligible members.

Highlights of SNP Alliance Comments on Proposed Integration and Grievance and Appeals

Overall our view is that the new definitions of D-SNP, FIDE SNP and HIDE SNPs as well as “aligned enrollment” are helpful in clarifying differences between SNP types and levels of integration, while consolidating previous language for several current provisions. We appreciate the flexible approach to carve outs that CMS appears to be taking in considering which plans fit into these definitions.

The new D-SNP definition requires broader coordination of Medicaid services beyond services that are provided through state Medicaid contracts with the D-SNP or its parent company. While we also support this interpretation of coordinated care, it is essential that CMS do more to facilitate the necessary sharing of hard to access provider and enrollment information that will make this and the new grievance and appeals assistance provision possible, and to build additional state capacity for supporting such integrated requirements without which these care coordination mechanisms cannot be successful. For example, CMS could create a centralized enrollment data base that D-SNPs can query for Medicaid plan information about their unaligned D-SNP members, or CMS could explore allowing D-SNPs access to TMSIS member level data. We make a number of recommendations about this issue throughout our comments.

Many of these provisions are complex and raise questions such as what is meant by “comprehensive services”, how that term applies to FIDE and HIDE SNPs and how it would be determined in relation to the discussion of carve outs “consistent with state policy”, how enrollment alignment ultimately impacts the status of integration, how “single entity” is defined vs “D-SNPs who have or whose parent company or other entity owned and controlled by the parent organization and has a capitated contract” and whether there should be some additional coordination expected between separate Medicare and Medicaid plans owned by a parent organization. In our detailed comments we suggest clarifications in these areas.

For all D-SNPs not meeting FIDE and HIDE standards, a new integration requirement is outlined, involving sharing data with state for SNF and hospital admissions. We support this particular standard for non-FIDE/HIDE SNPs; however, we propose circumstances where an alternative approach should be allowed. We are concerned about how states will react to this requirement and whether they will understand their role in it or have the capacity to support this requirement. In addition, it is not clear what happens to compliance if the state refuses, or can’t accommodate, can’t use or doesn’t want the information and data the plans are required to provide. CMS should clarify what happens to D-SNPs that are willing to comply in a state that is not interested in pursuing this data sharing requirement.

We recommend CMS allow additional flexibility for alternatives when the state and plans agree that a different data set or a substitute requirement would be more useful. We also propose that as an alternative to this data sharing, plans that provide Medicaid services in states with MLTSS and behavioral health carve outs, should be allowed to be considered having met this standard through alternatives when agreed upon between the state and the plan.

CMS also adds new contract requirements for all D-SNPs for coordination of benefits and assistance with grievance and appeals regardless of source of payment and delivery. While these new contract expectations seem relatively consistent with current care coordination expectations for D-SNPs, these requirements are very broad and will likely require additional guidance and investment, and compliance and documentation will be difficult in the absence of additional shared data on enrollment where there is lack of enrollment alignment. We recommend that CMS do more to identify and develop data sources and promote data sharing where there is misaligned enrollment. We also recommend that CMS should avoid detailed and burdensome documentation requirements which may very well end up hindering the very kind of assistance CMS is encouraging. Further, when D-SNPs are providing good-faith assistance to someone and they are not satisfied with the outcome, CMS should not count these complaints to Medicare (CTMs) against the D-SNP, and should exclude them from any Stars measures related to CTMs so that D-SNPs do not face penalties for providing this assistance. Member plans are also concerned about how they will get access to accurate information about Medicaid covered services their members may have access to beyond the D-SNP’s covered benefit and obtaining protection from additional liabilities that can arise from providing this assistance in good faith where the assistance to the member does not result in what the member had hoped for in these appeals. In addition, it will be important that states and Medicaid plans understand the role of the D-SNP in providing this assistance

to prevent misunderstandings, especially when a successful appeal results in provision of additional services covered under a non-SNP source.

The unified grievance and appeals provisions appear to impact a small number of plans. We appreciate that CMS has chosen most realistically to apply them only to FIDE and HIDE SNPs that meet criteria for “exclusively aligned enrollment”. This smaller group of plans can serve as “learning laboratory” for future evolution of a unified process. In addition we support CMS’ proposal to specifically exclude D-SNPs with companion Medicaid plans that are PIHPs and PAHPs in this criteria because those Medicaid plans do not cover comprehensive Medicaid services.

CMS also says it lacks authority to develop a unified post plan appeals external review process, so would keep the two existing tracks for Medicare and Medicaid external reviews and decisions while asking for comment on alternatives. We recognize that states, plans and consumers subject to both appeals processes might have difficulty in keeping track of multiple systems.

However, the SNP Alliance recommends support for this approach at this point, until more experience and information is gained with the unified grievance and appeals process and there are more plans with exclusively aligned enrollment that could participate in such a unified system.

(1) (P. 54993) Definitions of a “Dual Eligible Special Needs Plan”, “Fully Integrated Dual Eligible Special Needs Plan”, “Highly Integrated Dual Eligible Special Needs Plan”, and “Aligned Enrollment” (§ 422.2)

Summary of Proposed Rule:

CMS is consolidating statutory and regulatory provisions and is proposing new definitions for the terms “dual eligible special needs plan,” “fully integrated dual eligible special needs plan,” “highly integrated dual eligible special needs plan,” and “aligned enrollment,” for purposes of applicable MA rules and this proposed rule. These definitions serve to describe different types of D-SNPs based on the degree to which they integrate Medicaid benefits at the plan level. CMS asks for comment on whether additional regulatory provisions should be added or alternatives considered.

D-SNP Definition Changes:

A dual eligible special needs plan is described as a type of specialized MA plan for individuals who are eligible for Medicaid under Title XIX of the Act that provides, as applicable, and coordinates the delivery of Medicare and Medicaid services, including LTSS and behavioral health services, for individuals who are eligible for such services; has a contract with the state Medicaid agency consistent with § 422.107 that meets the minimum requirements in paragraph (c) of such section; and satisfies at least one of following integration requirements:

(1) it meets the additional state Medicaid agency contracting requirement at proposed §422.107(d) (described in section II.A.2.a. (2)) of this proposed rule that surpasses the minimum requirements in current regulations at § 422.107(c);

- (2) it is a highly integrated dual eligible special needs plan (HIDE SNP), as described in further detail later in this section; or
- (3) it is a FIDE SNP.

While CMS did not explicitly cite or summarize the integration requirement at section 1859(f)(8)(D)(i)(III) of the Act in this proposed regulatory definition, they state that they interpret the statutory language on assuming clinical and financial responsibility for benefits to mean that such a D-SNP would always satisfy the requirement of being a FIDE SNP or HIDE SNP and solicit comment whether their proposed definition meets these goals or should be revised to incorporate other regulatory provisions that establish requirements for D-SNPs.

CMS also proposes to interpret “coordination of benefits” or “arranging for benefits” as requiring a D-SNP, at a minimum, to coordinate the delivery of Medicare and Medicaid benefits including long term services and supports and behavioral health services, and to relocate this provision to the revised D-SNP definition. Coordination would encompass a wide range of activities including verification of Medicaid eligibility for behavioral health or LTSS services and follow up and making arrangements with other entities for meaningful access to such. CMS solicits comment on whether their proposed definition should be more prescriptive in identifying which plan activities constitute coordination or whether it should remain broadly defined as proposed.

SNP Alliance Comments:

We appreciate the approach that CMS takes in their revision of the D-SNP definition and interpretation of the integration requirements. We generally agree that being a FIDE or HIDE SNP should satisfy integration requirements as outlined.

However, we find the preamble statements that “parent companies with clinical and financial responsibility would always meet requirements for HIDE and FIDE SNPs” confusing. It seems possible that a parent company could sponsor Medicaid plans and D-SNP products that might be operated quite separately with little or no coordination while still accepting “clinical and financial responsibility with respect to any individual enrollee”. We recommend that CMS provide further clarification of this preamble statement and its relationship to FIDE and HIDE SNP status. In addition, when discussing this provision, in order to avoid confusion, CMS should incorporate the concept outlined in the statute that such organizations are accepting clinical and financial responsibility with respect to *any individual enrolled in both plans*. This concept is essential to CMS’ interpretation that such organizations would serve some degree of aligned members in each product and would therefore be able to meet coordination requirements for HIDE and FIDE SNPs.

In addition, we don’t think CMS is precluded from recognizing additional gradations or sub-classifications of integration, or is limited to application of only one standard of integration for D-SNPs within the first category of non-HIDE/FIDE SNPs. (The BBA specifically refers to a “set” of integration standards.) We recommend that CMS consider creating an additional integration standard specific to D-SNPs sponsored by parent

companies that provide and are at risk for a set of Medicaid services in cases where the state does not capitate either MLTSS or BH, in order to recognize these D-SNPs as more integrated than those D-SNPs which have MIPAA agreements limited to coordination of benefits. These D-SNPs can serve as important stepping stones toward further alignment and should be recognized as such by allowing alternative reporting that could be linked to the services provided as determined by the state and plan and serve as an incentive or pathway to integration status for D-SNPs. (See more detail under the new integration standard comments below.)

We also recommend that the definition of coordinating or arranging for benefits remain broadly defined as proposed as long as it is reasonably interpreted and some additional guidance is developed to respond to the inevitable day to day questions this broad interpretation will evoke. Members have suggested that CMS might be able to develop sub-regulatory guidance to provide a set of standardized approaches or acceptable frameworks that would assist states and plans in developing aligned approaches to this requirement, including best practices for data transfers and tips on overcoming administrative hurdles. (See more discussion under the integration standards below)

We recommend that CMS provide additional clarification so that rule language in the definition stating “that provides, as applicable, and coordinates the delivery of Medicare and Medicaid services, including long term services and supports and behavioral health services” is not misunderstood to *require* that all D-SNPs actually *provide or deliver* LTSS AND behavioral health services.

In addition, we repeat the need for a more comprehensive system for collecting and sharing data on where D-SNP members are enrolled for Medicaid when enrollment is not aligned, to enable meaningful implementation of this provision and other expansions of coordinated care required in this proposed rule.

FIDE SNP Definition Changes:

CMS has codified the FIDE SNP definition which is generally consistent with current provisions from MMCM 16b but with more specificity in some areas. FIDE SNPs are D-SNPs whose capitated contract with Medicaid agency includes “coverage of specified primary care, acute care, *behavioral health*, and LTSS” under a “single entity”. CMS also codifies the current policy that FIDE SNPs include NF coverage for “at least 180 days during the plan year.” CMS proposes revisions at § 422.2 to align with the proposed definition of a D-SNP and to codify current policy, specifically:

- Striking the reference to a “CMS approved MA-PD” plan in the current FIDE SNP definition and paragraph (1), which refers to the individuals eligible for enrollment in a FIDE SNP, because those provisions duplicate elements of the new proposed definition of a D-SNP at § 422.2;
- Replacing the reference to “dual eligible beneficiaries” with “dual eligible individuals” to align with the BBA.
- Adding to newly re-designated paragraph (2) that a FIDE SNP’s capitated contract with

a state Medicaid agency may include specified behavioral health services, as well as replacing the term “long-term care” benefits with “long-term services and supports” to better describe the range of such services FIDE SNPs cover in capitated contracts with states.

- CMS also proposes codifying in paragraph (2) the current policy that the FIDE SNP’s capitated contract with the state provide coverage of nursing facility services for at least 180 days during the plan year; Striking references to coordination of covered Medicare and Medicaid “health and long-term care” and referring more broadly to Medicare and Medicaid services in in newly redesignated paragraph (3); and
- Replacing the reference to “member” materials with “beneficiary communication materials,” consistent with the definition of “communication materials” at § 422.2260.

SNP Alliance Comments:

The SNP Alliance generally supports these clarifications to the FIDE SNP definition. However, we are concerned about the following:

- Does this definition create a new expectation for FIDE SNPs to cover additional behavioral health services for which they have not been responsible for in the past under state Medicaid contracts? Would any current FIDE SNPs lose FIDE status due to the rewording around behavioral health in particular or will CMS continue to take into consideration state carve out policies around behavioral health as discussed in the preamble? While we appreciate that CMS seems flexible about recognizing that most states have some carve outs and recognizes behavioral health carve outs “consistent with state policy” in the context of both the FIDE SNP and HIDE SNP definitions in the preamble, CMS also states that FIDE SNPs are expected to provide “comprehensive” services. This statement makes it more unclear as to what “comprehensive” means in this context. CMS should consider defining “comprehensive” or provide other clarifications such as guidance outlining principles and processes they intend to use in making these distinctions and determinations of FIDE versus HIDE SNP status.
- We ask CMS to clarify that the 180 day nursing facility minimum coverage would be interpreted similarly to long standing policies in Minnesota, meaning that this policy is applied at the individual beneficiary level for an enrollees’ initial stay as follows: After 180 days of SNF or NF coverage by the plan is reached (either consecutively or intermittently) the long stay (post 180 days) nursing facility enrollee remains enrolled in the plan while the nursing facility per diem is paid by the state (in Minnesota’s case under FFS) for the rest of their stay unless they return to the community, in which case the plan would regain liability for another 180 days after 180 days in the community. The plan remains responsible for all other Medicare and Medicaid services outside of the per diem in all cases. Without this long standing interpretation, the policy could result in a very unwieldy system of having to switch NF payments back and forth from the plan to the state each year for each long staying NF resident.

