DEPARTMENT OF HEALTH AND HUMAN SERVICES, Centers for Medicare & Medicaid Services 42 CFR Parts 405, 417, 422, 423, 460, and 498

Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program

Section/Item - Summary	Page #	SNPA Comment (<i>Italics</i>) and other Summary	CMS Response & Final Determination
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Uniformity Requirements Flexibility CMS proposed to provide MA organizations the ability to reduce cost sharing for certain covered benefits, offer specific tailored supplemental benefits, and offer lower deductibles for enrollees that meet specific medical criteria related to health status or disease state, provided that similarly situated enrollees (that is, all enrollees who meet the identified criteria) are treated the same. Implementation proposed for CY 2019.	p. 153-171	snpa supported this provision with caution about the following issues: Need for greater transparency to reduce confusion around benefit communications to members, how comparative information is presented across plans, affirmation of ability of C-SNPs to adjust benefits and cost sharing, allowing D-SNPs to also tailor benefits to duals, clarification of how this provision relates to C-SNPs in VBID demonstrations, encourage use of the VBID demonstration for testing best practices to be applied to other MA plans, clarification of how additional benefit flexibility impacts Highly Integrated DSNPs who have had additional benefit flexibility originating in 422.202 as outlined in the MM Chapter 16b, allow those DSNPs to tailor benefits beyond IADL and ADL needs to subpopulations with behavioral health and to partial vs FBDEs.	CMS is reinterpreting existing statutory language at section 1854(c) and 1852(d) of the Act, and the implementing regulation at § 422.100(d), to allow MA organizations the ability to reduce cost sharing for certain covered benefits, offer specific tailored supplemental benefits, and offer lower deductibles for enrollees that meet specific medical criteria effective for CY 2019 for Part C only. (This does not apply to Part D.) CMS will provide additional operational guidance before CY 2019 bids are due, including information as to how this impacts SNPs. CMS states they do not have the authority to restrict or mandate which diagnoses or health conditions a plan chooses for this flexibility so plans may determine which diagnoses or health conditions they choose to offer these flexibilities. CMS encourages plans to consider the population of their plan when making these decisions. The Bipartisan Budget Act of 2018 expands supplemental benefits available to chronically ill enrollees effective CY 2020 to include benefits that "have a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollee and may not be limited to being primarily health related benefits." These additional supplemental benefits will be qualitatively different than the supplemental health care benefits that MA plans may currently offer and may continue to offer to enrollees who are not chronically ill. Because the new benefits will not be limited to the primarily health related standard, it is possible for certain offerings to address issues beyond a specific medical condition, such as social supports. However, the basis for offering the new benefits will be based solely on an enrollees' qualification as "chronically ill" and may not be based on conditions unrelated

to medical conditions, such as living situation and income. In addition, this provision provides authority for the waiver of uniformity requirements "only with respect to supplemental benefits provided to a chronically ill enrollee."

Beginning in 2020, MA plans may offer three forms of supplemental benefits: "standard" supplemental benefits offered to all enrollees; "targeted" supplemental benefits offered to qualifying enrollees by health status or disease state; and "chronic" supplemental benefits offered to the chronically ill. The first two (standard and targeted) will be allowable in 2019. Only "chronic" supplemental benefits will be evaluated under the new expansive definition in the Bipartisan Budget Act and be eligible for a waiver of the uniformity requirements. Standard and targeted supplemental benefits will be evaluated under the existing interpretation of whether the benefit is "primarily health related."

It is possible that an enrollee qualifies for a "targeted" supplemental benefits as well as "chronic" supplemental benefits. In that circumstance, the MA plan must provide the targeted supplemental benefits as long as the enrollee establishes the required health status or disease state and the benefits are medically appropriate. However, the MA plan must only provide "chronic" supplemental benefits if the benefit has a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollee.

Based on these differences, it will be important for MA plans to identify in their bids and in their Evidence of Coverage documents which supplemental benefits are offered as "standard", "targeted", or "chronic" benefits.

In the 2019 ANCL, CMS is also reinterpreting "supplemental health care benefits" to allow such benefits to include benefits related to daily maintenance. In order for a service or item to be "primarily health related" under the three-part test for supplemental health care benefits, it must diagnose, prevent, or treat an illness or injury, compensate for physical impairments.

			act to ameliorate the functional/psychological impact of injuries or health conditions, or reduce avoidable emergency and healthcare utilization. CMS cites the example of "fall prevention devices"- and similar items and services that diminish the impact of injuries/health conditions and reduce avoidable utilization and could be provided as a supplemental benefit for a defined period of time and in certain situations, even if a significant purpose of the item or service is daily maintenance. Supplemental benefits under this broader interpretation must be medically appropriate and recommended by a licensed provider as part of a care plan if not directly provided by one. In the ANCL CMS also states that forthcoming detailed guidance will further differentiate newly allowable supplemental benefits under this reinterpretation and those new supplemental benefits that will be allowed for the chronically ill beginning CY 2020.
Benefit Flexibility for Service Area Segments CMS proposed to allow MA plans to vary supplemental benefits, in addition to premium and cost sharing, by segment, as long as the benefits, premium, and cost sharing are uniform within each segment of an MA plan's service area.	p. 171-174	SNPA supported this change.	CMS adopted this proposed reinterpretation of section 1854(h) of the Act and §§ 422.100(d)(2) and 422.262 to allow MA organizations the ability to vary <i>supplemental benefits</i> , in addition to premium and cost sharing, by segment, as long as the benefits, premium, and cost sharing are uniform within each segment of an MA plan's service area effective for CY 2019 consistent with the MA regulatory requirements defining segments at §422.262(c)(2). However, any Part D benefits must continue to be offered consistently throughout the service area.
Meaningful Differences in Medicare Advantage Bid Submissions and Bid Review (§§ 422.254 and 422.256) CMS proposed to eliminate the requirement for the evaluation of meaningful differences between	P.192-209 Summary: Page 208	SNPA supported this change for Part C, but did not submit comments on the Part D proposal.	CMS received over 65 comments on this item, reflecting mixed support with many concerns about increasing beneficiary confusion. Some commenters raised the issue of potential impacts on states and D-SNPs. However, CMS finalized the elimination of the meaningful difference requirement from §§ 422.254 and 422.256 as proposed based on the value of

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products based on premium levels			increased competition, innovation and access to affordable
and CMS review. Meaningful			plans that are tailored to beneficiaries' unique health care needs
difference is currently not			and financial situations. Under their existing authority at §
applicable to D-SNPs, but			422.2268, CMS will monitor to ensure organizations are not
currently may apply to I-SNPs			engaging in activities that are discriminatory or potentially
and C-SNPs. This provision related			misleading or confusing to Medicare beneficiaries. CMS will
to Part C, however, CMS proposed a			communicate and work with organizations that appear to offer
similar provision for Part D.			a large number of similar plans in the same county, raising and
			discussing with such MA organizations any concerns. CMS
			plan checks would include plans offered under each contract,
			unique plan type, and county. Plan types currently include: (1)
			HMO and HMO-POS not offering all Parts A and B services
			out-of-network, (2) HMO POS offering all Parts A and B
			services out-of-network, (3) LPPO, (4) RPPO, (5) PFFS, and
			(6) unique SNP types (that is, different chronic diseases,
			institutional categories, and dual-eligible sub-types). From a
			beneficiary's perspective, CMS would expect plans within the
			same contract, plan type, and county to be distinguishable by
			beneficiaries using such factors as the inclusion or exclusion of
			Part D coverage, provider network, plan premium, Part B
			premium buy-down, estimated out-of-pocket costs, and benefit
			design so that MA organizations can market their plans clearly.
			CMS intends to issue guidance through the annual Call Letter
			process and HPMS memoranda to help organizations design
			plan options that avoid potential beneficiary confusion prior to
			bid submission. CMS said that MMCO may be available to
			work with states and D-SNPs related to this provision. CMS
			also adopted a similar proposal for Part D services.
Coordination of Enrollment and	p.209-233	In general SNPA supported these changes	CMS finalized the proposed changes to §§ 422.66© and 422.68(d)(1)
Disenrollment Through MA	1	with these added suggestions:	and (5) for seamless default enrollment of newly eligible dually
Organizations and Effective Dates		• Extend to other SNPs serving duals	eligible beneficiaries into D-SNPs offered by the same parent
of Coverage and Change of		such as those focused on HIV and	organization as their existing Medicaid plan as well as a new
Coverage (§§ 422.66 and 422.68)		AIDs,	simplified "opt-in" process for all MA plans with commercial,
CMS proposed codifying		Provide states and plans with additional	Medicaid, or other non-Medicare products with the following
requirements for seamless default		guidance to clarify timelines and roles	modifications:
enrollments upon conversion to		•	• Paragraph 422.66©(2)(i) will be revised to clarify that CMS will
Medicare for dual eligible special		and reduce complexity of the current	allow default enrollment into a FIDE-SNP administered by an MA
needs plans (D-SNPs) offered by the		process	organization under the same parent organization as the organization
same parent organization as their			that operates the Medicaid managed care plan in which the individual
existing Medicaid plan, subject to			remains enrolled.

