This is a summary and analysis by the SNP Alliance of sections from two recent CMS rules:

1) **Medicare and Medicaid Programs; Contract Year 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly** [42 CFR Parts 405, 417, 422, 423, 455, and 460]

   AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

   ACTION: Final Rule. January 19, 2021. **EFFECTIVE DATES**: 60 days after the date of publication in the *Federal Register* Vol. 86, No. 11.

2) **Announcement of Calendar Year (CY) 2022 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies**

   AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

   ISSUED: January 15, 2021.

FINAL RULE

Medicare and Medicaid Programs; Contract Year 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly [42 CFR Parts 405, 417, 422, 423, 455, and 460]

NOTE: This summary is for the Performance Evaluation/Quality Leadership Group of the SNP Alliance and therefore only focuses on the following areas:

- ***Model of Care ("Care Management") Requirements for SNPs***
- ***Star Rating measures***
- ***Quality Bonus Payment***

A summary of the whole Final Rule is available from the SNP Alliance through visiting the website at: www.snpalliance.org

For more information about this summary on these sections, contact Deborah Paone at dpaone@snpalliance.org

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OVERALL SUMMARY OF THESE SECTIONS OF THE FINAL RULE

Section A: Improvements to Care Management Requirements for Special Needs Plans (SNPs) (§ 422.101) [Model of Care requirements- found on Pages 24-62 of 894 of Advance copy and pages 5867 to 5883 of the *Federal Register*, Vol. 86, No 11/Tuesday, January 19, 2021]

CMS finalizes regulations in this Final Rule to implement the provisions of the BBA of 2018 that establishes new care management requirements at § 422.101(f) for C-SNPs and extends these to all SNPs, including minimum benchmarks for SNP models of care. [Begins on page 5871 of the *Federal Register*] These requirements (applicable for Model of Care submissions in 2022 for 2023 effective date) are:

- Interdisciplinary care team (ICT or IDT) required for all enrollees [p. 5873 of the *Federal Register*]
- Requires a face-to-face encounter with each enrollee [p. 5875]
- Requires the results of the initial assessment and annual reassessment (HRA) for each enrollee be addressed in the individual's individualized care plan (ICP) [p. 5878]
- As part of the evaluation and approval of the SNP model of care, the National Committee for Quality Assurance (NCQA) must evaluate whether goals were fulfilled from the previous model of care [p. 5873]
- Requires a minimum benchmark for each element of 50% be met [p. 5881]

Section f: Medicare Advantage (MA) and Part D Prescription Drug Program Quality Rating System - §§ 422.162, 422.164, 422.166, 422.252, 423.182, 423.184, and 423.186; (Page 12 of 894 and Pages 177 to 227 of advance copy and pages 5916 of the *Federal Register*).

CMS is:

- Implementing updates to the Health Outcomes Survey measures,
- Adding new Part C measures,
- Clarifying the rules around contract consolidations and application of the adjustment for extreme and uncontrollable circumstances when data are missing due to data integrity concerns [p. 5926-5929]
- Codifying additional existing rules for calculating the ratings used for MA Quality Bonus Payments, and
- Making additional technical clarifications.

Unless otherwise stated data will be collected and performance measured using these rules and regulations for the 2022 measurement period effective for the 2024 Star Ratings.

NOTE – Summary of the **2022 Rate Announcement** begins on page 17 of this document.

DETAIL ON SECTIONS of the FINAL RULE

Section A: Improvements to Care Management Requirements for Special Needs Plans (SNPs) (§ 422.101)

[These are known as Model of Care requirements and are found on Pages 24-62 of 894 of the advance copy and pages 5871 to 5883 of the *Federal Register*]

The Bipartisan Budget Act of 2018 (BBA)--enacted into law on February 9, 2018--amended section 1859(f) of the Act to include new care management requirements for C-SNPs. CMS finalizes regulations in this Final Rule to implement the provisions of the BBA of 2018 that establishes new care management requirements at § 422.101(f) for C-SNPs and extends these to all SNPs, including minimum benchmarks for SNP models of care. These requirements are:

A. *Interdisciplinary care team (ICT or IDT)* – Final rule requires the ICT/IDT to include providers with demonstrated expertise, including training in an applicable specialty, in treating individuals similar to the targeted population of the plan (a statutory requirement for C-SNPs). The Final Rule extends this requirement to all SNPs.

B. *Face to face annual encounter* – Final rule requires a face-to-face encounter with each enrollee (statute specifies for C-SNPs) and extends the requirement to all SNPs. Face-to-face encounters have to be between each enrollee and a member of the enrollee's ICT or the plan's case management and coordination staff on at least an annual basis, beginning within the first 12 months of enrollment, as feasible and with the individual's consent. CMS also indicates that the face-for-face encounter must be either in-person or through a visual, real-time, interactive telehealth encounter [not telephone].