- We also suggest that CMS clarify a definition for “single entity” to distinguish between “single entities” and those “D-SNPs who have, or whose parent company or other entity owned and controlled by the parent organization” has, a capitated contract.

Highly Integrated D-SNP Definition:

CMS proposes to define a HIDE SNP as a type of D-SNP offered by an MA organization that has – or whose parent organization or another entity that is owned and controlled by its parent organization has – a capitated contract with the Medicaid agency in the state in which the D-SNP operates that includes coverage of LTSS, behavioral health services, or both, consistent with state policy.

All the requirements of a D-SNP would also apply to a HIDE SNP, such as the obligation to provide, as applicable, and coordinate Medicare and Medicaid benefits. In contrast to a FIDE SNP, a D-SNP could satisfy the requirements of a HIDE SNP if its parent organization offered a companion Medicaid product that covered only LTSS or behavioral health services, or both, under a capitated contract.

CMS discusses carve out policies in relation to the HIDE SNP definition and interprets the phrase “consistent with state policy” as allowing CMS to permit certain carve-outs where consistent with or necessary to accommodate state policy, except for where specifically prohibited (such as for nursing facility services in the FIDE SNP definition). As such, among the states that have capitated contracts with D-SNPs or the D-SNPs’ parent organizations, CMS can still determine that D-SNPs meet the FIDE SNP or HIDE SNP definition despite these types of variations allowed under this proposal. (See Interpretation of “to the extent permitted under state law” below.) CMS solicits comment on this proposed definition, including on whether additional requirements for HIDE SNPs should be addressed in the definition.

SNP Alliance Comments

The SNP Alliance appreciates the long needed clarification of the HIDE SNP term and plan status and the proposed carve out flexibility. This new definition appears to allow HIDE SNPs to cover either MLTSS or behavioral health or both which will better recognize additional D-SNPs that have integrated Medicaid services “consistent with state policy” despite state carve out policies (especially for MLTSS services), thereby allowing them to meet integration standards.

We repeat our recommendations made under the FIDE SNP definition that CMS provide additional guidance including the principles and processes CMS will use in its determinations and review of FIDE and HIDE SNP distinctions and for more clarity about the carve out policy, without loss of the flexibilities CMS intends.

In the actual HIDE SNP definition in the rule language where CMS references parent organizations, as noted above, we recommend including language that the parent organization must assume clinical and financial responsibility for benefits provided “*with respect to any individual enrolled in both plans*”, which better reflects the meaning of the full statute and avoids confusion of how that language could be interpreted in the rule compared to the statute.

Also, in the spirit of building glide paths toward additional coordination or integration where states have made such choices about how to handle their contracting and carve outs, we support CMS' proposal that D-SNP/PIHP or PAHP combinations could meet criteria for clinical and financial responsibility for HIDE SNPs. However the same caveat mentioned earlier should apply, i.e. that the two products under such parent company responsibility should be expected to be coordinated.

Aligned Enrollment:

CMS proposes to define aligned enrollment as follows: "Aligned enrollment refers to the enrollment in a dual eligible special needs plan of full benefit dual eligible individuals whose Medicaid benefits are covered by such plan or by a Medicaid managed care organization, as defined in section 1903(m) of the Act, that is the same organization, its parent organization, or another entity that is owned and controlled by its parent organization." When State policy limits a dual eligible special needs plan's membership to individuals with aligned enrollment, this condition is referred to as *exclusively aligned enrollment*. CMS intends to exclude PAHPs or PIHPs in this definition because they are not comprehensive.

CMS notes that some states limit D-SNP enrollment to full-benefit dual eligible individuals who also choose to receive Medicaid benefits through the D-SNP or a Medicaid MCO operated by the same entity (that is, by the MA organization) or by the MA organization's parent organization. Such a limitation would be included in the state Medicaid agency contract with the D-SNP. Exclusively aligned enrollment is also relevant to how CMS proposes to apply the integrated grievance and appeals requirements described in section II.A.2.b. of this proposed rule.

CMS solicits comment on this definition given its relevance to the category of D-SNPs to which the integrated grievance and appeals procedures apply and whether CMS should consider other types of Medicaid managed care arrangements beyond companion Medicaid MCOs, as defined in section 1903(m) of the Act and modified at § 438.2, operated by a HIDE SNP's parent organization.

SNP Alliance Comments

The SNP Alliance welcomes this definition of aligned enrollment and exclusively aligned enrollment and the recognition of the enrollment alignment concept and its relationship to achieving additional integration between Medicare and Medicaid. We also appreciate and support the CMS proposal for limited application of the grievance and appeals process to plans with exclusively aligned enrollment as the most feasible option for implementing the required statutory requirements as intended. We also support the reference to inclusion of Medicaid plans operated by the same organization or parent company. However, as noted above, we recommend that CMS incorporate the concept from the statute that such plans have "*clinical and financial responsibility for any individual enrolled in both programs*". This language would better reflect the additional concept from the statute that such plans also have some aligned enrollment as discussed in the preamble. In this case, we also support CMS exclusion of PIHPs and PAHPs in determining "exclusively aligned enrollment" for HIDE SNPs for application of the

unified grievance and appeals process as the most practical and workable decision. Given the very limited nature of the services provided under each of those Medicaid plan types we do not think it would be feasible to apply the unified system to such plans.

We note that the term *aligned enrollment* is not utilized in determining integration status, except in relation to *exclusively aligned enrollment* for the purpose of application of the unified grievance and appeals process. However, as outlined in our initial summary comments, given that the current state of enrollment alignment seems relatively small and also is not well understood, in the future we hope to see rewards or incentives, data sharing on enrollments, stepping stones, and/or new tools and pathways to facilitate improvements in enrollment alignment even if plans and states are not at the point of being able to be exclusively aligned. While we believe there is great value to beneficiaries in aligned enrollment, the complications for states and plans related to procurements and market forces are becoming even more challenging, and additional incentives and tools for all parties to move toward increased alignment seem to be required.

Interpretation of “To the Extent Permitted Under State Law”:

BBA statutory language requires that MA organizations seeking to provide a D-SNP must meet one or more statutorily identified integration requirements in section 1859(f)(3)(D)(i) of the Act *to the extent permitted under state law*. CMS acknowledges the flexibility provided to states under the Medicaid program while imposing on D-SNPs integration requirements that Congress has deemed necessary. Recognizing that many states have *Medicaid policies* that preclude D-SNPs from meeting FIDE or HIDE SNP criteria, a carve-out by the state of a minimal scope of services is permissible **so long as comprehensive services are covered under the capitated Medicaid contract**. Therefore CMS proposes to interpret this statutory provision in a way that provides multiple avenues for a MA plan to qualify as a D-SNP.

However, CMS considered additional alternatives, such as whether this phrase should mean that in states that have Medicaid managed care programs for dual eligible individuals, all MA organizations seeking to offer a D-SNP could do so only if they were under contract with the state to offer a companion Medicaid managed care plan in that state, on the grounds that such an opportunity is permitted under state law. CMS solicits comment on this and other alternatives and also how the proposed definition should be revised consistent with their statutory interpretation.

SNP Alliance Comments:

The SNP Alliance generally supports CMS’ interpretation of “consistent with state policy” and “to the extent permitted under state law” and appreciates the flexibility CMS seems to be intending.

While the preamble discussion on this topic was very useful, it was also somewhat confusing. In the preamble discussion on the new definitions, CMS refers to carve out of a minimal scope of services as permissible, and seems to indicate a more extensive carve out policy for HIDE SNPs compared to FIDE SNPs. We appreciate this distinction. However, CMS also states that “comprehensive services” must be covered under the

“capitated contract for FIDE *and* HIDE SNPs.” In addition, though that statement appears in the preamble, there is no reference to “comprehensive services” as part of the FIDE or HIDE SNP definitions. CMS also indicates in other preamble discussion that FIDE SNPs have to provide “comprehensive” Medicaid benefits but does not include HIDE SNPs in that statement. Because this term appears so often in the preamble we now are wondering how it will impact determinations of FIDE and HIDE status.

In addition to the understanding that D-SNPs now known as HIDE SNPs have had a more liberal carve out policy in the past, there has historically been some consideration of carve outs for FIDE SNPs as well. However now the reference to the term ‘comprehensive’ without definition make it less clear what flexibility for carve outs might be allowed to either HIDE or FIDE SNPs. (As CMS points out, nearly all states have some carve outs).

If it is CMS’ intent to allow both FIDE and HIDE SNPs some varying levels of additional flexibility (besides the MLTSS and behavioral health distinctions in statute), CMS should clarify this flexibility either by creating a definition of comprehensive services or providing guidance and principles they will follow in making determinations related to carve outs for FIDE SNPs and HIDE SNPs including any differences between them. CMS should also clarify what process it will use for making these determinations. At the same time, we want to emphasize that we request this additional clarification while maintaining the flexibility CMS seems to intend.

We appreciate that CMS did not choose to restrict D-SNPs to those “under contract with the state to offer a companion Medicaid managed care plan in that state, on the grounds that such an opportunity is permitted under state law” and will continue to allow multiple avenues for qualification of D-SNPs. While we recognize that that states do have this discretion we oppose the CMS alternative that all MA D-SNPs must have companion Medicaid managed care contracts. We are concerned that many D-SNPs would cease to operate leaving no platform for moving integration forward.

Clinical and Financial Responsibility:

In the preamble CMS states their belief that an entity can only truly hold “clinical and financial responsibility” for the provision of Medicare and Medicaid benefits, as described at section 1859(f)(8)(D)(i)(III) of the Act, in the scenarios of exclusively aligned enrollment. *Therefore, the plans that meet this criterion would be FIDE SNPs and HIDE SNPs that have exclusively aligned enrollment, as these terms are defined under the CMS proposal.* By virtue of these exclusively aligned plans’ status as a FIDE SNP or HIDE SNP, they would satisfy the statutory integration requirements.

SNP Alliance Comments:

While the SNP Alliance supports this CMS interpretation as discussed earlier, this interpretation appears only in the preamble, and not in the rule language. We recommend that CMS should more explicitly clarify in the rule definitions that this means that such plans must have clinical and financial responsibility for both benefit sets *for any individual enrolled* and should be coordinated.

D-SNPs That Must Meet Additional Medicaid Contracting Requirements:

Under section 1859(f)(8)(D)(i) of the Act, those D-SNPs that are neither FIDE SNPs nor HIDE SNPs must meet an additional state Medicaid contracting requirement beginning in 2021. The new requirement entails the provision of notice when an individual who belongs to a group of high-risk dual eligible individuals has a hospital and skilled nursing facility admission as discussed in section II.A.2.b.(2). CMS solicits comments on this proposal and, in particular, on alternative approaches to classifying D-SNPs consistent with the requirements of the BBA.

SNP Alliance Comments:

The SNP Alliance understands and appreciates the CMS approach to this proposal for classifying D-SNPs for the purpose of meeting integration standards in the BBA.

With reference to classifying D-SNPs, as stated earlier, we don't think CMS is precluded from recognizing additional gradations or sub-classifications for integration, or is limited to application of only one standard of integration for D-SNPs within the first category of non-HIDE/FIDE SNPs. (The BBA specifically refers to a 'set' of integration standards.)

We recommend that CMS consider creating an additional integration standard specific to D-SNPs sponsored by parent companies that provide and are at risk for a set of Medicaid services for any individual enrolled in both plans, in cases where the state does not capitate either MLTSS or BH in order to recognize these D-SNPs as more integrated than D-SNPs which have coordination only agreements. These D-SNPs should be recognized as such by allowing alternative reporting that could be linked to the services provided as determined by the state and plan. (See more detail under Contracts section below.)

As we state throughout our comments, we are very concerned about what happens to the ability of D-SNPs to comply with this particular requirement if the state is not interested or able to accommodate, facilitate or utilize this specific data or notice exchange. We understand that such information could be provided in a variety of ways, such as directly between providers, through health information exchanges or claims data, secure email by care coordinators, etc. but we note it will be highly challenging to provide such notices in any manner timely enough to use it for the stated purpose of improving transitions and that current lack of alignment of enrollment will pose even more barriers to any form of data exchanges and attribution for tracking of compliance. Some of these methods may also be highly inefficient and require in person audits which we would oppose. But these issues raise concerns about how these challenges will impact the determinations of compliance with this requirement. Please see recommendations outlined in more detail under (2) (P. 54996) Dual Eligible Special Needs Plans and Contracts with States (§ 422.107). (5) (P. 54999) Suspension of Enrollment for Non-Compliance with D-SNP Integration Standards (422.752).