five substantive conditions including approval from the state and CMS. CMS requested comment whether authority to rescind approval should be broader and whether a time limit on the approval (such as 2 to 5 years) would be appropriate so that CMS would have to revisit the processes and procedures used by an MA organization in order to assure that the requirements are still being followed.

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

CMS also requested comment on these proposals:

- Permit default MA enrollments for dually-eligible beneficiaries who are newly eligible for Medicare under certain conditions and
- Permit simplified elections for seamless continuations of coverage for other newly-eligible beneficiaries who are in non-Medicare health coverage offered by the same parent organization that offers the MA plan.
- The form and manner in which these enrollments may occur, and whether the CMS authority to rescind approval of an

- Provide model/boilerplate standards to ensure consistency and understanding among plans and states
- Pay attention to issues with the necessary eligibility data sources and MMA files, which may not always be received in time
- Allow for both elderly and disabled populations or either depending on the feasibility of implementation in the state.
- Paragraph 422.66©(2)(i) will be revised to require a minimum star rating on the contract receiving default enrollments for an MA organization to be approved for default enrollment. They will revise the paragraph to require that, for an organization to be approved for default enrollment, it must have an overall quality rating, from the most recently issued ratings, under the rating system described in §§ 422.160 through 422.166, of at least 3 stars or is a low enrollment contract or new MA plan as defined in § 422.252. In addition, the MA organization must not be under an enrollment suspension.
- Paragraph 422.66©(2)(ii) will be revised to include an approval period not to exceed 5 years, subject to CMS authority to rescind or suspend approval if the plan is non-compliant.
- Paragraph 422.66©(2)(iv) will be revised to require that the notice issued by the MA organization include information on the differences in premium, benefits and cost sharing between the individual's current Medicaid managed care plan and the dual eligible MA special needs plan and the process for accessing care under the MA plan; an explanation of the individual's ability to decline the enrollment, up to and including the day prior to the enrollment effective date, and either enroll in Original Medicare or choose another MA plan; and a general description of alternative Medicare health and drug coverage options available to an individual in his or her Initial Coverage Election Period.
- Paragraph 422.66©(2)(iv) will be revised to clarify that the mandatory notice is in addition to the information and documents required to be provided to new enrollees under § 422.111. CMS is not adopting their alternative proposal for default enrollment into other MA organizations, and will clarify that these provisions must include both aged and disabled dual beneficiaries.

organization's request to conduct default enrollment should be broader or limited to a specific time frame. CMS also requested comment on these alternatives: Codify the existing parameters for this type of seamless conversion default enrollment such that all MA organizations would be able to use this default enrollment process for newly eligible and newly enrolled Medicare beneficiaries in the MA organization's non-Medicare coverage. Codify the existing parameters for this type of seamless conversion default enrollment, as described previously, but allow that use of default enrollment be limited to only the aged population.			
Passive Enrollment Flexibilities to Protect Continuity of Integrated Care for Dually Eligible Beneficiaries. (§422.60(g)). Summary of Changes: CMS proposes to add authority to long standing existing passive enrollment provisions to passively enroll full-benefit dually eligible beneficiaries who are currently enrolled in an integrated D-SNP into another	P 233-254 Summary: p 254	 The SNP Alliance supported this provision with several suggested changes. Supported the two notices suggested plus possible telephonic outreach for beneficiaries from whom the notices were returned, as well as for beneficiaries who do not speak English as a primary language. Do not support limiting new authority to those circumstances in which such exercise would not raise total cost to the Medicare and Medicaid programs. 	 CMS finalized adoption of the for expansion of CMS' regulatory authority to initiate passive enrollment for certain dually eligible beneficiaries who are currently enrolled in an integrated D-SNP into another integrated D-SNP with similar network and benefits, at § 422.60(g) with some modifications below: A technical revision to paragraph (g)(1)(iii) to clarify that a plan must meet all the requirements established in paragraph (g)(2) to be eligible to receive passive enrollment. Revising paragraph (g)(2)(iii) to require a minimum Star Rating that applies for a plan to be eligible to receive passive enrollment. For a plan to be eligible to receive passive enrollment, it must have an overall quality rating,

integrated D-SNP under certain circumstances to preserve continuity of integrated care. CMS anticipates that these proposed regulations would permit passive enrollments only when all the following conditions are met:

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

In addition to the proposed minimum quality standards and other requirements for a D-SNP to receive passive enrollments, CMS requests comments on whether to limit this proposed new passive enrollment authority to those circumstances in which such exercise would not raise total cost to the Medicare and Medicaid programs.

All individuals would be provided with a special election period (which, as established in subregulatory guidance, lasts for 2 months), as described in §

- We proposed that CMS expand this provision to allow passive enrollment into a D-SNP or MMP offered by the same parent organization as their existing Medicaid plan, when a state Medicaid agency is passively enrolling members into a mandatory Medicaid LTSS plan, allowing for both an opt out process and a special election period as proposed here, consistent with most Medicaid procedures.
- Recommended that CMS clarify in the preamble how this provision is impacted by the reductions in access to a SEP for dually eligible beneficiaries.
- We request that CMS provide an exception to the proposed SEP restriction in § 423.38 for these passive enrollment purposes even when related to enrollment when related to enrollment in an integrated plan.

- from the most recently issued ratings, under the rating system described in §§ 422.160 through 422.166, of at least 3 stars or is a low enrollment contract or new MA plan as defined in § 422.252.
- Adding new paragraph (g)(4)(ii) to require that plans receiving passive enrollments under paragraph (g)(1)(iii) send two notices to enrollees that describe the costs and benefits of the plan and the process for accessing care under the plan and clearly explain the beneficiary's ability to decline the enrollment or choose another plan.
- Adding new paragraph (ii)(A) to specify that the first notice provided under paragraph (ii) must be provided, in a form and manner determined by CMS, no fewer than 60 days prior to the enrollment effective date.
- Adding a new paragraph (ii)(B) to specify that the second notice must be provided, in a form and manner determined by CMS, no fewer than 30 days prior to the enrollment effective date. New paragraph (g)(4)(i) will retain the original requirement that one notice be provided to passively enrolled individuals under paragraphs (g)(1)(i) and (ii).
- Modifying § 422.60(g)(5) by replacing the current language describing the SEP for passively enrolled individuals at § 422.60(g)(5) with a cross-reference to the new SEP described at § 423.38(c)(10), which provides a 3-month SEP when an enrollee has been auto-enrolled, facilitated enrolled, passively enrolled, or reassigned into a Part D plan as a result of a CMS or state-initiated enrollment action. (The 3 month SEP is more aligned with Medicaid managed care).
- CMS notes they will consult with states, encourage sharing of language information between involved plans, encourage telephonic outreach, will closely monitor this process and that they expect to provide additional sub-regulatory guidance on this topic.

p.279-298

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

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

The SNPA strongly opposed this provision because it would create disincentives for enrollment in integrated plans. For example, most aged duals are already enrolled in a Part D plan prior to becoming dual, and they may be locked into that Part D plan having used all of their SEPs while enrolled in a Medicaid managed care plan, and then be precluded from enrolling in a comprehensive integrated D-SNP offered by the same MA organization.