C. *Individualized Care Plan* - new paragraph (f)(1)(iv) of § 422.101 - Final rule requires the results of the initial assessment and annual reassessment (HRA) for each enrollee be addressed in the individual's individualized care plan (ICP) and extends this requirement, which is statutory for C-SNPs, to the model of care for all SNPs.

D. *Fulfillment of previous MOC's goals* - The Final Rule requires that the evaluation and approval of the model of care by NCQA take into account whether the health plan fulfilled the previous MOC's goals (this change is required by statute for C-SNPs). The Final Rule extends this evaluation component to all SNP models of care, rather than limiting it to C-SNPs.

E. *New requirement of NCQA for review* – at § 422.101(f)(3)(ii) - CMS implements a requirement for NCQA-- that, as part of the evaluation and approval of the SNP model of care, the National Committee for Quality Assurance (NCQA) must evaluate whether goals were fulfilled from the previous model of care. There are three parts to this:
    a. (A) plans must provide to NCQA relevant information pertaining to the MOC's goals as well as appropriate data pertaining to the fulfillment of the previous MOC's goals;

b. (B) plans submitting a new model of care to NCQA must provide relevant information pertaining to the MOC's goals for review and approval; and
c. (C) if the SNP model of care did not fulfill the previous MOC's goals, the plan must indicate in the MOC submission how it will achieve or revise the goals for the plan's next MOC.

In addition, the Final Rule moves an existing regulation at § 422.101(f)(2)(vi) that requires all SNPs must submit their MOC to CMS for NCQA evaluation and approval in accordance with CMS guidance to a new paragraph at § 422.101(f)(3)(i), using the same language.

F. *Minimum benchmark for each element of 50%* - Section 1859(f)(5)(B)(v) of the BBA requires minimum benchmarks for C-SNPs. The Final Rule implements a new regulation to impose the requirement for a minimum benchmark for each element of the C- SNP model of care, and that the MOC can only be approved if each element meets a minimum benchmark. The Final Rule extends these benchmarks to all SNP models of care.

Timing - Due to operational considerations, revisions to the Special Needs Plan Model of Care requirements in § 422.101(f) are intended for implementation (that is, applicability) for models of care for contract year 2023. Plans that are required to submit models of care for contract year 2022 are due to submit MOCs by February 17, 2021; those submissions will be evaluated based on the regulations in effect at that time (that is, without the amendments adopted here) and SNPs must implement and comply with their approved MOCs in connection with coverage in 2022.

CMS states that moving the applicable implementation of the SNP MOC provisions to contract year 2023 will allow SNPs and CMS to construct the necessary processes for full implementation and enforcement of the final rule. When MOCs for contract year 2023 are submitted for review and approval in early 2022, the regulations in this final rule will be used to evaluate those MOCs for approval.

SNP ALLIANCE ANALYSIS & POSITION:

The SNP Alliance agrees with the importance of Specialized Care Management for vulnerable populations with highly complex clinical conditions, such as those served by C-SNPs. We also agree that the care management approach by special needs plans is part of what sets them apart from other general Medicare Advantage plans.

However, we are concerned that increasing process-focused regulations may restrict the customization needed to tailor care and are being applied beyond statutory intent. We understand that Congress had a particular interest in C-SNPs when they passed the legislation.

When this was in proposed rule, we indicated our concerns. We pointed out that all SNP types are not the same – and that the purpose for care management and the plan's Model of Care is to address the needs of individuals with services and supports, care settings, and providers who can tailor help when and how needed. These rules and the Model of Care standards should allow for flexibility by SNP type. At least some elements should be tailored to address unique characteristics of people and provider networks and not prescribe a process.

We hold to the view that some factors of the Model of Care guidelines need to be re-worked to allow for tailoring for specific populations and SNP types, as well as accommodate the range of approaches that could be needed. The processes for I-SNPs serving very frail elderly individuals living in a nursing facility are likely to be different from the processes of a D-SNP serving people with substance abuse and bipolar disorder living in the community. From one person to another, the clinical, behavioral health, and service support providers may need to adapt their care management approach to respond to individual preferences or circumstances. The care management approach may need to incorporate new supports and service providers who are key to the individual reaching his/her goals. These people may be outside of the designated care team. It is hard to anticipate for each person the range of care and support providers who will be needed.

For example—the regulations specify plans must perform an assessment on various domains via a health risk assessment tool. It may be the case that practitioners other than those part of a regular ICT are involved in assessing one or more of these domains. One may assess mental and emotional health. Another functional status. A third cognitive status. These may occur at points in time throughout the year. Though this new information might be outside of the timeframe when an annual HRA is performed—it should be recognized. It could be used to populate and update the plan of care and likewise update the domain-specific assessment sections of an overall health risk assessment—dropping in the new information at different times throughout the year. If this practice were followed, what would be the actual "date" for the HRAT? --when the last information was entered? When the first HRAT with old data was done? The later seems not to offer much value.