(2) (P. 54996) Dual Eligible Special Needs Plans and Contracts with States (§ 422.107)

Under this section CMS proposes to clarify language related to contracts between states and D-SNPs and to incorporate other required changes by:

- Deleting language in current contract requirements (paragraph (b)) that is extraneous and duplicative of the proposed definition of a D-SNP in § 422.2;
- Making clarifying edits in paragraphs (c)(1) through (c)(3), which govern the minimum requirements of the contract between the D-SNP and the state Medicaid agency;
- Redesignating paragraph (d) as paragraph (e), which relates to compliance dates; and
- Establishing a revised paragraph (d) that describes the new minimum contracting requirement under the Bipartisan Budget Act of 2018 that the newly designated paragraph (e)(2) would make effective January 1, 2021.

CMS seeks comment on whether the regulatory changes fully communicates what they wish. They intend to issue sub-regulatory guidance to address any changes made under this rulemaking that impact D-SNPs contracts with State Medicaid Agencies.

Additional Integration Requirements

A new minimum contracting requirement would provide that any D-SNP that is not a FIDE SNP or HIDE SNP is required to notify the state Medicaid entity or individuals or entities designated by the state Medicaid agency, of hospital and skilled nursing facility (SNF) admissions for at least one group of high-risk full-benefit dual eligible individuals, as determined by the state Medicaid agency. CMS would also permit the D-SNP to authorize another entity or entities (such as a D-SNP's network providers) to notify the state Medicaid agency and/or individuals or entities designated by the state Medicaid agency on its behalf, with the understanding that the D-SNP ultimately would retain responsibility for complying with this requirement.

CMS states this provision is intended to promote successful transitions of care into a setting of the beneficiary's choice, and increase coordination among those involved in furnishing and paying for primary care, acute care, LTSS, and behavioral health services. CMS discusses broad state discretion to choose the group of individuals for which data would be shared, the mechanisms by which data is shared as well as the ability to scale up or down the individuals and data involved.

CMS asks for comment on whether reasoning for why this proposal is preferable to more prescriptive or alternative proposals is sound; whether there are other minimum contacting requirements not considered that are superior to our proposal; and whether the proposal provides sufficient incentives for plans and states to pursue greater levels of integration. CMS considered other options including application to all FDBES, setting a minimum number, adding ED, specific time frames for submission such as within 48 hours, more coordination of assessments, identification and notification of members who need MLTSS (though this is already required through care plans), additional staff and provider training, solicitation of state involvement in MOCs and sharing data on services more broadly. However, CMS decided that many D-SNPs without aligned enrollments would not be able to effectively conduct some of this data sharing.

SNP Alliance Comments:

The SNP Alliance appreciates the preamble discussion that outlines the extensive alternatives that CMS has carefully considered and their insights into the choice of this particular additional contracting requirement for notices around hospital and SNF admissions and we understand why this decision was made.

However, to our knowledge, very few states have any experience with this type of data sharing and we are concerned that many states will not have the capacity to support or utilize this requirement, making this well meant requirement unduly burdensome for plans and states and providers. We are especially concerned about state capacity in Medicaid FFS environments where this form of data sharing will be even more challenging because states are less resourced to deal with D-SNPs and managed care.

If this requirement is to be successful, we highly recommend that CMS needs a robust strategy for assisting states, particularly those without integration interest or experience to build capacity to support this data exchange. Further, we are concerned about how this requirement will be evaluated for compliance especially where there are states with limited capacity to support this requirement, this issue is discussed further below in the section related to enrollment sanctions.

Therefore, we have a number of questions and recommendations around this provision.

- Are there indications that states or their delegates will accept and utilize these notices of hospitalization or SNF admissions? What happens to D-SNPs if states are not interested in this particular data set? (See enrollment sanctions section below).
- We are also concerned that expectations that such data notices would or could practically be shared on a basis timely enough for care coordination action or intervention might be overstated. In order to be useful for transition planning and care coordination purposes we believe such a system would have to be built into models of care and care coordination for both benefit sets (which are currently separate for most plans), which is a more extensive undertaking that may be daunting to some states.
- We appreciate that CMS provides flexibility for the state to delegate this responsibility to providers or other entities because we are not convinced that collection of this information at the state level is most useful. But whichever level is actually responsible for collection, any expectation of timely notice will be heavily reliant on providers, especially hospitals and nursing facilities who are the primary source of this kind of information, not health plans, to provide (or in the case of Medicaid providers, those out of network to receive) this information. This will require very aggressive provider education and oversight from both states and D-SNPs. We also appreciate that CMS recognizes that state health information exchanges could play an important role in this process, particularly where provider requirements to provide this data to the exchange are tied to a provider's license. Where ever possible we recommend that CMS encourage states to build on such existing data collection and sharing efforts. But however, this data is obtained and shared, it will be a large undertaking for all parties that CMS must recognize will also take time and administrative resources.
- Lack of provider willingness or capacity to cooperate could also interfere with tracking information needed to fairly determine D-SNP compliance with this integration

requirement. We recommend that CMS take these provider challenges into consideration when determining compliance.

- CMS notes that many D-SNPs without aligned enrollments would not be able to effectively conduct some of the data sharing alternatives. Given the prevalence of unaligned enrollment, does CMS have information or analysis that indicates it would be more feasible to share this particular data versus other information in these cases? For example, could there be data sets that would be more mutually beneficial to states and plans as first steps, such as requirements for sharing of enrollment information and care coordination contacts across plans in cases where there is unaligned membership? (See other SNP Alliance comments on CMS role in providing enrollment information in compliance section below.)
- Does CMS intend that this data include discharges as well as admissions? If so, CMS should clarify this, discharges can be even more important than admissions for improved transitions.
- Have all potential HIPPA barriers to sharing this information between providers, plans and states or their delegates been resolved?

In addition to responding to the issues above, we recommend that through additional guidance, CMS could simplify this requirement for states and plans by proposing a few options for standardized models or sets of requirements based on best practices that states could use as templates when contracting with D-SNPs to implement this provision. CMS could seek assistance from a group of plan and state stakeholders in developing this guidance and best practice models. In this guidance, CMS could further outline where specific state flexibility will be allowed, taking into consideration the full range of approaches already in place. This would provide greater consistency between states and help avoid significant administrative issues for plan sponsors operating across a number of states, while also preserving some needed state flexibilities. These options could include a review process for equivalent alternative data set exchanges where states and plans agree that a different set of notices or data would be more useful to them.

As part of that alternative data exchange consideration process, and as stated earlier we also recommend that D-SNPs that are actually providing Medicaid services (even though those services don't include behavioral health or MLTSS) be recognized as more integrated than plans that do not provide actual Medicaid services, by allowing additional flexibility as determined with the state as to which data elements to share consistent with the scope of Medicare and Medicaid services they are already providing.

Coordination of Medicaid Benefits in All Cases

CMS deleted some language in the general SNP rule, intending to clarify that in some cases, the D-SNP may cover (that is, provide directly or pay health care providers for providing) Medicaid benefits under a capitated contract with the State Medicaid agency, but *in all cases*, it must coordinate the delivery of Medicaid benefits. CMS intends to impose an affirmative duty on D-SNPs to provide benefits, as applicable, and otherwise coordinate the delivery of benefits and clarifies that D-SNPs must play an active role in helping beneficiaries access such services as necessary. CMS states that "coordination" more aptly describes the activity in which some D-SNPs are engaged with respect to a beneficiary's Medicaid benefits.

SNP Alliance Comments:

The SNP Alliance generally supports this revised interpretation of care coordination, but again we are concerned that states, various types of non-D-SNP related Medicaid plans and non-contracted providers may present barriers to sharing of information needed to make this coordination work. In addition, without information about enrollment in unaffiliated plans, duplicative care coordination could easily result, creating additional confusion for beneficiaries.

As noted above and further below, we recommend that CMS can do more to assist this process by developing and sharing data it collects for the purpose of addressing enrollment misalignment and by providing guidance or policy changes and provider education designed to ensure that such enrollment and care coordination information is allowed to be shared for coordination purposes under HIPPA.

Documentation of Categories of Dual Eligibles Enrolled

In §422.107(c)(2), CMS proposes to revise the current requirement that the contract between the D-SNP and the State Medicaid Agency document the categories of dual eligible individuals who are eligible to enroll in the D-SNP. This provision currently requires the contract to specify whether the D-SNP can enroll categories of partial-benefit dual eligible individuals or whether enrollment is limited to full-benefit dual eligible individuals. CMS proposes revisions to specify the categories of eligibility and also any additional criteria to account for such conditions of eligibility under Medicaid as nursing home level of care and age. These criteria could also include a requirement for D-SNP enrollees to enroll in a companion Medicaid plan to receive their Medicaid services

SNP Alliance Comments:

The SNP Alliance supports this change and believes this will provide useful clarification for all parties.

Documentation of Specific Medicaid Services Covered by the D-SNP

At 422.107(c)(3), CMS proposes that the contract between the D-SNP and the State Medicaid Agency document the Medicaid services the D-SNP is responsible for covering in accordance with a capitated contract with the D-SNP directly or through a risk contract, defined at § 438.2, with the companion Medicaid managed care organization operated by the D-SNP's parent organization. We believe that this change, if finalized as proposed, would reduce burden on D-SNPs to identify and document in the contract every Medicaid-covered service. D-SNPs often submit to CMS a list of all Medicaid services in their State Medicaid Agency contracts, even those for which the D-SNP is not under a capitated contract and for which the D-SNP bears no risk. This clarifying change would enable CMS to identify the particular Medicaid services that are covered under a capitated contract for FIDE SNPs and HIDE SNPs

SNP Alliance Comments:

The SNP Alliance supports this change and welcomes how this might help CMS achieve more consistency in determining HIDE and FIDE SNP status. We recommend that in cases

where the state Medicaid contract encompasses all MIPPA requirements and already lists both plan covered services as well as non-covered benefits with clarity as to responsibilities and where such items are found in the contract, a separate document duplicating this information should not be required.

(3) P. 54998) Conforming and Technical Changes (§§ 422.60(g), 422.102(e), 422.107(b), and 422.111(b)(2)(iii))

CMS proposes to make conforming changes to several sections of Part 422 that address D-SNPs by adopting consistent terminology with respect to dual eligible individuals and creating cross-references to the newly proposed definitions.

- § 422.60(g), addressing CMS authority to implement passive enrollment, CMS proposes using the term “highly integrated dual eligible special needs plan” in place of text referring to D-SNPs that meet a high level of integration.
- CMS proposes clarifying at § 422.102(e) that not only HIDE SNPs meeting minimum quality and performance standards are eligible to offer supplemental benefits, but FIDE SNPs that similarly meet minimum quality and performance standards may do so as well.
- At § 422.107(b), CMS proposes to substitute a “special needs plan serving beneficiaries eligible for both Medicare and Medicaid (dual-eligible)” with “dual eligible special needs plan” to remove extraneous language that is already explicit in the definition (that D-SNPs exclusively serve dually eligible individuals.)
- At § 422.111(b)(2)(iii), requiring D-SNPs to provide written information to dual eligible enrollees about their eligibility for cost-sharing protections and Medicaid benefits, we propose to use the term “dual eligible special needs plan” consistent with the proposed definition.

SNP Alliance Comments:

The SNP Alliance appreciates codification of this clarification that supplemental benefit flexibility applies to FIDE as well as HIDE SNPs, and is anticipating additional guidance from CMS to clarify current supplemental flexibility provisions in Chapter 16b that allow HIDE (and now more clearly also FIDE) SNPs this additional flexibility in light of recent major changes providing similar supplemental benefit opportunities for all MA plans. The SNP Alliance commented on this in the previous MA rule and requested that CMS continue to preserve some additional flexibility or incentives around supplemental benefit flexibilities for FIDE/HIDE D-SNPs that are not allowed to other MA plans.

While we recognize that this provision has not been utilized by eligible D-SNPs in the past, we observed confusion and a lack of understanding about this option among plans and state policy makers that may have led to that result. We recommend that through this revised guidance, CMS can clarify opportunities for D-SNPs that could be designed to create incentives for D-SNPs to work toward achieving HIDE and FIDE SNP status as well as to address specific needs of dually eligible beneficiaries. These could include allowing these plans to identify which services make sense for which members by exempting them from the chronic condition requirement, and allowing them broader use of services that directly relate to social determinants of health such as expanded in home meals and personal assistance with IADLs like grocery shopping.

The current 16b provision for FIDE/HIDE SNPs has also been tied to non-duplication of Medicaid benefits. However CMS has stated in response to our questions, that this non-duplication provision is not applicable to the broader MA supplemental benefit provisions. We recommend that CMS clarify this and other differences between this benefit flexibility for FIDE and HIDE SNPs in new guidance as soon as possible so that information is available for the next bid cycle.