The SNPA proposed that if CMS must make a change we would support the option of use of the continuous SEP for the purpose of enrollment into a FIDE or highly-integrated D-SNP and for alignment with a Medicaid managed care plan.

We also pointed out that the numerous SEPs and proposed changes to the SEPs were very confusing and that CMS should clarify the interactions between them in the preamble.

We also recommended that any outreach to communicate changes to the SEP must include community-based outreach in multiple languages to ensure that dually eligible While CMS received some comments supporting this change, the majority of commenters opposed it citing issues similar to those expressed by the SNPA. CMS is amending its original proposal so that the Dual SEP can be used once per calendar quarter during the first nine months of the year (that is, one election during each of the following time periods: January-March, April-June, July-September). During the last quarter of the year, a beneficiary can use the AEP to make an election that would be effective on January 1. In addition, the exception outlined at \$423.38(c)(4)(ii) related to CMS and State-initiated elections will not be finalized as proposed. Instead, CMS will be using its authority under \$423.38(c)(8)(ii) to establish a coordinating SEP for those who are enrolled into a plan by CMS or a State at new \$423.38(c)(10).

This new SEP will allow individuals who have been autoenrolled, facilitated enrolled, or reassigned into a plan by CMS, as well as those who have been subject to passive enrollment processes discussed in section II.A.8, an opportunity to change plans. Unlike the proposed SEP, this new SEP will be available even if a beneficiary meets the definition of an at-risk beneficiary or potential at-risk beneficiary. Beneficiaries would be able to use this new CMS/State assignment SEP before that enrollment becomes effective (that is, opt out and enroll in a

a SEP to make an election within two months of the change or being notified by the change: CMS also asked for comment on alternatives including a limit of two or three uses of the SEP per year and limits on midyear MA-PD plan switching. CMS also sought input on the following areas: - Are there other limited circumstances where the dual SEP should be available? - Are there special considerations CMS should keep in mind if we finalize this policy? - Are there other alternative approaches CMS should consider in lieu of narrowing the scope of the SEP? - In addition to CMS outreach materials, what are the best ways to educate the affected population and other stakeholders of the new proposed SEP parameters?		beneficiaries in all communities are aware of this choice.	different plan) or within three months of the assignment effective date, whichever is later. CMS states that plans are responsible for determining the eligibility for a SEP, and that MARx will be updated to reject ineligible requests and that plans must continue to inform the individual of this action and given the infrequent use of this SEP, the burden for additional notices should not be great. CMS clarifies that the SEP for LIS/Dual status change is still available and has revised the SEP at 423.38(c)(9) to three months. SEPs will be considered 'used" based on application dates. CMS also provides a summary chart describing most of the SEP options on page 292. CMS discusses methods of educating members about these SEP changes and will consider suggested education strategies proposed by commenters. (p. 296). CMS clarifies that this SEP limitation applies to MMPs unless waived. CMS intends to provide additional detail in subregulatory guidance, and states they will monitor this provision.
Section 11. Medicare Advantage and Part D Prescription Drug Plan Quality Rating System Summary of Proposed Rule: CMS proposed to codify current Quality Management System (QMS) and Stars. CMS laid out goals for the QMS.	Pages are from FR: 298 & 316 to 319	SNPA supported the goals but stated that the current system has methodological and measurement inequities and pointed out specific changes and 16 recommendations on: 1. HOS instrument changes needed 2. Minimum standards for measure developers needed 3. Modeling the effect of stratification into plan cohort groups 4. Modeling the effect of taking into account community characteristics 5. Improving the CAI 6. Reducing measurement burden on SNPs	CMS is codifying the QMS and existing Star Rating system for MA and Part D programs with some changes to take into account the Bipartisan Budget Act of 2018. The changes CMS refers to include more clearly delineating rules for adding, updating and removing measures, timing of application of some of the provisions, and on the calculation of Star Ratings for contracts that consolidate. In terms of procedure, CMS will continue to use the Call Letter to make non-substantive changes, suggest and solicit feedback on new measures that will be proposed in regulation. Substantive and non-substantive changes are defined, but there is no exhaustive list.

		 Recognizing additional costs of high Dual/LIS/Disabled population Providing for additional measure exceptions and exclusions Allow for PBP to contract conversion Test PBP-level quality measurement and reporting Make adjustments to the cut-point methodology Add to robustness of measure testing prior to new measures and keep 2 years on Display page Address potential inequities in application of the Improvement measures Align a small set of core measures across providers and plans Use caution on patient experience measures and weighting Do not create another survey of physicians for health plans We believe CMS has the statutory authority to consider accommodation and tailoring of quality measures and the quality management system for special needs populations—as evidenced by the legislation enacting this particular form of MAO. 	In light of the passage of section 53112 of the Bipartisan Budget Act of 2018 (Pub. L. 115-123), the consolidation policy described at §§ 422.162(b)(3) and 423.182(b)(3) will be implemented for the 2020 QBP ratings and 2020 Star Ratings. We will finalize additional text at §§ 422.160(c), 422.162(b)(3)(v), 423.180(c) and 423.182(b)(3)(iii) to apply the regulations that govern the calculation of Star Ratings for surviving contracts when the contract consolidation is approved on or after January 1, 2019, consistent with the ACCESS Act provision.
Section/Item - Summary	Page #	SNPA Comments / Focus	CMS Response & Final Determination
Under Section 11 b. Background – Measure on adoption or use of new technology	309	We commented on the proposed HEDIS measure and said we supported telehealth visits and remote technology when appropriate. (See also SNPA comments through ANCL)	CMS is not adopting the measure about use of technology at this time. They deferred to NCQA and new HEDIS measure on use of telehealth
Under Section 11 b. Background — Taking into account community or market characteristics within Stars New measure concepts — including taking functional status into account.	313	We agreed that examination of community characteristics, such as (example) neighborhood deprivation, is warranted and we supported CMS modeling methods to take these characteristics into account for adjustment of Star Ratings scores. SNPA strongly supported examining a functional status adjustment and taking these issues into account under quality measurement.	CMS is considering these issues. With regard to taking into account community characteristics, they do not want to "mask true differences in quality of care across the country."

Under Section 11 b.	315	We did not support the development/application	CMS received a lot of negative response to this idea. They are not
Background –		of a physician survey of health plans and	pursuing this presently but will continue to get feedback and listen to
Physician survey of health plans		provided many sound reasons why.	stakeholders.
Section 11 e. Contract Ratings (by unit of analysis)	324 to 332	SNPA did not oppose staying at the contract level of reporting, but did support more thorough pilot test or examination of plans reporting at the PBP vs. contract level.	CMS will retain contract level ratings vs. PBP level, except for the 4 SNP-specific measures which are rolled up to the contract level using enrollment weighted means.
			The final rule provides a little more detail on CMS' analysis about the effect of reporting at the PBP level. In essence, CMS does not appear to support moving to PBP level reporting, indicating that based on their analysis, they believe too few plans would have enough data to report at this unit of analysis. They propose to continue as is, reporting all PBPs under the H# contract. They do say they will continue to receive feedback and study this more.
			CMS also discussed where some measures, such as call center measures, might be at the parent organization level of reporting, rather than contract level. They note that under the Bipartisan Budget Act of 2018 the Secretary of HHS is required to determine the feasibility of measurement at the plan level. Therefore more study will be done on this.
			CMS Language: We proposed to continue calculating the same overall and/or summary Star Ratings for all PBPs offered under an MA-only, MA-PD, or PDP contract and to codify this policy in regulation text at §§ 422.162(b) and 423.182(b). However, we realized that paragraphs (b)(1) as proposed did not specify that summary ratings also include the reward factor and the Categorical Adjustment Index as described in §§ 422.166(f) and 423.186(f); we are finalizing additional text to clarify that in paragraphs (b)(1). In addition, we are slightly revising the last two sentences of paragraphs (b)(2) of the same regulation sections to clarify that the rule for including plan-level only measures is applicable to the SNP-specific measures that are reported only at the plan level.
			We agree that all of the benefits and disadvantages need to be weighed before a final decision is made about how to proceed and CMS is committed to continuing to obtain feedback from the industry on changes to the level of reporting. CMS continues to evaluate this issue. Additionally, in light of the passage of the Bipartisan Budget Act of 2018, CMS is required to examine the feasibility of plan-level reporting for both SNP and non-SNP plans. Any related changes would be proposed through future rulemaking.

Section 11 e. Contract	333	SNPA did not comment on this.	CMS will continue as proposed with their process on consolidation
Section 11 e. Contract consolidation	333 to 344	SNPA did not comment on this. SNPA did ask for relaxation of the moratorium on splitting into two or more H# contracts a set of PBPs now under one (already consolidated).	CMS will continue as proposed with their process on consolidation contract Star reporting. They will use enrollment-weighted means of the measure scores of the consumed and surviving contracts to calculate ratings for the first and second plan years following the contract consolidations. However, the substantive change is that the policy will be implemented for the 2020 Star Ratings and the 2020 QBPs. This change in timeframe is due to the Bipartisan Budget Act. CMS asserts that the statute does not set a ceiling (maximum) but a floor—with reference to the CMS proposed rule having a more comprehensive approach than what was in statute. Following publication of our proposed rule, Congress enacted the Bipartisan Budget Act of 2018. Section 53112 of the Act amended section 1853(o) to require an adjustment to the Star Ratings, quality bonus under section 1853(o) and rebate allocation under section 1854 based on the quality rating to "prevent the artificial inflation" of Star Ratings after consolidation. That required adjustment applies for consolidations approved on or after January 1, 2019. The statutory change requires the adjustment be applied when a single MA organization consolidates contracts and reflect an enrollment-weighted average of scores or ratings for the underlying contracts. We believe that our proposal is generally consistent with the new statutory requirement, with minor exceptions. The proposal would not have applied until a later period, but, as noted in section II.A.11.c of this final rule, we will finalize these provisions to be applicable beginning with the 2020 QBPs and 2020 Star Ratings produced in fall 2019 to be consistent with the statute. Our proposal was for consolidations involving a single parent organization while the statute focused on consolidations involving a single MA organization; applying the proposed policy to consolidations at the level of the parent organization instead of the specific MA organization captures more consolidations. We read the Bipartisan Budget Act as se
			authority to establish and set the rules governing the Stars Rating system. In addition, our proposal also was more specific as to how enrollment-weighted ratings at the measure and contract level would be used following the consolidation.
Section 11, g. Data Sources – Summary/Background: Section 1852(e)(3)(B) of the Act	344	SNPA (in ANCL) noted the need for adjustment in some measures related to exclusions and exceptions. SNPA requested better collaboration	CMS is finalizing the provisions regarding the data sources for measures and ratings as proposed with two modifications:
prohibits the collection of data on quality, outcomes, and beneficiary		and synergy of measures on similar items between NCQA and PQA.	In § 422.162(c)(1), we are finalizing additional text to clarify that CMS administrative data will be used in the scoring for measures; the
quanty, outcomes, and beneficiary		between NeQA and FQA.	CMS daministrative data will be used in the scoring for medsures; the

satisfaction other than the types of data that were collected by the Secretary as of November 1, 2003; there is a limited exception for SNPs to collect, analyze, and report data that permit the measurement of health outcomes and other indicia of quality. The statute does not require that only the same data be collected, but that CMS cannot change or expand the type of data collected until after submission of a Report to Congress.		SNPA discussed the challenges with proliferation of measures and the accuracy, reliability, completeness, and burden issues with regard to various data sources. SNPA discussed (at length) the challenges with HEDIS measures derived from HOS survey data	new text aligns the Part C regulation with the parallel Part D regulation. In addition, in § 423.182(c)(2), we are finalizing additional text to clarify that the reported data permit measurement of health outcomes and other indices of quality, consistent with the scope of the measures in the Star Ratings program. CMS reasserts (several times) their authority to collect data, and the requirement by plans that the data be timely, accurate, and complete.
Section 11, h. Adding, Updating and Removing Measures – Summary: CMS proposed specific rules for updating and removal that would be implemented through subregulatory action, so that rulemaking would not be necessary for certain updates or removals (Use of Call Letter). CMS also proposed annual review of the quality of the data on which performance, scoring, and rating of measures is based. CMS proposed adoption of new measures when they are aligned with best practices and the needs of end users, as today, for example through NCQA and PQA and with endorsement by NQF. For the 2021 Star Ratings, CMS proposed to have measures that encompass outcome, intermediate outcome, patient/consumer experience, access, process, and improvement measures. CMS provided a timetable and definitions of what would be considered substantive and non- substantive changes.	349	SNPA did not oppose this process as it is consistent with present day actions, but we did raise some concerns about delays/time lag with regard to measure updates. Additional SNPA Comments: We also urged attention to the HOS instrument and methods. We discussed our concerns with the accuracy and reliability of measures derived from HOS. We pointed to the need for minimum guidelines for measure developers around testing for effect of social determinants of health on measure results.	CMS comments on HOS derived measures in the Part C measures tables starting on page 368 (377 for comments) and also in the "Summary of Additional Comments" see page 395. CMS mentions the RAND Technical Expert Panel (Note: SNPA will be on that TEP). With regard to reliability and measure steward accountability, here is their language: CMS agrees that measures need to be fully defined, tested and validated by measure stewards before used as the basis for Medicare payment. Placing new measures on the display page provides transparency about CMS' intention to use the measure in the future as part of Star Ratings and an opportunity for sponsors to see their scores and performance before the measure is used in the Star Ratings. The display measures are not assigned Star Ratings or used in the development of measure, domain, summary, or overall Star Ratings, so there are no payment consequences. Retaining new measures on the display for two years gives CMS additional opportunities to identify any data issues prior to the measures being included in the Star Ratings program. CMS will use endorsed measures as they are available. For some areas which CMS judges to be important for the Star Ratings program, endorsed measures may not be available. CMS emphasizes that if reliability issues with a display measure are identified, the regulations proposed and finalized in this rule at §§ 422.164(c)(4) and 423.184(c)(4) prevent the measure from moving to a Star Ratings measure.