(4) (P. 54999) Eligibility of Partial-Benefit Dual Eligible Individuals for Dual Eligible SNPs

CMS considered limiting the enrollment of partial dual eligible members, citing barriers to simplifying communication materials and the fact that no Medicaid services are being provided as reasons they continue to question the value of D-SNP enrollment to members. They did not impose such limits in this rule, but continue to consider it, and are asking for comments on enrollment of partial duals.

SNP Alliance Comments:

The SNP Alliance continues to support the enrollment of partial dual eligibles into D-SNPs. We continue to be puzzled that CMS does not cite or mention the value of the D-SNP Model of Care (MOC) in providing additional care coordination of Medicare primary, acute and specialty care for this subset of D-SNP enrollees. The MOC provides individual risk assessment, care plans, interdisciplinary teams, and additional care coordination and navigation assistance that these members would not get in a regular Medicare Advantage program. While the characteristics of partial duals show them to be somewhat less complex than FBDEs, they are still more complex than the average MA enrollee. We do not understand why CMS would propose to reduce access to these valuable benefits for this subgroup of the dually eligible population.

Further, the partially dual population, because they are often LIS eligible and close to meeting financial status for full Medicaid benefits and yet not eligible for the LTSS services available to full benefit dually eligible beneficiaries, could benefit the most from the new proposed requirements for coordination or assistance to access services outside of the D-SNP. In fact, plans that currently serve partial duals, often discover that such duals are eligible for FBDE status and LTSS, but need navigation assistance to work through the often daunting LTSS eligibility process with the state. In such instances the D-SNP can facilitate their movement to full status since the LTSS financial eligibility threshold is usually more generous for duals who meet LTSS criteria. This seems very consistent with the requirement for D-SNPs to assist members in accessing Medicaid services outside their contracted benefits.

We also think that states might find new value in working with D-SNPs specifically serving partial duals, particularly with the additional supplemental benefit flexibility now allowed under MA which might be creatively utilized to help them avoid spending into FBDE status.

We recognize the additional complexities and obstacles to integration posed by including partial duals under the same PBP as FBDEs due to the differences in benefit packages, member materials, grievance and appeals etc. However, we do not believe it is necessary to take the extreme step of denying access to coordinated care especially designed for vulnerable duals of which this group is a subset, in order to resolve any integration issues. We recommend that CMS

resolve those issues through administrative changes instead of disrupting access to the only source of care designed to meet their needs.

(5) (P. 54999) Suspension of Enrollment for Non-Compliance with D-SNP Integration Standards (422.752)

The BBA created an intermediate sanction for stopping all new enrollment into a D-SNP if the Secretary determines that the D-SNP is failing to comply with the integration requirements set forth in section 1859(f)(8)(D)(i) of the Act. CMS believes the goal of establishing these integration requirements was for all dual eligible beneficiaries enrolled in D-SNPs to receive a greater level of integration of Medicare and Medicaid benefits than under current regulations.

Because the BBA limited the applicability of the Secretary's authority to impose an intermediate sanction on plans that do not comply with the integration requirements to plan years 2021 through 2025, CMS believes that the intent of this provision is to offer an alternative to outright contract or plan termination for D-SNPs that fail to meet the new integration requirements during the period of 2021 through 2025. CMS says they believe this enrollment sanction authority is a lesser penalty than a contract or plan termination to provide time for D-SNPs to transition to the new integration requirements without creating potentially significant disruption to current D-SNP enrollees as a result of outright termination.

In addition to authorizing this lesser sanction, the statute requires a corrective action plan, which CMS believes strengthens their interpretation by illustrating a preference for ultimate compliance by D-SNPs with the integration requirements. The Secretary has discretion in imposing such sanctions. CMS would impose this enrollment penalty prior to seeking plan termination or other enforcement actions.

CMS states that their proposal would establish predictability for states, beneficiaries, and MA organizations by requiring its imposition for non-compliant plans in lieu of termination or other actions while leaving discretion for CMS, if the D-SNP does not submit an acceptable corrective action plan or fails to abide by the correction action plan, to determine that contract termination or other action is still possible. In the event that any harm to enrollees is imminent, CMS retains authority to immediately terminate the contract. CMS also proposes in § 422.752(d) that the suspension of enrollment would continue in effect until CMS is satisfied that the deficiencies that are the basis for the sanction determination have been corrected and are not likely to recur. The procedures, remedies, and appeal rights available to plans subject to intermediate sanctions provided in §422.756 would apply to D-SNPs that are sanctioned under this new authority.

SNP Alliance Comments:

The SNP Alliance generally supports this interpretation and process for implementation of the BBA provisions for enrollment sanctions as consistent with the statute. However, it is clear that achieving additional levels of integration is dependent on state interest and capacities. As indicated many times in previous comments we continue to be concerned about what will happen in cases where states do not have the capacity or inclination to assist D-SNPs in meeting the integration standards, and how that will impact how compliance will be tracked and determined, in particular for non-HIDE/FIDE SNPs.

Specifically, lack of state capacity will be a barrier to the three new requirements for sharing of SNF and hospital admissions, provision of care coordination for services outside of the plan benefit packages, and for documentation of the requirement to assist members with grievance and appeals regardless of payer source, all of which will require some determination by CMS of compliance. For example, what if states cannot provide information about payers or providers of services outside the D-SNP network when D-SNPs need to contact them for effective SNF or hospitalization data exchange or when those providers refuse to share information when D-SNPs are required to follow up for care coordination or to coordinate with them for grievance and appeals assistance? This will make it difficult for CMS to fairly determine D-SNP compliance. Without additional incentives and/or assistance for/to states to build this capacity or additional action by CMS, we are concerned that it will be nearly impossible for some D-SNPs to successfully comply. Therefore we have a number of recommendations below.

We strongly recommend that CMS must do more to assist states and encourage them to track aligned and misaligned enrollments and to share this information with D-SNPs subject to this requirement. CMS and states each have essential pieces of data needed for this purpose that D-SNPs lack. One of the most frustrating challenges D-SNPs face is lack of information on what Medicaid plan their members are enrolled in when they are not the Medicaid plan sponsor. We know many dual beneficiaries are enrolled in two different plans and we are concerned about how D-SNPs will be able to provide such assistance effectively and efficiently without information on where their members are enrolled for Medicaid. This lack of information will make it difficult for D-SNPs to achieve the additional coordination CMS is expecting in this proposed rule.

In cases where states lack experience or resources to begin this process, we recommend that CMS consider developing data bases or data sharing mechanisms (such as data portals) to provide access to this information directly to plans. Collecting and sharing this data would be more efficient and less burdensome than each plan having to have each care coordinators or member service personnel try to figure out where each enrollee is enrolled on a case by case basis. Though direct care coordinator knowledge will also be necessary to provide the additional care coordination, trying to gain information from care coordinator contacts with enrollees is not useful for developing aggregate numbers for tracking and deploying public policies around enrollment alignment and documentation of compliance and it would be much more efficient to have that data and share it with care coordinators ahead of time to facilitate their assistance.

We recommend that CMS work across both Medicare and Medicaid to provide additional regulatory guidance and assistance to states to ensure that it is possible and feasible for D-SNPs to comply with these new BBA expectations and that CMS consider the following steps and provide information on barriers to each if they cannot address them.

- CMS should provide extensive education to all states around these new provisions including specific outreach to states that are not non-involved in integration activities to educate them about these new requirements states and provide additional support for state efforts to determine enrollment alignment or the lack thereof, especially where people are enrolled in two or more separate plans for Medicare and Medicaid.

- CMS and states could match and share Medicare and Medicaid enrollment data files with plans or develop centralized data portals for plans and/or providers to provide and access data. For example, CMS could request Medicaid files from states and match them to MA files or vice versa and share them with plans on a monthly basis or via data portals where plan enrollment could be queried. CMS could seek an enhanced IT Medicaid match for states for activities related to collecting and sharing this data with expedited timelines for approval of such IT match. CMS might also explore whether allowing plans access to TMIS data for queries on plan enrollment could accomplish this.
- CMS should seek to collect the additional necessary data needed if it does not exist.
- CMS should provide assurance to states and plans that when the enrollee is enrolled in two different plans or under different parent company products, there should not be a HIPPA barrier in sharing information for these COBA and TPL purposes.

b. (P. 54999) Unified Grievance and Appeals Procedures for Dual Eligible Special Needs Plans and Medicaid Managed Care Plans at the Plan Level (§§ 422.560 – 562, 422.566, 422.629 – 634, 438.210, 438.400, and 438.402)

Summary of CMS Grievance and Appeals Changes:

Section 1859(f)(8)(B) of the Act, as added by the Bipartisan Budget Act of 2018, directs the Secretary to establish new procedures that unify, to the extent feasible, Medicare and Medicaid grievance and appeals procedures for D-SNPs. CMS cites many differences between the Medicare and Medicaid grievance and appeals systems that present obstacles to resolution for dual eligibles, but also that represent challenges to developing a unified system. However, experience with PACE and MMPs indicates that the process can be improved and that such improvements can benefit dual eligibles.

Using the statutory framework, CMS developed the following goals to guide development of proposals to implement the unified grievance and appeals provisions:

- Adopt provisions that are most protective of the enrollee;
- Reduce burden on beneficiaries (and those assisting them), plans, states, and providers;
- Maintain state flexibility and minimize disruption by building on existing rules and policies.

CMS proposes to establish requirements for all D-SNPs, relative to the role they play in assisting full-benefit dual eligible individuals, to assist with Medicaid-related coverage issues and grievances (§ 422.562(a)). They also propose new requirements in accordance with section 1859(f)(8)(B) of the Act to create integrated grievance and appeals systems for a limited subset of D-SNPs (“applicable integrated plans”), identified using terms and concepts they propose to define in amendments to § 422.561, with the integrated processes established by proposed new regulations (§§ 422.629-422.634). Finally, they propose a number of changes of a technical and conforming nature to existing provisions in parts 422 and 438 (§§ 422.560, 422.562, 422.566, 438.210, 438.400, and 438.402). While the changes are required to be implemented for the 2021 contract year, states may choose to adopt procedures consistent with these requirements through their contracts prior to that date.

SNP Alliance Comments:

Overall, the SNP Alliance supports the approach CMS has taken for implementation of statutory requirements for a unified grievance and appeals system. We believe it is the only practical and largely feasible option at this time and we appreciate CMS' careful consideration of enrollee protections and operational details. We expect that much will be learned to build upon as we continue to gain experience with and learn about how states, plans and enrollees react to and benefit from the proposed changes.

However, we have some more serious concerns about how the provision to provide assistance for grievance and appeals regardless of payer source will be implemented and documented. Please see below for additional comments on this and other specific provisions.

(1) (P. 55001) Assisting with Medicaid Coverage Issues and Grievances (§422.562(a)(5))

CMS proposes an additional integration requirement specifically related to requiring all D-SNPs to provide assistance to FBDE enrollees (not applicable to partial-benefit dual enrollees) regarding Medicaid-related coverage issues and grievances, including authorization of services, and appeals. All D-SNPs must assist enrollees with resolving Medicaid coverage problems, including assistance with filing grievances, requesting coverage, and requesting appeals. CMS states this is consistent with their interpretation of existing guidance and expectations and with the proposed standard for minimum coordination across Medicare and Medicaid in the D-SNP definition.

The supplementary requirement provides that when a D-SNP receives an enrollee's request for services, appeal, or grievance related to Medicaid-covered services (regardless of whether such coverage is in Medicaid fee-for-service or a Medicaid managed care plan, such as a Medicaid MCO, PIHP, or PAHP as defined in § 438.2), the D-SNP must provide a certain level of assistance to the enrollee. CMS provides examples of such assistance, such as specific instructions on how to contact the entity that may cover the service (for example, the Medicaid managed care plan or a contact in the fee-for-service system), assistance in obtaining and filling out forms necessary for the next steps in the process, assistance in the actual filing of grievances and appeals (though not representing the enrollee), and assist the enrollee in obtaining documentation in support of a request for authorization or appeal. CMS states telling a member having difficulty accessing services or needs help with a grievance or appeal to contact Medicaid is insufficient and suggests that care coordinators could play a role in providing assistance.

CMS does not intend to exclude any type of service delivery system in this provision and requests comment on whether other systems should be noted and whether there are instances where such coordination is ill-advised or infeasible. CMS notes that full compliance with this proposal requires that D-SNPs and states maintain data sharing that allows D-SNPs to determine the type and source of Medicaid coverage of their enrollees but this may be challenging. However they believe it is reasonable to expect that D-SNPs, as plans focused on serving dually eligible beneficiaries, take steps to access such information to provide effective care coordination for dual eligible enrollees and to implement more seamless (even if not unified) grievance and appeals systems, and that providing such assistance may be in a

D-SNP's interest, such as providing access to HCBS services that may reduce hospitalizations.