Measure removal ("topped out") measures	366	SNPA discussed this issue briefly with regard to cut-points. We discussed the issue of some measures are particularly difficult for plans with high need, complex, chronic care populations who also have high SDOH where care complexity issues may affect ability to reach the member and that differences in underlying populations (e.g., as compared to general MA population) sets an uneven playing field affecting comparisons. We did not call for the removal of topped out measures, but rather attending to plan cohort groups where like plans are compared, based on beneficiary characteristics.	CMS is maintaining its process for review of "topped out" measures and has discretion on when to remove these. Here is their language: Measure scores are determined to be 'topped out' when they show high performance and little variability across contracts, making the measure statistically unreliable. However, although some measures may show uniform high performance across contracts and little variation between them, CMS needs to balance these concerns with how critical the measures are to improving care, the importance of not creating incentives for a decline in performance after the measures transition out of the Star Ratings, and the availability of alternative related measures which address the specific clinical concerns.
Star Measures Tables – Part C & Part D	368 To 376 Also 396 to	In the PR and/or the ANCL, SNPA commented on measures or measurement issues with: Diabetes measures – We call for greater consistency between NCQA and PQA on med-related measure specifications Improvement measures – We assert that methods/processes used by CMS may disadvantage smaller plans Members Choosing to Leave the Plan – We support removal Beneficiary Access and Performance Problems – We support removal Reducing Risk of Falling (temporary removal) – We reiterated concern about HOS; support CMS temporary removal HOS-derived measures – We discuss the challenges with HOS at length SNP specific measures – We discuss the measure burden equity issue for SNPs and also concerns about overlap with upcoming proposed measures	CMS addresses each measure. Some had no comments. The following measures had some changes: Plan All-Cause Readmissions - In that NCQA is planning to make significant changes to the Plan All-Cause Readmissions measure (changes to be published in 2018 and applied in measurement year 2019) CMS is not finalizing this as part of the measure set for the 2019 performance period and the 2021 Ratings. CMS is finalizing this as a display measure and consistent with \$422.164(d)(2) will include this measure on the display page for two years. They mention the following possible (future) changes based on feedback received: Breast Cancer Screening – addt'l exclusions – referred to NCQA the measure steward. Osteoporosis Management in Women - – addt'l exclusions – referred to NCQA the measure steward. Controlling High Blood Pressure – referred to NCQA the measure steward.
HOS derived measures – Improving or Maintaining Physical Health and Improving or Maintaining Mental Health	377 (in table) and 378 See comments	HOS is a key issue for SNPs. SNPA provided extensive comments. Among them, that the survey needs translation in more languages, that the methods of administration may leave out persons with high social risk factors, that the 2-year longitudinal look back design is especially	CMS defended the HOS instrument and reliability, accuracy, and utility. In the Part C measure table and again in the "Additional Comments," the agency provided the following description of the measure, emphasizing the adjustments they make in the calculation which they seem to suggest should be sufficient in addressing beneficiary

on 396 to 399	difficult with high need/high complexity populations, that the sampling under-represents diverse and complex populations. We also provided comment on use of proxies	characteristic issues and addressing the high need/complex degenerative illness population: CMS Response: HOS yields two patient-reported outcome measures of change in global functioning, by using 2-year change in scores on the Physical Component Score (PCS) and the Mental Component Score (MCS), both of which come from the Veterans RAND 12-Item Health Survey (VR-12) portion of the larger survey. HOS assesses health outcomes for randomly selected beneficiaries from each health plan over a two-year period by using baseline measurement and a two-year follow up. In general, functional health status is expected to decline over time in older age groups, mental health status is not, and the presence of chronic conditions is associated with declines in both3s. Longitudinal HOS outcomes (including death) are adjusted for baseline age and other well studied risk factors, including chronic conditions, baseline health status, and socio-demographic characteristics that include gender, race, ethnicity, income, education, marital status, Medicaid status, SSI eligibility, and homeowner status. Because each beneficiary's follow up score is compared to their baseline score and adjusted for these risk factors, each beneficiary serves as his/her own control. CMS recognizes that Physical Component Summary (PCS) and Mental Component Summary (MCS) may decline over time and that health maintenance, rather than improvement, is a more realistic clinical goal for many older adults. Therefore, MA Organizations are asked to improve or maintain the physical and mental health of their members. Change scores are constructed and the results compare actual to expected changes in physical and mental health of their members. Change scores are derived. This may be an opportunity for us. See CMS Response below.] CMS is supportive of increasing sample sizes and is not opposed to oversampling to ensure a representative sample but to date has received no HOS oversampling requests from any plans. We are currently reexamining the HOS with a focus on d
		oversampling to ensure a representative sample but to date has

			status, Medicaid status, SSI eligibility, homeowner status, chronic conditions, and baseline health status. CMS does not plan to discontinue the HOS proxy response option. Because the HOS has both mail and telephone components, it is likely that some mail questionnaires would be completed by proxies whether permitted or not. CMS is working on a Korean and Russian language translation of HOS in addition to English, Spanish, and Chinese. Health plans with significant other-language speakers are urged to request additional translations from their vendors. CMS says they respond to vendor requests. CMS restates existing policy that plans are not able or allowed to provide translation of the HOS for members.
SNP Specific Measures: Care Management Measure Care for Older Adults – Medication Review Care for Older Adults – Functional Status Assessment Care for Older Adults – Pain Assessment	379	SNPA discussed the four extra SNP-specific measures and the possible overlap with proposed (new) measures under development by NCQA as well as increased measurement burden on SNPs.	For the Care Management measure, timely completion of an HRA is required for all SNP members— CMS re-asserts the importance of this for SNPs and SNP populations. CMS notes that health plans may report when members are unreachable after documented attempts and when members refuse to complete the HRA, but those data are not used in calculating this measure. CMS states that there are no planned changes to this measure and also that stratification by SNP type is not planned. CMS reminds plans that "once data validation findings are submitted to HPMS, sponsors may formally submit their disagreement to CMS if necessary." Therefore, there was no movement on this issue.
Patients with Advanced Illness	399	SNPA (like others) suggested additional exclusions and exceptions to specific measures for persons with advanced illness.	CMS defers to NCQA which it notes is working on cross-cutting exclusions for persons with advanced illness. However, CMS currently has no plans for excluding persons with advanced illness from HOS (or the improving or maintaining physical/mental health measures).
Section 11. j. Improvement Measures	403	SNPA supports the concept of improvement measures; however we suggested some attention to plans with small enrollment where there may not be sufficient data to complete enough measures so that the plan can be included in improvement measures. We stated that there exists a potential disadvantage for SNPs and Medicare/Medicaid plans due to their propensity of having lower enrollments which ultimately results in fewer of	CMS has not heard that small plans are being excluded from improvement measures due to lack of data/small sample sizes. It does acknowledge that: "there did exist minor deviations in the protocol for sampling in the Star Ratings in the past, CMS is confident that the ratings were not affected and the measures possessed all attributes necessary to preserve and maintain the high standards of the Star Ratings program." [NOTE: SNPA will need more small plans to provide evidence if this is the case.] CMS proposes to continue the current methodology around improvement measures. The agency makes note of two modifications:

		these types of plans from meeting the requirements for the calculation of an improvement measure rating (must have enough data for scores for at least half of the improvement measures). The issue is attenuated by the sampling requirements for a subset of the population, like the HOS measures.	(1) additional cross referencing, and (2) clarification on the algorithms methods for Part D. The improvement methodology is detailed in the annual Technical Notes available at http://go.cms.gov/partcanddstarratings . Upon request, CMS will provide a detailed calculation worksheet for a contract's improvement measures. Contracts should contact the Part C & D Star Ratings Team at PartCandDStarRatings@cms.hhs.gov for answers to any questions related to the MA Star Ratings.
1. Measure-Level Star Ratings ("cut-points") Background: To separate a distribution of scores into distinct groups or star categories, a set of values must be identified to separate one group from another group. The set of values that break the distribution of the scores into non-overlapping groups is a set of cut points. CMS proposed to use a clustering method for all Star Ratings measures, except for the CAHPS measures. They proposed using another method using percentile standing relative to the distribution of scores for other contracts, measurement reliability standards, and statistical significance testing to determine star assignments for the CAHPS measures.	439	SNPA provided comment on the cut-point methodology, suggesting refinements and options that could be explored, including methods that would eliminate standard deviation outliers and also set stable parameters. We also discussed the "moving target" issue and the challenges with that as plans improve, but the cutpoints also increase. We discussed the issue of some measures are particularly difficult for plans with high need, complex, chronic care populations who also have high SDOH where care complexity issues may affect ability to reach the member and that differences in underlying populations (e.g., as compared to general MA population) sets an uneven playing field affecting comparisons. We suggested testing a method for cut-points that would differentiate by plan beneficiary characteristics—effectively creating like beneficiary cohorts to compare plans that have similar enrollment characteristics.	CMS received a large number of comments that suggested changes to the cut-point methodology—though they indicate there was widespread support overall. Given the diversity of suggestions, they are finalizing the rule as proposed while they study other options/refinements. Specifically they are finalizing the clustering algorithm for the determination of cut points (for non-CAHPS measures) as proposed while they continue to simulate alternative options. CMS is examining a number of potential options for determining cut points that would capture the greatest number of desirable attributes that our stakeholder have identified (pre-determined, stable, predictable cut points with minimal (if any) influence by outliers, restricted movement across years) while maintaining the integrity of the Star Ratings in order to propose a new or enhanced policy for establishing measure-level ratings in the near future. We believe that the number and scope of alternatives require additional consideration and testing before we can finalize a different methodology for setting cut points for non-CAHPS measures. CMS will use the feedback to guide and examine options for an enhanced methodology for converting the measure scores to measure-level Star Ratings, which would be proposed in a future regulation. CMS does not believe setting beneficiary cohorts for comparing like plans is compliant with the underlying principles for the QMS/Stars rating system. CMS believes that the CAI addresses these beneficiary characteristic differences/effects.
q. Measure Weights – Background – Differential weights were applied to measures starting in 2012.	464	SNPA expressed concern about the HOS-derived HEDIS measures weighted as 3, given the methodological issues raised (improving or maintaining physical or mental health).	CMS does not agree with revising down the HEDIS patient outcome measures. They believe the instrument is valid, the data appropriately reflects outcomes which can be affected by a health plan, and that stakeholders have ample input into the measure.

		SNPA did not support weighting patient	CMS is moving the weight from 1.5 to 2 for the patient experience
		experience measures as a 3.	measures. Thus, this is a small concession to the extensive comments
			on this proposed change (most commenters did not support moving to a weight of 3).
r. Application of Improvement	475	We did discuss the importance of improvement	CMS has a hold harmless provision for high performing plans in
Measure scores	То	measure incentives and equity.	terms of including or excluding the improvement measures.
	479		After deliberation of comments, CMS has decided to modify the
			proposed methodology for the application of the improvement
			measures. The methodology will be changed such that if the highest
			rating for a contract is less than 4 stars without the use of the
			improvement measure(s) and with all applicable adjustments (CAI
			and the reward factor), the rating will be calculated with the
			improvement measure(s). The modification of the application of the
			improvement measure(s) preserves the safeguard for a highly-rated
			contract's highest rating, but removes what could be perceived as a
			safeguard for contracts with a highest rating of 2 stars or less.
s. Reward Factor	480	SNPA did not comment specifically on this – we	CMS notes that the CAI final adjustment categories per contract are
		focused on CAI.	available in the annual public use files available using the following
			link: http://go.cms.gov/partcanddstarratings. While the thresholds for
			the reward factor are published each year in the Technical Notes, the
			recipients of the reward factor are not part of the public use files.
			However, we are persuaded that this is important information for
			beneficiaries and could assist in providing greater transparency into
			the development and assignment of the Star Ratings. Therefore, CMS
			will begin incorporating information related to the distribution and
			characteristics of contracts receiving the reward factor in the annual
			Fact Sheet for the 2021 Star Ratings.
t. Categorical Adjustment Index	Final Call	SNPA thanked CMS for attending to	CMS will continue use of CAI as is while awaiting response (final
	Letter p.	SES/SDOH, but urged for more work on the	study) from ASPE as required by the IMPACT Act (Fall, 2019).
	134	CAI or an alternate methodology, as this (as is)	
		has limited impact in terms of adjusting for	The measures selected for adjustment for the 2019 Star Ratings
	FR	social determinant of health risk factors that	include seven Part C measures and two Part D measures 17. For MA
	Pages:	affect outcomes independent of plan or provider	(MA-only, MA-PD) and 1876 contracts, the Part C measures selected
	486	action.	for adjustment for the 2019 Star Ratings include:
	to	XX 1 11 10 11 1 1 1 1 1 1 1 1 1 1 1 1 1	Annual Flu Vaccine,
	516	We also called for additional descriptive	Breast Cancer Screening, Dislates Care Bland Sugar Cantrolled
		statistics and transparency in CMS reporting.	Diabetes Care – Blood Sugar Controlled, Mulicutian Properties: Properties: Diabetes Care – Blood Sugar Controlled,
		We used CMC to get at least as in immediate	Medication Reconciliation Post- Discharge, Ostoproresis Management in Women who had a Freeture
		We urged CMS to set at least minimum	Osteoporosis Management in Women who had a Fracture, Padvaing the Pick of Falling and
		guidelines for measure developers and stewards	 Reducing the Risk of Falling, and Plan All-Cause Readmissions
		to comply with/use to test or re-test their	
		measure for effects arising from SES or SDOH.	For MA-PDs and PDPs, the two Part D measures selected for
			adjustment for the 2019 Star Ratings include: Part D Medication

We also urged CMS to consider stratification by Adherence for Hypertension and MTM Program Completion Rate for cohort groups. CMR. CMS makes a distinction between purpose for CAI which is to adjust for quality differences arising from LIS/Dual/Disabled characteristics for specific measures that affect outcomes independent of plan behavior, and payment which is to be addressed through HCC risk adjustment. They also mention the role and accountability of NCQA and PQA as measure stewards to test for adjustment needed. They note that: measure scores cannot be adjusted for differences in enrollee case mix unless the specifications for the measure are adjusted by the measure steward. Measure re-specification is a multiyear process. CMS will finalize modified selection rules for identifying the adjusted measures: we will not finalize the second set of rules for determining the adjusted measure set that we proposed at paragraphs (f)(2)(iii)(A)through (C) that provided for identifying measures for adjustment based on an analysis of the dispersion of the LIS/DE within contract differences. [SNPA NOTE: In the Final Call Letter the LIS/DE and Disability quintiles are provided. See Initial and Final Tables for detailed breakdowns by category adjustment pp. 134 – 145] The Call Letter reads: *Under the rule we are finalizing, the 2021 CAI values will be* determined using all measures in the candidate measure set for adjustment identified . . . A measure will be adjusted if it remains after applying the following four bases for exclusions as follows: the measure is already case-mix adjusted for SES (for example, CAHPS and HOS outcome measures); the focus of the measurement is not a beneficiary-level issue but rather a plan or provider-level issue (for example, appeals, call center, Part D price accuracy measures); the measure is scheduled to be retired or revised during the Star Rating year in which the CAI is being applied; or the measure is applicable to only Special Needs Plans (SNPs) (for example, SNP Care Management, Care for Older Adults measures). With this modification to the CAI calculations, the ratings will continue to be data driven in order to be a true reflection of plan quality and enrollee experience, and continue to treat all contracts fairly and equally. While the CAI would be employed, we proposed to release on CMS.gov an updated analysis of the subset of the Star Ratings measures identified for adjustment using this rule as ultimately

			finalized. Basic descriptive statistics posted would include the minimum, median, and maximum values for the within-contract variation for the LIS/DE differences. We also proposed that the set of measures for adjustment for the determination of the CAI would be announced in the draft Call Letter in paragraph (f)(2)(iii). CMS further states: We look forward to continuing to work with stakeholders as we consider the issue of accounting for LIS/DE, disability and other social risk factors and reducing health disparities in CMS programs. We are continuing to consider options on to how to measure and account for social risk factors in our Star Ratings program. Although a sponsoring organization's administrative costs may increase as a result of enrolling significant numbers of beneficiaries with LIS/DE status or disabilities, our research thus far has demonstrated that the impacts of SES on the quality ratings are quite modest, affect only a small subset of measures, and do not always negatively impact the measures. CMS notes that NCQA is considering stratification for a set of their measures and defers to that organization. They state: Both NCQA and PQA will be modifying the measure specifications for a subset of their measures that are used in the Star Ratings program and will require stratified reporting. A summary of the NCQA analysis and recommendations can be accessed at: http://www.ncqa.org/hedis-quality-measurement/research/hedis-and-the-impact-act. A summary of the modification of the PQA measures can be accessed at: SDS Risk Adjustment PQA PDC CMS Part D Stars. CMS will be reviewing the data submitted as a result of these changes in the measure specifications which impacts the measures' reporting requirements. CMS looks to NCQA and PQA to determine measurement testing methods for SES/SDOH and defers to them.
Medicare Advantage Plan	p. 636-641	The SNPA requested that CMS provide an	Basically, this has been their position since 2016, so no real change. CMS finalized this provision as proposed.
Minimum Enrollment Waiver	p. 050 041	opportunity for SNPs serving smaller	One manage and provision as proposed.
(§ 422.514(b))		specialized populations to reapply for the	CMS addresses issues around plan level low enrollment in the
CMS proposed to revise the text		waiver or ask for extensions. Even though	2019 Call Letter (Page 191) with the following statement:
in § 422.514(b) to provide that		this provision is applied at the contract	"CMS recognizes there may be certain factors, such as the
· , 1			
the waiver of the minimum		level, we feared that some unique	specific populations served and geographic location of the plan

enrollment requirement (done at the PBP level) may be in effect for the first 3 years of the contract. Further, CMS proposed that they would only review and approve waiver requests during the contract application and removes the requirement for MA organizations to submit an additional minimum enrollment waiver annually for the second and third years of the contract.

freestanding SNPs (such as ISNPs, and SNPs serving HIV-AIDs) may not meet the minimum enrollment due to smaller population subsets they serve, or due to state contracts with limits on service areas, or other factors not directly within a SNP's control.

that led to a plan's low enrollment. SNPs, for example, may legitimately have low enrollments because they focus on a subset of enrollees with certain medical conditions. CMS will consider this information when evaluating whether specific plans should be non-renewed based on insufficient enrollment."

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

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

p.641-651

In general the SNPA supported these changes and recommended that CMS expand on the underlying objectives of these changes by considering how additional changes could assist states utilizing integrated materials and/or wishing to further integrate and streamline such materials through simplification of language describing both Medicare and Medicaid services and issuance of merged documents where state timelines or requirements may differ from these CMS requirements.

We suggested that for FIDE and highly integrated SNPs, CMS should consider allowing development and use of a model Member Handbook in place of the current EOC as tested and found successful under the FAI for MMPs and the Minnesota D-SNP administrative alignment demonstration.

We also suggested that CMS consider further methods for provision of this information to hard to reach beneficiaries including beneficiaries who are homeless or CMS finalized as proposed revisions to § 422.111(a)(3) and § 423.128(a)(3) to require delivery by the beginning of the Annual Coordinated Election Period of the Evidence of Coverage and other materials and information described in paragraph (b) of each regulation. In addition, they finalized revisions to the regulation text as follows:

- in §422.111(a), the proposed revision to add "in the manner specified by CMS" at the end of the introductory sentence;
- in §422.111(h)(2)(ii), the proposed revision to specify that posting of the EOC and provider directory but not the summary of benefits on the plan's website does not relieve the plan of the obligation to provide hard copies of those materials upon request under paragraph (a) when requested by the beneficiary;
- in § 422.111(h)(2)(iii), new text to move the requirement to post the Summary of Benefits on the plan's website from paragraph (h)(2)(ii) to this new paragraph and a provision clarifying that posting does not relieve the plan of the obligation to deliver hard copies of the Summary of Benefits when CMS determines that it is in the best interest of beneficiaries.

CMS also states that they intend to suggest in sub-regulatory guidance that when a beneficiary requests hard copy delivery of a required document in place of electronic delivery, the plan may wish to continue to provide hard copies to that beneficiary on an ongoing basis, so that the beneficiary does not have to request hard copy format again. In addition CMS indicated they would allow plans the option to include the hard copy notification about electronic posting of the EOC and provider directories along with the ANOC; and will allow plans the option to include other information with the ANOC,

		have other communications and language barriers.	especially additional benefit information (for example, supplemental benefits).
Revisions to §§ 422 and 423 Subpart V, Communication/Marketing Materials and Activities Summary of Changes: CMS proposes several changes to communications and marketing provisions in Subpart V of the part 422 and 423 regulations in four areas of focus: (1) including new definitions for "communications" and "communication materials;" (2) amending §§ 422.2260 and 423.2260 to add (at a new paragraph (b)) a definition of "marketing" in place of the current definition of "marketing materials" and to provide lists identifying marketing materials	p.651-683	In general the SNP A supported this proposal but asked for clarification in the preamble on: • How it will impact FIDE-SNPs and D-SNPs that have integrated some of these materials, • How it will align with state marketing requirements and thus impact joint marketing efforts with states, • How the OEP marketing restrictions will impact access for dually eligible members who want to move during that time to a FIDE or other highly integrated D-SNP. • We requested that CMS review both Medicare and Medicaid marketing requirements and provide guidance to states and plans for further alignment including examples of specific	 CMS finalized the changes as proposed with some modifications: New definitions are proposed at §§ 422.2260 and 423.2260 with corrections to the list of exclusions from marketing materials to exclude disclosures required by §§ 422.111 and 423.128 unless CMS directs otherwise and to exclude materials specifically designated by CMS as not meeting the definition of the proposed marketing definition based on their use or purpose. CMS is clarifying that translation requirements are adopted as proposed with modification that the translation provision is applicable to "vital documents" instead of to "documents specified by CMS". CMS adds language to clarify that "unsolicited marketing materials" "knowingly" sent to MA enrollees during the OEP are prohibited. CMS also clarifies that a SEP is allowed to enrollees where a sponsoring organization or its representative have misrepresented the plan's provision in communications,

to and review by CMS. Materials	to the discussion in this rule related to dual SEP restrictions
that are not considered	so additional guidance here could be helpful.)
marketing, per the proposed	- CMS states they intend to develop a successor to the
definition of marketing, would	current MMG that will include guidance for both
fall under the less stringent	communications and marketing and will further distinguish
communication requirements and	which current materials are considered marketing vs
grievance and appeals notices	communications. CMS will seek comment as a part of the
and materials would also be	-
	development of the new guidelines.
handled separately. For example,	
CMS proposes to exclude	
materials that do not include	
information about the plan's	
benefit structure or cost-sharing	
or from the definition of	
marketing materials such as	
factual information that is not	
intended to influence the	
enrollee's decision to make a	
plan choice or stay enrolled in	
their current plan such as	
monthly newsletters which	
remind them of preventive	
services a \$0 cost sharing, or	
other certain post enrollment	
materials. The use of measuring	
or ranking standards such as	
CMS star Ratings would be	
included in marketing.	
CMS also makes revisions related	
to translated materials in certain	
areas where there is a significant	
non-English speaking population	
to clarify that translation applies	
to all communications materials,	
not just marketing materials and	
that sponsoring organizations	
must provide translated	
*	
materials, as defined by CMS,	

unless in the language of these individuals. CMS welcomes comment on proposed distinctions between these types of prohibitions and whether certain standards or prohibitions from current §§ 422.2268 and 423.2268 should apply more narrowly or broadly than proposed. In addition, CMS requests comments related to the Cures Act which prohibits marketing to individuals eligible for the new OEP during the OEP. CMS solicits comment on how a sponsoring organization could appropriately control who would or should be marketed to during the new OEP, such as such as through as mailing campaigns aimed at a more general audience.		
Elimination of Medicare Advantage Plan Notice for Cases Sent to the IRE (§ 422.590) Summary of Changes: Currently, MA plans are required to notify enrollees upon forwarding cases to the IRE, as set forth at § 422.590(f). The IRE also is required to notify the enrollee of receipt of the case. Under this proposal, the IRE would be responsible for notifying enrollees upon forwarding all cases – including	The SNP Alliance appreciated CMS attempt to reduce administrative burden for MAOs and duplicative notices for beneficiaries but noted that some plans would prefer to notify their members of their action as soon as possible and are concerned that such notice would be delayed if left to the IRE notice only, which could then cause other administrative burdens such as additional calls to the plan. In these cases CMS could allow plans to continue to provide notices to members on an options basis.	change does not preclude plans from continuing to notify enrollees upon forwarding cases to the IRE; plans are permitted to continue the current practice of notifying members upon forwarding case files to the IRE if they choose to do so. While plans opting to notify members upon forwarding cases to the IRE may continue using CMS' model notice, CMS will no longer expect MA plans to utilize the current model notice.