Enrollees would not need to make a formal request and are free to accept or reject offers of help, but CMS provides some language around a plan's requirement to provide assistance and enrollees acceptance of help, and compares it to existing requirements for assistance with interpreters. CMS also discusses other forms of assistance such as self-advocacy or other mechanisms. CMS requests comment on whether these provisions and examples are clear enough or whether more detailed guidance is necessary. CMS also proposes that a D-SNP provide documentation to CMS upon request that demonstrates how the D-SNP is providing the assistance proposed under this provision.

SNP Alliance Comments:

SNP Alliance recommends general support for this provision, but we believe it will require additional substantial guidance to states and access to data which is not currently available to most D-SNPs.

Documentation of such broadly defined assistance will be challenging, particularly because the methods of assistance may vary greatly according to the needs and reactions of the enrollees, there is a lack of information on enrollment in non-affiliated plans, and state capacities to share necessary information will vary. The same issues and recommendations provided in earlier sections related to sharing SNF and hospitalization data, providing care coordination for Medicaid services outside the D-SNP, and achieving compliance where there is a lack of state capacity are relevant to developing efficient and successful implementation of documentation approaches for this proposed requirement.

Members note that D-SNPs do not always have access to information about whether or how Medicaid benefits that members are seeking to appeal are covered under the state's Medicaid program, or even who is providing them, all of which impacts the members' grievance and appeal rights and pathways including those for external reviews. We recommend that CMS could consult states and D-SNP stakeholders in developing additional guidance to help evaluate recommended pathways for these situations, including how to ensure that sufficient information for the separate external reviews is collected to reduce conflicting or inappropriate coverage decisions.

We repeat our earlier recommendation that CMS develop mechanisms and provide assistance for building state capacity for tracking and sharing enrollment information between CMS, states and plans and the need to conduct further education for states and providers, particularly those that are not involved in integration activities to ensure that they understand these requirements for D-SNPs and do not misinterpret them as interfering with Medicaid MCO responsibilities, or other related state or provider activities.

Until there is more clarity on sharing such information, CMS should avoid burdensome documentation requirements which may very well end up hindering the very kind of assistance CMS is encouraging.

We also recommend that CMS consult expert state and D-SNP stakeholders to develop further guidance addressing a number of clarifications and terms including:

- Clarification of the term “provide assistance” which could build upon previously issued guidance on the term “reasonable assistance” used for MMPs.
- What would trigger a D-SNP’s requirement to provide assistance such as what “becoming aware” of an issue means, and outline which specific types of support need to be provided and documented, for example:
 - Completing forms
 - Filing grievances
 - Filing an appeal
- Examples of what is meant by “coaching on self-advocacy”.

D-SNPs are audited based on Medicare standards and requirements, which may pose a conflict between their need to pay attention to Medicare improvement metrics and the need to provide this assistance. CMS should assure that plans have incentives to coordinate with Medicaid agencies or provide protections from possible negative repercussions resulting from the Medicaid appeals and grievances. Specifically, when D-SNPs are providing good-faith assistance to a D-SNP member who is not satisfied with the outcome, CMS must not count these complaints to Medicare (CTMs) against the D-SNP, and should exclude these incidents from any Stars measures related to CTMs so that D-SNPs do not face penalties for providing and documenting this assistance.

CMS must also be aware that many D-SNPs will be concerned about potential liabilities attached to the plan should the member not be successful or in hind sight should a better approach have been available for the member than the one proposed by the plan, particularly when deciding if or how to inform the member that their services may be allowed to continue while their appeal is pending should they file through the Medicaid process. Again, we strongly recommend that CMS implement protections against liability for D-SNPs that are providing good faith guidance and assistance to members in providing this support as well as clear guidance to define the support they should provide including appropriate examples. For example, CMS must clarify whether CMS will expect D-SNP staff to assist the member in accessing and navigating the Medicaid MCO/ agency appeals and grievance process or expect the D-SNP to act as an advocate for the member in pursuing an overturn of the appeal or grievance. CMS should require that in either case it should be clearly stated to the member that staff providing the assistance are not able to offer an opinion regarding the validity of the appeal or grievance.

In addition, as part of the effort to track and document this requirement, we recommend that CMS work toward common definitions and reporting requirements between Medicare and Medicaid. This is particularly important for facilitation of this requirement for unaligned or partially aligned D-SNPs beyond the FIDE and HIDE SNPs that will participate in the unified grievance and appeals system.

(2) (P. 55003) Statutory Basis and Scope for Unifying Grievances and Appeals (§ 422.560)

In § 422.560, CMS adds new paragraphs (a)(4) and (b)(5) to address the statutory basis and scope of their proposal to establish unified grievance and appeals processes for a subset of D-SNPs. These provisions specify that the procedures under section 1859(f)(8) that

section apply in place of otherwise applicable grievance and appeals procedures with respect to items and services provided by certain D-SNPs and add language to identify the scope of the new proposed requirements for *applicable integrated plans* with regard to unified appeals and grievance procedures.

SNP Alliance Comments:

Overall, the SNP Alliance supports this interpretation. However, CMS should be very clear as to whether this means that the proposed procedures for unified grievance and appeals if adopted, would supersede or override any conflicting current Medicaid state law or rules as well as federal statutes and rules related to D-SNPs and under what process any of those potential conflicts can be addressed. The SNP Alliance anticipates that states will have difficulty in implementing the intent of Congress and CMS without either additional state specific accommodations or clarifications on override authority with strong guidance to accompany either or both options. The alternative appears to be that CMS would have to accommodate many state variations that could impact or delay the intent of the overall process to provide simplification and clarity for beneficiaries.

In addition, even for this narrow group of integrated plans, significant additional guidance and clarification are required to ensure that such plans are able to effectively guide beneficiaries and conduct and oversee an integrated process. Ensuring that staff members are appropriately informed of the unified requirements and, where they apply, and of the processes that will remain separate will be challenging. CMS will need to take into account both operational and institutional challenges posed by unifying the processes.

We recognize that CMS also requests comment on how to accommodate state variations but that request appears to be in conjunction with adopting beneficiary protections. We suggest that CMS may need to broaden that accommodation beyond beneficiary protections. However, we would still be concerned about CMS' capacity for such accommodation and on what basis CMS would allow variations in some states and not others. It would be unfortunate if this lack of clarity resulted in legal actions that delay the implementation of this provision. As suggested earlier, we recommend that CMS convene expert stakeholders from plans and states to continue to clarify and refine this overall approach in order to develop additional guidance.

(3) (P.55003) Definitions of “Applicable Integrated Plan”, “Integrated Appeal”, “Integrated Grievance”, “Integrated Organization Determination”, and “Integrated Reconsideration,” and General Requirements for Applicable Integrated Plans (§§ 422.561 and 422.629)

CMS discusses the challenges of applying a unified grievance and appeals process in the face of the many different enrollment scenarios across states. CMS discusses their belief that it is most feasible to apply a new unified grievance and appeals process only to plans with exclusively aligned enrollment and notes that most plans do not have exclusively aligned enrollment so very few plans meet this definition. They propose to add new terms to define “*applicable integrated plan*” that includes only a subset of D-SNPs, that is, only FIDE SNPs and HIDE SNPs with exclusively aligned enrollment, as defined at proposed § 422.2 and described in section II.A.2.a.(1).

They propose that the affiliated Medicaid plan be a Medicaid managed care organization, as defined in section 1903(m) of the Act, that is offered by-- (1) the D-SNP with *exclusively aligned enrollment*; (2) the parent organization of such D-SNP; or (3) another entity that is owned and controlled by the parent organization of such D-SNP. They state that their proposal for unified grievance and appeals procedures would apply only to the enrollees of the subset of D-SNPs that are FIDE SNPs or HIDE SNPs with *exclusively aligned enrollment* and the affiliated Medicaid managed care organizations through which such enrollees receive their Medicaid services.

The requirements for non-fully integrated D-SNPs would remain unchanged, meaning that there would be different sets of requirements for different types of D-SNPs and CMS proposes new defined terms to make these separate requirements distinct. They request comment on this approach and whether the term “*exclusively aligned enrollment*” serves their stated purposes.

CMS also proposes to propose to establish definitions for “integrated organization determination,” “integrated appeal,” “integrated reconsideration,” and “integrated grievance” which would apply exclusively to “*applicable integrated plans*”. These definitions would encompass both Medicare and Medicaid actions by applicable integrated plans by referring to existing definitions and adding new integrated organization procedures. The proposed definitions for integrated grievance, integrated organization determination, and integrated reconsideration are intended to replicate the scope and meaning of the parallel terms in parts 422 subpart M and part 438 subpart E regarding the appeals and grievance procedures required of MA organizations and Medicaid managed care plans. CMS is proposing that the regulations and procedures proposed here take the place of those part 422 and part 438 procedures for *applicable integrated plans* and CMS requests comments on this approach.

CMS also sets forth general requirement that applicable integrated plans create integrated processes to administer these grievance and appeals requirements. In addition, CMS allows flexibility to states to utilize Medicaid regulations (through the State Medicaid contract) which establish a floor for enrollee protections, while also offering states flexibility to impose more stringent requirements for timeframes and notices so long as they are more protective of beneficiaries, and is considering codifying opportunities for such flexibilities. CMS specifically requests comment on this provision.

Finally in this section, CMS describes a long list of Medicare and/or Medicaid requirements many of which are currently similar but may encompass slight differences, and spells out the process would apply to applicable integrated plans. CMS appears to determine which process applies by considering its protective value to the enrollee including in some cases combining features of both processes. These cover processes for allowing enrollees to present arguments and information, written acknowledgment of receipt of grievance and appeals, related record keeping, protections from punitive actions for provider reporting, providing assistance in completing grievance and appeals, provisions for who must review integrated organization determinations and integrated reconsiderations, and information that must be considered in that process (information that has not been previously shared with a plan must be considered).

SNP Alliance Comments:

The SNP Alliance commends CMS for its proposal to apply the unified grievance and appeals only to plans with exclusively aligned enrollment. In general we agree with the choices and rationales CMS has presented. We believe this is the most feasible and realistic approach to implementing the unified system. We also appreciate CMS' thoughtful discussion of a wide range of related issues considered in the preamble.

However, we wonder how states will react to being subject to multiple systems and other potential statutory issues as outlined in the previous comment. It is difficult to anticipate how the decisions incorporated into this approach impact the variety of current state features even with the corresponding changes proposed for Medicaid.

As stated earlier, we remain concerned about how CMS will be able to accommodate and evaluate state flexibilities and how these flexibilities would be consistent with application of a more standardized and unified process.

(4) (P. 55006) Authorization for Filing Appeals (§ 422.629(l))

CMS proposes to combine the MA and Medicaid requirements, such that a treating provider or authorized representative can file an appeal on behalf of an enrollee with written consent from the enrollee only when there is a request for continuation of benefits, and invites comments as to whether an approach closer to Medicaid's, in which written authorization would be required in all cases when a provider files an appeal on behalf of a beneficiary, would be preferable.

SNP Alliance Comments:

The SNP Alliance supports this provision. It appears to be a reasonable compromise between the two program requirements which include competing beneficiary protections. However, members suggest that providers should sign the appeal and any relevant medical need assessments (they would likely have to do so if it went to a secondary appeal process), and be able to document that the member has agreed to allow the provider to submit it as well as to update the member on the appeal status. We also recommend clarification of whether this provision applies to both pre and post service appeals and both contracted and non-contracted providers. In addition, CMS should clarify whether a non-treating provider such as a durable medical equipment provider would be authorized to file an appeal on behalf of an enrollee.

(5) (P. 55006) Integrated Grievances (§ 422.63)

CMS proposes to largely parallel Medicare and Medicaid requirements where these requirements are the same with regard to the treatment of integrated grievances. Where MA includes a requirement that Medicaid does not, or vice versa, or where the MA and Medicaid regulations conflict, they propose applying the requirement that best aligns with the principles and statutory requirements of this preamble. They propose to adopt the requirement that is most protective for enrollees and that ensures timely, clear, and understandable resolution and notification including the following:

- That an applicable integrated plan provide meaningful procedures for timely hearing and resolving integrated grievances filed by an enrollee.

- To define the scope of the required procedures as being applicable to any grievances between the enrollee and the plan or any entity or individual through which the applicable integrated plan covers health care services including act or decisions by a contracted provider or vendor.
- That enrollees can file a grievance at any time (as is allowed in Medicaid) either orally or written
- To include current state processes, where they exist, for enrollees to file grievances with the state that relate to Medicaid benefits.
- Process for expedited grievance resolution mirroring MA.
- 30 day timeframe for resolution of grievances and 14 day extensions parallel to MA with immediate notification but no later than within 2 calendar days to enrollee of the extension.

CMS invites comment specifically on whether the proposed regulation text accurately incorporates the standards from the underlying part 422 or part 438 regulation that are more beneficial to the enrollee and whether they have adequately captured all relevant enrollee protections.

SNP Alliance Comments:

The SNP Alliance supports this provision. The specific choices made seem to be a reasonable blend of protections and features from both programs.

(6) (P. 55007) Integrated Organization Determinations (§ 422.631)

CMS proposes that all requests for benefits covered by applicable integrated plans must be subject to the same integrated organization determination process. CMS proposes requirements covering the following issues: requests can be either orally or in writing except request for payment must be in writing, expedited requests (combines Medicare and Medicaid), address other timeframes and notices, notices must be in plain language, written integrated notices are required for adverse determinations when any amount, duration or scope is less than requested or there is any reduction in ongoing treatment, adverse determinations notices must be provided for non-timely responses, Medicaid 10 day advance notice timeline is adopted with some exceptions, notice provisions are outlined for extensions, CMS adopts Medicare requirements for 72 hour response with 14 day extension for expedited determination notices and/or denials and for notices to non-contracted providers.

SNP Alliance Comments:

The SNP Alliance recommends support for this approach. Integrated benefit determinations are essential to simplification of grievance and appeals for D-SNPs and enrollees, and such processes have been utilized by D-SNPs within and outside of demonstration authority. They appear to be a necessity for a unified grievance and appeals process for “applicable integrated plans.” We would ask CMS to clarify how this might impact the use of the current Integrated Denial Notice (CMS-10003) and to confirm that the Integrated Denial Notice meets the proposed notice requirements. We suggest that CMS could expand use of this notice to plans with some aligned enrollment beyond the “applicable integrated plans” if it is not already being utilized.

(7) (P. 55008) Continuation of Benefits Pending Appeal (§ 422.632)

CMS interprets the BBA as requiring CMS to apply continuation of benefits to all Medicare and Medicaid benefits under the proposed unified appeals. Recognizing that Medicaid provisions are much more extensive, the provision would apply to current Medicare A or B benefits, and not only those that are already permitted to be continued under current law but would not apply to supplemental benefits. Based on their experience with the Financial Alignment Demonstration (FAI), CMS proposes a parallel process based on Medicaid requirements, while preserving the current QIO process for Medicare hospitalizations.

Enrollees could request that a benefit continue to be provided at currently authorized levels while the enrollee's appeal is pending through the integrated reconsideration. CMS uses Medicaid requirements for timely filings, Citing no adverse cost related experience from MMPs or states on the FAI process, CMS proposes to prohibit recovery of the costs of services provided pending the integrated reconsideration and, for Medicaid-covered benefits, any state fair hearing, to the extent that services were continued solely under § 422.632, for all applicable integrated plans and state agencies. CMS considered alternatives to this process (i.e. apply Medicaid's recoupment process to Medicare or adopt Medicaid rule for only Medicaid services, but rejected them for a number of reasons, but requests comment on alternatives.

SNP Alliance Comments:

The SNP Alliance supports this provision as consistent with the BBA requirements. CMS states that MMPs have not had cost issues with this provision in the FAI, however CMS should monitor this issue to assure that it does not raise any unintended consequences for applicable D-SNPs and to assure that any such costs are considered allowable for bid purposes. We appreciate CMS' consideration of alternatives and agree that neither alternative considered appears to be workable.

However, CMS should consider establishing an expedited process to hear these appeals when a member is continuing to receive the benefits. In situations where a member regains eligibility for a service before the appeal or grievance is heard, CMS should allow for the dismissal of that appeal without a decision to avoid unnecessary member confusion.

(8) (P. 55010) Integrated Reconsiderations (§ 422.633)

CMS proposes one level of integrated appeal at the plan level with one plan level internal reconsideration. CMS states that the ability to elect external medical review would apply only to Medicaid covered services that are the subject of an adverse integrated reconsideration issued by an applicable integrated plan because D-SNPs, like all MA plans, are not subject to state external review procedures. CMS proposes a right for each enrollee, and their representatives, to review the medical records in the enrollee's case file, consistent with the protection for Medicaid enrollees under § 438.406(b)(5), and will adopt Medicaid's provision prohibiting plans from charging for copies of records. CMS proposes that an integrated reconsideration, including oral inquiries must be filed within 60 days of the date of the denial notice, but are not proposing to require beneficiaries to provide written confirmation of oral requests.

In addition, CMS proposes Medicare provisions for expedited reconsiderations, because it is more detailed but asks for comments on whether more detail is required. Notices required for expedited reconsideration would parallel Medicaid when requests are denied and content would follow MA requirements. Requirements around non-contracted providers would mirror Medicare. Resolutions for either pre- or post-service determinations would be 30 calendar days. CMS would require 72 hours for notices for expedited extensions. Even though notices are no longer required in MA for next level appeals, CMS proposes they be provided for both Medicare and Medicaid, and include information that enables the enrollee to understand which program covers the benefit, information about the next level process, and rights to continuation of benefits pending appeal.

SNP Alliance Comments:

The SNP Alliance supports these provisions for plan level reconsiderations. We agree with CMS choices as practical and consistent with the beneficiary protection principles laid out for implementing these provisions.

(9) (P. 55012) Effect (§ 422.634)

CMS proposes the same standard as in existing MA and Medicaid regulations related to a plan's failure to make a timely determination. Failure would constitute an adverse determination, such that the enrollee could move forward with the next level of appeal procedures. Case files and timing involving Medicare benefits would be forwarded through current Medicare processes to the independent entity. For Medicaid benefits the beneficiary would have to initiate a State Fair Hearing request no later than 120 days from the date of the applicable integrated plan's notice of resolution with the requirement that a provider who has not already obtained the written consent of an enrollee must do so before filing a request for a state fair hearing, in accordance with existing Medicaid requirements.

CMS proposes to specify that this means that, in the event that an enrollee pursues an appeal in multiple forums simultaneously (for example, files for an external state medical review and an integrated reconsideration with the applicable integrated plan, and the integrated reconsideration decision is not in the enrollee's favor but the external state medical review decision is), an applicable integrated plan would be bound by, and must implement, decisions favorable to the enrollee. If a decision is favorable to the enrollee, the applicable integrated plan must authorize or provide the disputed benefit as expeditiously as the enrollee's health condition requires but no later than 72 hours from the date it receives notice reversing the determination. The proposed rule maintains the same effectuation timelines for reversals by the Medicare independent review entity as apply to other MA plans. CMS parallels Medicaid requirements for governing how services that were continued during the appeal must be paid for, if the final determination in the case is a decision to deny authorization of the services. For Medicare-covered services, CMS proposes that the applicable integrated plan will cover the cost of the benefit. CMS would also require providers obtain written consent of enrollees (if not already obtained) before filing a request on behalf of an enrollee.

SNP Alliance Comments:

The SNP Alliance supports CMS approach to these issues as best for the beneficiary.

(10) (P. 55012) Unifying Medicare and Medicaid Appeals Subsequent to Integrated Determinations

The BBA requires CMS, to the extent determined feasible, to include consolidated access to external review under an integrated process. CMS interprets “external review” in this statutory provision as meaning review outside the plan, including by a government agency or its designee. For MA, this includes the independent review entity (IRE) and ALJ review. For Medicaid, this includes the state fair hearing process, as well as any additional external review offered under state law.

While such a process would be simpler for enrollees, current processes are very different posing many challenges which CMS outlines including differences in reconsideration by an independent entity, immediate access to an administrative hearing, amount in controversy, reviewing agency and subsequent review, and timelines and procedural rules which vary by state. Further the statute provides authority to waive only section 1852(g)(1)(B) of the Act (which imposes certain notice requirements for MA organizations) and directs unification – rather than amendment or elimination of procedures. Where those statutory provisions are specific, CMS says it generally does not have authority under section 1859(f)(8)(B) of the Act to waive those specific requirements in establishing unified procedures and processes.

Therefore CMS does not believe it is feasible to propose a unified post-plan appeals process (that is, adjudication of appeal subsequent to an applicable integrated plan’s integrated reconsideration of an initial adverse determination) at this time. Instead CMS asks for comments on viable paths forward given the constraints presented by the statutory mandates for the MA and Medicaid appeals processes and experience gained through demonstrations. CMS hopes to propose the establishment of a unified post-plan appeals process in a future rulemaking, based on comments from this request for information and additional experience.

CMS states that any procedures established for a unified post-plan appeals process should be available as an option for states to implement in partnership with CMS, rather than a nationwide requirement. CMS experience with the New York FIDA demonstration indicated that operating a unified process requires considerable commitment, planning, and coordination by both CMS and the state Medicaid agency. Given the resources and knowledge required, CMS believes such an option would apply to very few states and pursuit for all states would be unwise and infeasible. In addition CMS believes an appeals system that is integrated at the plan level but which diverges subsequently can also be effective at ensuring appropriate review of plan decisions. CMS believes that any post-plan appeals process should be limited to appeals of decisions made by applicable integrated plans as they propose to define them.

CMS states that any regulation to establish a post-plan unified appeals process would need to address the following misalignments in particular:

- *Harmonizing the Medicare Advantage requirement for an external independent review with Medicaid’s prohibition on additional levels of administrative review between a plan decision and a state fair hearing:*

CMS requests comment on a scenario where a state entity with expertise in both Medicare and Medicaid coverage rules would review all adverse integrated reconsiderations issued by the plan. This entity would conduct its review in the form of an automatic state fair hearing consistent with Medicaid hearing procedures (such as the opportunity to present evidence), as is done in the New York FIDA demonstration. The automatic fair hearing would also constitute the independent external review required by section 1852(g)(4) of the Act. In order to comply with the statute, CMS and the state entity would have to enter into a contract to perform the independent review, and there would be additional appeals rights beyond the state conducted review and fair hearings process for Medicare with additional challenges.

CMS requests instructive analogous examples of state-federal contracting that successfully demonstrate states performing a task subject to federal oversight and input regarding any advantages and disadvantages to providing the automatic review in the form of a state fair hearing. CMS welcomes suggestions for alternative models that could harmonize the MA and Medicaid managed care requirements while maintaining compliance with all statutory provisions.

- *Preserving the right to hearing before the Secretary:*
In order to preserve the right to this statutorily required hearing for amounts in controversy, a unified process would need to allow a beneficiary whose appeal is unsuccessful at the independent review level to request a hearing before the Secretary (presumably through the Office of Medicare Hearings and Appeals (OMHA)) when an appeal involves a Medicare item or service (meaning a Part A benefit, Part B benefit, or supplemental benefit offered under the Medicare Advantage contract) meeting the amount in controversy threshold. But this appeal level would not be available for appeals of Medicaid-based cases or for Medicare cases not meeting the amount in controversy.

In effect, this would mean beneficiaries would need to split their cases into separate Medicare and Medicaid pathways if they wished to seek a hearing before the Secretary for their Medicare claims meeting the amount in controversy. In addition, it would essentially create the possibility for two hearings: first an automatic integrated independent review and fair hearing at a state level integrated entity, followed by an optional Medicare-only hearing at OMHA for Medicare matters meeting the amount in controversy threshold. Although such a process could be operationalized CMS thinks it would be confusing, and is therefore seeking comments on how best to preserve beneficiaries' rights under section 1852(g)(5) of the Act and simultaneously establish a unified process.

- *Pathways for subsequent review:*
CMS says any unified procedure must preserve both state-specific avenues for further review of Medicaid-related fair hearing decisions (for example, additional administrative review and state court review) and ensure that Medicare-related decisions are reviewable consistent with section 1852(g)(5) of the Act (for example, review by the Medicare Appeals Council and federal judicial review under certain circumstances) and would therefore remain confusing for enrollees. CMS is considering providing state Medicaid

agencies with the authority to delegate review of a state fair hearing decision to a federal entity (at state option and only with the federal entity's consent) in order to keep the unified appeal together. This is the approach in the New York FIDA demonstration, where the Medicare Appeals Council can review Medicaid aspects of a FIDA decision. Such an approach may be technically feasible, but CMS seeks input regarding the advantages and disadvantages of such a delegation.

- *Specificity of rulemaking:*
CMS states that it would require additional rule changes for exceptions to IRE and governmental administrative appeals processes as well as statutory Administrative Procedures Act provisions for rule making, also requiring comment by stakeholders. Further it would also curtail CMS ability to accommodate state specific flexibilities. CMS seeks comment on what aspects of a unified post-plan appeals process would necessitate state-specific flexibility, including discussion of whether any of those aspects would implicate rights under MA statute or would otherwise necessitate additional federal rulemaking.

To summarize, CMS believes that establishment of a unified post-plan appeals process may be feasible in the future if these issues can be addressed, and that such a process could offer benefits to beneficiaries, plans, states, and the federal government. CMS welcomes feedback on these issues and others pertaining to a post-plan appeals process.