both standard and expedited cases. This proposal is meant to reduce duplication by requiring one notice. Reduction of Past Performance Review Period for Applications Submitted by Current Medicare Contracting Organizations (§§ 422.502 and 423.503) Summary of Changes: CMS conduct past performance reviews in accordance with a methodology published each year used to score each applicant's performance by assigning weights based on the severity of its non-compliance in several performance categories. Under the annual contract qualification application submission and review process, organizations must submit their application by a date, usually in mid-February, announced by CMS. CMS now proposes to reduce the past performance review period from 14 months to 12 months.	SNP Alliance Comment and Recommendations: We support this change and appreciate CMS' recognition of the unintended negative effects of the previous 14-month period, which should now be addressed.	CMS believes it is critical to consider an applicant's most recent record of contract performance at the time of the submission of the application to CMS in February. The adoption of a calendar year past performance period would create an unacceptable gap between the end of the review period and the application deadline. Therefore, CMS will not accept this recommendation. While CMS cannot accommodate the recommendation that we adopt a calendar year review period, we note that CMS makes past performance resources available to organizations that they can use in making the decision to invest resources in preparing an application. Each year, CMS conducts mid-year performance reviews of contracting organizations and share those results with the organizations. While the results of such reviews are not final, they give organizations a real sense of how CMS views their contract performance to that point in the year. We also draft the annual past performance methodology in a way that allows organizations to track their own past performance scores throughout the year, allowing the organizations to determine, as the year goes on, the likelihood that CMS will deny their planned application.
Removal of Quality Improvement Project for Medicare Advantage Organizations (§ 422.152) CMS proposed to delete §§ 422.152(a)(3) and 422.152(d), which outline the QIP requirements.	The SNP A supported this change given that there has not been sufficient integration of QIPs between federal and state agencies, resulting in duplicative, overlapping, or conflicting efforts, particularly for those serving the dually-eligible. [Note that even with the QIP removal, CMS emphasizes that the MA requirements (including	CMS provides a thorough explanation of their experience with QIP. CMS found its implementation of the QIP and CCIP requirements had become burdensome and complex The complex sub-regulatory guidance led to a wide range of MA organization interpretations, resulting in extraneous, irrelevant, voluminous, and redundant information being reported to CMSmandated QIPs do not add significant value we concluded that the removal of the QIP and the continued CMS direction of populations for required CCIPs would allow MA organizations to focus on one project that supports

an ongoing CCIP) for QI Programs will remain improving the management of chronic conditions, a CMS priority, to ensure that the requirements of section while reducing the duplication of other QI initiatives. 1852(e) of the Act are met. As a part of the QI Program, each MA organization will still be required to develop and maintain a health information system; encourage providers to participate in CMS and HHS QI initiatives; implement a program review process for formal evaluation of the impact and effectiveness of the OI Program at least annually; correct all problems that come to its attention through internal, surveillance, complaints, or other mechanisms; contract with an approved Medicare Consumer Assessment of Health Providers and Systems (CAHPS®) survey vendor to conduct the Medicare CAHPS® satisfaction survey of Medicare plan enrollees; measure performance under the plan using standard measures required by CMS and report its performance to CMS; develop, compile, evaluate, and report certain measures and other information to CMS, its enrollees, and the general public; and develop and implement a CCIP. Further, CMS emphasizes here that MA organizations must have QI Programs that go beyond only performance of CCIPs that focus on populations identified by CMS. The CCIP is only one component of the QI Program, which has the purpose of improving care and provides for the collection, analysis, and reporting of data that permits the measurement of health outcomes and other indices of quality under section 1852(e) of the Act. CMS received over 40 comments and is studying the responses. Reducing Provider Burden -The SNP A pointed out underlying **Comment Solicitation** reasons for the burden including some CMS proposed to address arises from state and federal concerns from providers about governments—with regard to requests from MA organizations certification, billing, health information for their patients' medical record standards, quality reporting documentation and solicits requirements—others arise from comment from stakeholders to practice/discipline standards, quality and more fully more fully understand accreditation and measurement bodies, the issue and for ideas to internal health system and QI accomplish reductions in requirements set by employers, some from provider burden. risk management, and some from health plans. The proliferation of measures and reporting—applied to both providers and plans—and the move to value-based and alternative payment models, are additional forces driving this increasing

measurement and reporting burden. Many of these reporting requirements that involve medical record information, including specifications, transmission processes, and data integrity standards accuracy, completeness, timeliness—are driven by entities or standards not under the control of the health plan. It is important to note that health plans have the contractual authority and obligation for a variety of purposes to require access to medical records, including claims auditing, ensuring data integrity, and determining performance on various metrics. We strongly urge caution on rules that restrict access. Convening a diverse stakeholder group to discuss data collection and reporting burden across providers, plans and beneficiaries may offer better insight and potential solutions that address issues that all stakeholders currently face with the proliferation of measures, measurement requirements, and reporting expectations that involve medical records and other data sources that involve the practitioner. The SNP Alliance would welcome the opportunity to participate in stakeholder and expert discussions on strategies, studies, and solutions. We propose that the analysis start with the dually eligible, disabled, low-income and population with high social determinant of health needs—the highest cost, most complex population of beneficiaries—and go from there. Otherwise, the analysis on the scope of the problem and the forces at play--could be too narrow and inadequate.

Reducing the Burden of the	p.827-	The SNPA supported these changes, and	CMS finalized these changes as proposed, with the following
Medicare Part C and Part D		commended CMS for recognizing how	modifications:
Medical Loss Ratio		current provisions may curtail incentives for	- Revised provisions which exclude from QIA, activities that
Requirements		expanding fraud prevention and valuable	are designed primarily to control or contain costs, to
Proposed Regulatory Changes		MTM activities.	provide an exception for fraud reduction activities.
to the Calculation of the			 Revised to provide that costs related to fraud reduction
Medical Loss Ratio (§§			activities under §§ 422.2430(a)(4)(ii) and
422.2420, 422.2430, 423.2420,			423.2430(a)(4)(ii) are not subject to the exclusion that
and 423.2430)			applies to costs directly related to upgrades in health
CMS proposed to revise the MA			information technology that are designed primarily or
and Part D regulations by			solely to improve claims payment capabilities.
removing the current exclusion of			
fraud prevention activities from			
QIA, to expand the definition of			
QIA to include all fraud			
reduction activities, including			
fraud prevention, fraud detection,			
and fraud recovery and to no			
longer include in incurred claims			
the amount of claims payments			
recovered through fraud			
reduction efforts, up to the			
amount of fraud reduction			
expenses. Instead, all			
expenditures for fraud reduction			
activities would be included in			
the MLR numerator as QIA, even			
if such expenditures exceed the			
amount recovered through fraud			
reduction efforts. Costs of			
compliant MTM programs would			
also be considered part of QIA			
for MLR numerator purposes.			
CMS also proposes to reduce			
duplication of MLR reporting			
elements to align with			
commercial MLR requirements.			