SNP Alliance Comments:

The SNP Alliance commends CMS for its approach to post-plan appeal and grievance review processes. This approach seems most feasible given the statutory limitations outlined in CMS' discussion. In addition, if the unified process for integrated benefit determinations is followed, it should significantly reduce the number of appeals that reach this final review stage and the number of remaining issues should be able to be sorted appropriately to go down the existing corresponding Medicare or Medicaid external review pathway without unsurmountable problems. Until it is more clear how many plans and states would meet criteria for application of a unified process, this is a good interim approach and will provide more time for learning and gaining experience for consideration of alternatives. For example, this approach has worked in some FAI states and in the Minnesota D-SNP demonstration. However we want to note this approach is highly contingent on use of the integrated benefit determination process, which CMS has proposed as well.

We are grateful to CMS for its decision to not pursue the New York FAI model for a unified post plan approach at this time. While this approach may work well for dual beneficiaries in NY's FIDA program, it would be very expensive and complex to implement such a system at this time. However, it may ultimately be the best option if significant numbers of integrated dual programs were fully integrated and aligned.

It would be helpful if CMS could indicate which if any of the many options for pursuing a unified post plan review process are expected to be potential regulatory proposals in the future in order to focus further feedback from stakeholders.

In the meantime, the SNP Alliance recommends that CMS monitor the current proposed post plan appeals provision and its application as it is implemented to see whether the overall

unified grievance and appeals proposal reduces the number of post plan appeals and to assess any progress on enrollment alignment that might increase the number of exclusively aligned integrated plans to which any unified post plan process might apply. This will provide time to assess successes or problems with the proposed unified process and gather more information about exactly what is needed before pursuing further options or authorities for alternatives to the proposed two track approach for the post appeals review process.

(11) (P. 55015) Conforming Changes to Medicare Managed Care Regulations and Medicaid Fair Hearing Regulations (§ 422.562, § 422.566, § 438.210, § 438.400, and § 438.402)

CMS proposes a number of changes to Medicaid managed care, Medicaid fair hearing, and Medicaid single state agency regulations to conform with proposed unified grievance and appeals provisions including:

- In § 422.562(a)(1)(i) and (b), adding cross references to the proposed integrated grievance and appeals regulations along with new text describing how the provisions proposed in this rule for applicable integrated plans would apply in place of existing regulations.
- In § 422.566, adding additional language to paragraph (a) to establish that the procedures proposed governing integrated organization determinations and integrated reconsiderations at proposed § 422.629 through § 422.634 apply to applicable integrated plans in lieu of the procedures at §§ 422.568, 422.570, and 422.572.
- In § 438.210(c) and (d), adding cross references to the proposed integrated grievance and appeals regulations along with new text describing how the provisions proposed for applicable integrated plans would apply in place of existing regulations to determinations affecting dually eligible individuals who are also enrolled in a D-SNP with exclusively aligned enrollment
- In § 438.400, adding a new paragraph (a)(4) to include the statutory basis for the proposed integration regulations (section 1859(f)(8) of the Act) and to amend § 438.400(c) to clarify that these Medicaid changes apply to applicable integrated plans no later than January 1, 2021, but without precluding states from applying them sooner.
- In § 438.402, amending paragraph (a) to allow a Medicaid managed care plan operating as part of an applicable integrated plan to (apply) the grievance and appeal requirements laid out in §§ 422.629 through 422.634 in lieu of the normally applicable Medicaid managed care requirements.

SNP Alliance Comments:

The SNP Alliance supports these changes. However we have some concern about allowing states to implement them prior to January 1, 2021. We would support this early implementation if were implemented purely on a trial basis in order to better understand and learn about how the process works and how it might be improved without the potential for any negative consequences to plans. In doing so we would want to assure that all additional necessary guidance has been clarified and made widely available and that any FIDE or HIDE-SNPs affected by the unified process would not be negatively impacted or subject to penalties, sanctions or audits as a result of this early adoption.

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

CMS is proposing enhancements to the cut point methodology for non-Consumer Assessment of Healthcare Providers and Systems (CAHPS) measures. They are also proposing substantive updates to the specifications for a few measures for the 2022 and 2023 Star Ratings, and rules for calculating Star Ratings in the case of extreme and uncontrollable circumstances. Unless otherwise stated, data would be collected and performance measured using these proposed rules and regulations for the 2020 measurement period and the 2022 Star Ratings.

P. 55018 of the F.R. CMS reviews how it codified the Medicare Star Ratings and Quality Management System in April 2018 and provides background.

P. 55019. *Definitions* - CMS provides definitions of statistical and methodological terms pertaining to the proposed approaches.

Pp. 55020 and 55021. *Cut point Methodology* – CMS discusses how comments on the proposed rule codifying the Quality Management System/Stars Rating in April 2018 included recommendations from commenters that CMS make some enhancements on the clustering methodology to “capture the attributes they consider important.” Commenters expressed support for methods that yield cut points which are more: “stable, predictable, and free from the undue influence of outliers.” *SNP Alliance also expressed support for these attributes.* CMS goes on to state that they have been examining feasibility of various approaches with simulations and modeling. Detailed results of the modeling are not provided.

CMS proposes two enhancements to the hierarchical clustering methodology currently used to set cut points for non-CAHPS measures. The first enhancement is mean resampling, and the second enhancement is use of guardrails/caps. Mean resampling is described as helping to address the goal of reducing the effects of outliers and random variation that contributes to fluctuations in cut points. The use of guardrails/caps for measures that have been in the Part C and Part D Star Rating program for more than three years is described as helping to address the goal of greater predictability. CMS proposes an absolute 5 percent point cap for all measures scored on a 0 to 100 scale, and 5 percent of the restricted range for all measures not on a 0 to 100 scale. CMS states it would consider alternatives to the 5 percent cap, such as using a 3 percent cap.

SNP Alliance Comments:

General support - The SNP Alliance greatly appreciates CMS’ effort to consider how to improve the cut point methodology, such as through mean resampling and caps/guardrails to improve stability and predictability. The Star Ratings have significant implications for consumers and health plans. We thank CMS for recognizing that the cut point methodology has had limitations which may have unintended consequences for special needs populations.

Therefore, the SNP Alliance expresses appreciation for these proposed enhancements as an ***interim step*** while CMS works to improve the overall approach. We support the general concept of improving predictability and stability in the measurement ratings.

Need for more information - The definitions and brief description of the two enhancements offered to the existing methodology on setting cut points for Stars measures appear to be sound, although we do not have sufficient information about the full impact of CMS' mean resampling and guardrail proposals. To support transparency, accountability, and ensure fairness, we request that CMS provide technical notes or other information about the simulation model, data, and results. We request that CMS provide simulation data and share more information about the expected impact of these two modifications. We ask that these be provided in the forthcoming Call Letter or through other guidance.

Request to implement sooner - If, as described, the two modifications improve the stability and predictability of measure thresholds, we ask that CMS consider applying these modifications as soon as possible—*as an interim step toward improvement*.

Setting the cap - We appreciate the purpose of the guardrail/cap is to improve stability year to year, offer greater predictability about quality targets, and reduce the effect of outliers. We hope that these enhancements to the current methodology are applied as soon as possible as a promising interim step and that the impact will be fully examined.

In the meantime, in order to fully analyze the consequences of this change, we request that CMS provide more information about the simulation modeling done to date that demonstrates the impact of these guardrails. We ask that the results of this analysis particularly examine and report on impact on health plans, serving a high proportion of LIS/DE/Disabled individuals.

Based on information currently available, we support testing the utility of a 2 to 3 percent guardrail/cap year-to-year. Variability at 5 percent a year is clearly too high for many measures. We suggest CMS also consider a maximum, e.g., 5 percent cap/guardrail, over three consecutive years. We understand CMS will apply these enhancements as an interim step toward improvement and will report on their findings.

The issue of variability from year to year in measure scores is relevant to the application of guardrails, and we must raise the issue for two groups of measures: (1) measures that have shown wide swings in measure scores that may indicate underlying problems with the measure, adjustment methods, or scoring, and (2) measures that are topped out where most plans achieve a very high level of performance. We discuss the issue of topped out measures further in this response—requesting that CMS consider setting absolute thresholds for these measures vs. artificially forcing a 5-star distribution.

On the first group of measures—those with wide swings—the guardrails may help with predictability or stability year to year but will not address the underlying issues around the measure itself. For example, measures such as C04 (Improving or Maintaining Physical Health), and C05 (Improving or Maintaining Mental Health), had fairly substantial swings up and down over the last four years. We believe there are underlying problems with these two composite measures and the methods to arrive at scores.

Finally, in this interim phase applying guardrails/caps, we ask that CMS work with stakeholders and other experts to develop and specify parameters for guiding use and improving guardrails over time, toward the goals of accuracy, fairness, utility, and reliability.

Underlying fundamental limitations – While we appreciate the work done to date and this proposal, the SNP Alliance and its member health plans are concerned about fundamental underlying limitations of the cut point approach within Stars that will not be addressed by these proposed modifications.

We are particularly concerned that plans with a high proportion of LIS/DE/Disabled beneficiaries, with high SDOH and care complexity factors are disadvantaged by the cut point approach. We know that population-level characteristics including care complexity and social risk factors greatly affect what plans and providers can do, when, and how. Achieving thresholds on some of these Star measures requires exponentially more effort for people with high social risk factors and care complexities. Achieving, for example cancer screenings, and other clinical measure goals is compromised by the complex condition and life-situation management which will often drive prioritization--on what clinicians and mental health practitioners and individuals most care about and can impact. There is evidence to suggest that some differences in Star measure-specific scoring arises from differences in these variables vs. differences in actions by the plan or what is under the plan or provider control for at least some of the Star measures.

We therefore request that CMS consider more fundamental changes to the cut point methodology and commit to conducting additional modeling (as described below).

Five options for consideration - We believe it is important and timely to provide additional comment and offer five options for consideration. CMS could run simulations of these five techniques in 2019 to determine if they would make more substantive improvement to accuracy and utility of the measure scoring in conjunction with or as a substitute for applying the guardrails and mean resampling techniques proposed.

Options include:

1. ***Stratification Modeling into Plan Peer Cohorts*** - Model stratification of cohort/peer group quintiles prior to applying cut point thresholds, so that there are five sets of cut points (1 through 5 Stars) for each quintile group. The quintile groups would be based on proportion of enrollment LIS/DE/Disabled. Analyze results to discern if the peer group cut points for Star level ratings improve accuracy, validity, and utility of the Star rating assigned by the scoring methods. Report results. If the modeling shows merit, use the peer group Star rating thresholds rather than one overall/general MA set of cut points for measures where this step increases accuracy, validity, and utility. This would be a step toward addressing some of the underlying inequities. Mean resampling and guardrails could still be applied thereafter.

2. *Geographic Unit of Analysis* - Run simulations which use the state as the unit of analysis, rather than the contract. Measurement data associated with beneficiaries residing in a specific state would be aggregated. This would help address the problem of very large contracts which extend across multiple states and/or have enrollment scattered in various markets/regions. This would increase the meaningfulness of the cut points and Star measure ratings for consumers, tying the ratings closer to the locations where they receive care and experience plan actions. At a minimum, the state level score could be displayed, together with the aggregate score (all state level scores rolled up to a plan/contract level score, weighted based on enrollment volume in the measurement year). This could be tested for selected measures which are more sensitive to regional variation and provider behavior. Report results of simulations to inform stakeholders.
3. *Enterprise vs. Provider Sensitive Measures* – We ask CMS to consider whether some of the MA Star measures are more sensitive to provider actions and some are likely to be consistent across the enterprise of a MAO. For example, the appeals processes are likely to be similar within a health plan, regardless of how large it is and how wide the reach across states. Other measures, such as managing falls may be more sensitive to provider behavior and regional differences. This speaks to the predictability, variation, and attribution of measure results—all factors that are important when determining accurate cut points. Such analysis could identify regionally-sensitive measures and that would further inform and guide how cut points for Star ratings could be set to improve accuracy and relevance in Star ratings.
4. *Variability within Contracts*– We request that CMS analyze current Star measurement data and report on the variability of measurement data within contracts. The contracts with very large enrollment, covering multiple states and with many PBPs are likely to show wider variability than small contracts operating in single regions or states. If the variability is large for certain measures and if data from small PBPs or small regions are “washed out” from other PBPs within the same contract, this supports the view that this unit of analysis is too large for accurate scoring or reporting. Again, analyzing and reporting results would inform and guide where changes are necessary, prior to applying more modest cut point enhancements as proposed.
5. *Topped out measures*- The final request pertains to topped out measures where most plans are achieving a high level of performance. Rather than artificially force the measure data results into five Star levels where there may not be a meaningful difference, accept and assign high Star levels for any plan meeting population health level performance as indicated by clinical or public health guidelines. For example, it may be counterproductive and not clinically meaningful to assign one plan as “3 Star” level when they have reached 85% achievement and another plan a “4 Star” at 90% achievement, where 80% achievement for a complex Medicare population is considered laudable performance by clinicians or population health guidelines. This is an artificial difference which may impede quality improvement efforts or unfairly label health plans as “average” when they are actually performing very well. CMS could review measures that are topped out and consider setting a stable threshold for Star level performance. If all

plans reach a 4 Star level, then they all receive that score for this measure. We also strongly recommend that population differences, e.g., beneficiary characteristics within the enrollment be taken into account. Plans with a high proportion of LIS/DE/Disabled and persons with care complexity, SDOH risk issues should be grouped with other like plans to examine measure results.

The SNP Alliance is concerned that the current practice of assigning cut point thresholds to topped out measures especially disadvantages health plans with a high proportion of beneficiaries who have these complex medical, behavioral health, and social support need characteristics. In fact, sometimes achieving a higher score on a specific clinical indicator is contraindicated. For example, a person with advanced cognitive decline/impairment such as late stage Alzheimer's disease or severe physical frailty would not be considered a good candidate for a colonoscopy or mammogram as the person might be more harmed by the technique than advantaged by whatever the screening might reveal. Therefore, applying these screening measures to these individuals encourages harm rather than benefit and is not an indicator of "good" quality performance.

We have offered five key options for consideration to be modeled. These steps could produce greater accuracy and utility of the MA Star measurement system. All pertain to addressing underlying reasons for variability in measurement data that may be independent of plan action or quality of care provided.

Many of these suggestions/action steps could be modeled with existing data in 2019 or 2020 and the results provided to the field to promote transparency, accountability, fairness, and knowledge sharing toward improvement in the quality measurement system itself. These kinds of simulations with reported results would certainly help address concerns from consumers, providers, and plans that the system is biased, unfair, or unequal, and dispel notions that modifications offered only have marginal impact.

We urge CMS to consider these or other options and provide a timeline for when additional substantive methodological improvements to the cut point approach could be expected.

While we await such results, the proposed mean resampling and guardrails/caps applied as interim steps to enhance predictability and lessen the effects of outliers is, again, appreciated.

P.55021 to 55024. Measure Updates –Table 1A *Proposed Updates to Individual Star Rating Measures on/after Jan 2020.*

This section pertains to measure updates with existing Star measures where there are changes by the measure developer (e.g., NCQA) to the measure specifications which are substantive, meaning that they are moved to the Display Page for two years before being moved back to Star measure reporting. CMS will share comments received with the measure developer. The measures being temporarily moved to the Display Page for two years include: Controlling for High Blood Pressure, MPF Price Accuracy, Plan All-Cause Readmission, and Improvement Measures.

SNP Alliance Comments:

As an overall comment, we appreciate the process of moving to the Display Page measures which are undergoing substantive change. As part of this process, we encourage additional attention by the measure developer during this two-year period to the measure specifications, particularly examining exceptions and exclusions for complex populations where frailty, medical complexity or other clinical indicators may modify the target or strongly support exclusions. We also mention ongoing issues noted by health plans facing significant hurdles in accessing necessary information from providers, particularly where there is not electronic connectivity.

Part C – Controlling for High Blood Pressure Measure – HEDIS measure under NCQA.

Brief description: % of plan members 18-85 who had a diagnosis of HTN and whose BP was adequately controlled < 140/90. Measure moved to Display page for now, will have a weight of “1” in the first year and will have a weight of “3” thereafter.

SNP Alliance Comments:

The SNP Alliance and its special needs health plans appreciate the importance of controlling high blood pressure. SNPA supports adherence to standards of care. Special needs health plans wish to remain in compliance with hypertension treatment guidelines of the ACC and AHA where such recommendations are not contraindicated for specific high need, complex patients with special circumstances.

That said, plans with high proportion of persons with hypertension, who also have multiple chronic conditions, may show poorer performance on this measure, particularly if the achievement of the new guideline threshold negatively impacts the members’ ability to achieve other clinical, medical, functional, and health goals. The interplay between conditions, treatments, pharmaceutical management, and the members’ goals would need to be considered in total by the person’s principle physician(s) and the individual, and decisions made accordingly.

We note the American Geriatrics Society, a professional membership organization of physicians trained and certified in geriatrics as their specialty, have already identified risks which may outweigh benefits for some patients in use of some blood pressure control medications to achieve general targets. They have described persons age 65+ with hypertension who have a high burden of comorbidity, limited life expectancy, and patient preference for reduced medication to be persons who, in consultation with the clinical judgment of their physician and through deploying a team-based approach, should be considered for greater examination of the risk-benefit tradeoffs of treatment to reach general targets. See: <http://annals.org/aim/fullarticle/2670318/prevention-detection-evaluation-management-high-blood-pressure-adults-synopsis-2017>.

A consensus guideline on blood pressure targets for frail older adults also comes from physicians in Canada who discuss implications of high vs. lower blood pressure targets in this population. See: <https://www.mdedge.com/ccjm/article/96096/cardiology/promoting-higher-blood-pressure-targets-frail-older-adults-consensus>.

Alternate systolic targets that would be acceptable for patients who have reached age 80 were noted by a scientific committee of members with new recommendations developed in collaboration with the American Academy of Neurology, the American Geriatrics Society, the American Society of Hypertension, the American Society of Nephrology, the American Society for Preventive Cardiology, the Association of Black Cardiologists, and the European Society of Hypertension. See:

<https://www.medpagetoday.com/cardiology/hypertension/26110>

Given these findings and expert panel deliberations, we request that NCQA conduct further review and analysis in the two years while this measure is on the Display Page to adjust measure specifications to consider additional exceptions and exclusions. We ask that NCQA consult with clinical experts working with chronic care populations to determine if there are defined cases where achievement of the guideline is contraindicated or likely to be detrimental. We ask that NCQA report their findings to the field and provide thorough analysis in the measure justification and information forms, together with the measure specification, particularly on measure exclusions and exceptions.

In addition, the SNP Alliance appreciates the decision by NCQA to remove the medical record confirmation for HTN to allow for remote monitoring and telehealth management.

***Part D – MPF Price Accuracy Measure** – Score comparing prices members pay for drugs to the drug prices the plan provided for MPF website.*

SNP Alliance Comments:

The SNP Alliance supports this as it has the potential to improve transparency and accountability for consumers. However, we request CMS consider the frequency with which the MPF is updated. There is already a discrepancy in comparing real time drug price updates with what is reported in the MPF.

***PCR Measure – HEDIS** - % of acute inpatient stays followed by unplanned acute readmissions or observation stay for any diagnosis within 30 days for members 18+*

Measure has a weight of “3” and the clustering method is used to assign Star rating

SNP Alliance Comments:

We understand that the intent of adding observations stays to this measure is to curtail provider action that may be using observation beds to avoid hospital readmission thresholds, which are punitive. We agree that this use of observation stays is not consistent with high quality care. However, appropriate use of the observation bed can be very helpful and promote better care, e.g. for frail older adults or others who need to be observed for a longer duration prior to being sent home from an ER visit. People living in rural areas may especially benefit from the use of observation stays. If this measure change has the effect of reducing access to observations stays for these individuals, this could be harmful. We urge attention to this and request NCQA seriously consider exceptions and exclusions. We urge that there be the ability of clinical input or defined cases where observation stays should NOT be included in the PCR measure. NCQA is urged to seek additional expert opinion on

this issue and conduct a thorough analysis in the two years when this is on the Display Page. We further request that NCQA specific sub-groups of Medicare members, to see if there is disproportionate impact on some beneficiaries with certain characteristics or conditions. SNPA member plan insight would be helpful here and we welcome the opportunity to be involved.

Improvement measures - Improvement measures must have a numeric score for each of the two years examined. CMS is proposing to add an additional rule that would exclude any measure that receives a reduction for data integrity concerns in either of the two years examined—that is, the measure would not be eligible to be included in the Improvement measure for that contract.

SNP Alliance Comments:

The SNP Alliance supports this proposed change.

5. Medicare Advantage Risk Adjustment Data Validation (RADV) Provisions (§§ 422.300, 422.310(e), and 422.311(a))

CMS proposes to use extrapolation in RADV contract-level audits and that the extrapolation authority would apply to the payment year 2011 contract-level audits and all subsequent audits. And CMS proposes to not apply a fee-for-service (FFS) Adjuster to audit findings.

SNP Alliance Comments

The SNP Alliance is very concerned about this proposal and its potential harm to Special Needs Plans that, by definition, serve large numbers of high- risk members and often have smaller enrollments. We do not agree with CMS's proposed changes to the methodology. We believe this change could result in significant liability under RADV, which may impact the ability of plans to offer benefits that patients need, particularly the vulnerable beneficiaries of SNPs. Moreover, we think the proposal is inconsistent with the Medicare statute and past CMS positions on RADV. Finally, it is flawed and fundamentally unfair to MA plans.

In 2012, CMS indicated that a FFS Adjuster was necessary to extrapolate RADV audit findings. CMS said they would calculate the FFS Adjuster through a RADV-like review of FFS data. Since the original methodology was released in 2012, the only development was that the District Court in DC agreed that the Medicare statute requires the consideration of errors in FFS data before determining whether an MA plan has been overpaid. In the proposed rule, CMS abandons its prior methodology and contravenes the rationale of the DDC decision to determine that no FFS Adjuster is needed. Additionally, the proposal is mathematically flawed for several reasons. First, after finding HCC-specific claim level error rates that ranged from 21 to 46 percent, CMS made a series of theoretically flawed and factually false assumptions to reduce the average beneficiary error rate to 3 percent. Next after removing a percentage of codes from a claims set, it recalculated coefficients, but then normalized those coefficients using unaudited data, which has the effect of cancelling the impact of the errors on coefficients regardless of how many CMS assumed to be in the FFS data.

Implementation of a contract level extrapolation of payment error while not incorporating a FFS Adjuster to the calculation of payment recovery amounts resulting from RADV could greatly increase the stakes for plans selected for audit. The proposed RADV methodology seems to be extrapolating an error rate and systematically reducing all risk scores by that percentage. At the very least, the error rate should be reduced such that the average demographic component is not being adjusted downwards.

We understand that CMS proposes to choose samples for RADV audits based on clinical and enrollment data. We believe that sampling needs to be random in order to extrapolate results to the population and extrapolation needs to be applied consistently to the total population consistently with how the sample was derived. If the sample disproportionately reflects high cost conditions, an extrapolated error rate will exaggerate the effect of any true overstatement. If enrollees are stratified by risk score, then the extrapolation also needs to be applied separately to each risk score strata as well. Each strata must have an appropriate number of enrollees included in order to provide a statistically meaningful extrapolation. If certain populations are excluded from the sampling (e.g., ESRD enrollees), then these populations should not be included in the extrapolation. Unless the RADV audit is calculating the percentage change to the enrollee's full risk score (i.e., both demographic and HCC portions), extrapolation should not be applied as a percentage reduction to the risk score.

Overall, the SNP Alliance believes that the FFS methodology was much more rigorous and did a better job of recognizing the data being used is actually only a sample of the data (so not all claims/HCC combinations will look like what was provided in the sample). Furthermore, we believe the FFS Adjuster error rate should be calculated using the same methodology as the Medicare Advantage error rate because there is no evidence that providers change their coding behaviors for FFS vs managed care.

SNP Alliance members have also raised serious concerns with the study CMS is relying on to justify eliminating the FFS Adjuster because the study is very old, and coding processes have changed significantly since the study was published (i.e. it was based on ICD-9 codes while current coding used ICD-10. CMS needs to use more current data to support its conclusions. In addition the analysis included only Part B outpatient claims billed from an acceptable provider (that mapped to 1+ HCC). If no analysis was performed on Part A claims, CMS should not extrapolate the Part B error rate to Part A claims. It is also not clear whether outpatient claims also captured professional claims, CMS should clarify this.

In addition, the SNP Alliance opposes applying this approach retrospectively to 2011 as proposed. While the overall impact of the new CMS RADV proposals is estimated to be less than one half of one percent of total MA annual revenue, the impact on individual contracts selected for RADV would be much more significant, particularly on those with smaller high-risk populations such as SNPs that would be unfairly forced into additional compliance activities to avoid negative audit results.

Finally, beyond all of these methodological flaws, the RADV proposal is insufficient because CMS does not adequately explain its methodology or provide sufficient data to all the public to evaluate it, as required by the Administrative Procedures Act.

The SNP Alliance, again, wishes to express our appreciation for the work done by CMS on these challenging, yet important, issues. We are grateful for the opportunity to provide our comments. We are very happy to provide additional follow-up information or answer questions, if needed.

Respectfully,

A handwritten signature in black ink that reads "Cheryl Phillips, MD". The signature is written in a cursive, flowing style.

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