Given the multidimensional and often-changing needs of these special populations, it is unlikely that the information collected at one point in time (e.g., once a year) via a comprehensive HRA instrument is going to stay current for long. The information decays, and individual areas of focus around specific needs of the person emerge—so the updates to assessment may be piecemeal and at varying points in time—all driven by the person's condition and situation.

This is one example where the prescribed processes as described for the HRAT and required via the Model of Care scoring guidelines may need to be re-worked to allow for flexibility in how and when beneficiary needs are assessed/re-assessed and how the ICP may be developed or modified and individual practitioners that come in and go out of the virtual set of providers—in response to shifting needs and priorities. The goal is to tailor care and support. The characteristics of the population enrolled in different SNP types, and how/when/where they seek and receive care should lead the examination of re-working these guidelines to allow for greater flexibility and tailoring.

Section f: Medicare Advantage (MA) and Part D Prescription Drug Program Quality Rating System §§ 422.162, 422.164, 422.166, 422.252, 423.182, 423.184, and 423.186;

(See Page 12 of 894 and Pages 177 to 227 of 894 of the advance copy and pages 5916- of the *Federal Register*.)

SUMMARY

In this Final Rule CMS is:

- Implementing updates to the Health Outcomes Survey measures, including modifications to the case mix variables included and increase to 100 the minimum sample size for the HOS sample. Because these are substantive changes, the PCS and MCS measures are moved for two years to the Display page and out of Star Ratings for 2024 and 2025 and then back in for 2026 weighted as a "1" and then in 2027 weighted as a "3" again. [Pages 183-192 of advance copy; Pages 5917-5921 *Federal Register*]

- Proposed Measure Additions - Adding new Part C measures, including: HEDIS Transitions of Care and HEDIS Follow up after Emergency Department Visit for People with Multiple High-Risk Chronic Conditions (on Display page through 2023 Star Ratings, returning to Stars in 2024) as well as signaling their intent to add the Physical Functioning Activities of Daily Living measure which is derived from HOS (future rulemaking). [Pages 191 – 209; 5921-5926 of *Federal Register*]

- Clarifying the rules around contract consolidations and application of the adjustment for extreme and uncontrollable circumstances when data are missing due to data integrity concerns – finalizing their proposal to include contracts with at least 25 percent of enrollees in FEMA-disaster areas that were affected by different disasters for two consecutive years. Such multi-year affected contracts will receive the higher of the current year's Star Rating or what the previous year's Star Rating would have been in the absence of any adjustments from the previous year for each measure. Pages 211-217.

- Codifying additional existing rules for calculating the ratings used for MA Quality Bonus Payments, clarifying their methodology for new contracts and the time period for review of previous Star Ratings as well as use of weighted enrollment figures. Pages 218-227.

- Making additional technical clarifications, including removing reference to low Star Rating as the basis for denial of application (Page 465), specifying additional MOC provisions and CMS expectations for MOC review and approval (Pages 629-633), and discussing the Health Risk Assessment (HRA) (Pages 643 and 644).

Unless otherwise stated data will be collected and performance measured using these rules and regulations for the 2022 measurement period effective for the 2024 Star Ratings.

DETAIL ON THESE SECTIONS:

Health Outcomes Survey (page 183 to 192; Pages 5917-5921 *Federal Register)*

CMS is updating the Maintaining Physical Health and Maintaining Mental Health composite measures (PCS and MCS); these are considered substantive changes. This includes:

(1) Case-Mix Variables - changing the case-mix adjustment methodology from an "all or nothing" approach to replacing a missing adjuster with the mean value for that adjuster from beneficiaries in the same contract. This approach has been used for many years in CAHPS and is easier to implement.
(2) Sample Size - increasing the minimum required denominator from 30 cases to 100 cases for the PCS and MCS measures. This would bring the measures into alignment with the denominator requirements for other HEDIS measures that come from HOS and improve the reliability of these two measures.

These are substantive changes and, in accordance with § 422.164(d)(2), CMS will place these two measures on the Display page for at least 2 years prior to using them in measure calculations to assign Star ratings. Thus, the HOS - PCS and MCS measures are moved to the Display page for the 2024 and 2025 Star ratings **(**Page 185 of 894).

Further, CMS has opted to "let stakeholders review the updated measures on the Display page without simultaneously considering an alternate specification in the Star Ratings." We interpret this to mean that there is not a substitute for these measures in Star Ratings for the two years when the PCS and MCS measures are held on the Display page.

Finally, CMS states that the PCS and MCS measures will be weighted a "1" in the 2026 Star Ratings and a weight of "3" in 2027 Stars and beyond (Page 186 of 894 of the advance copy and page 5919 of the *Federal Register*).

CMS is exploring alternative PROs as potential replacements for the existing HOS outcome measures in the future (Page 189 of 894 of advance copy and 5921 of the *Federal Register*). CMS states: "we are particularly interested in less complex replacements that would facilitate MA plans directing their quality improvement efforts on a health focus relevant to their enrollee population."

SNP ALLIANCE ANALYSIS & POSITION:

We are pleased that CMS responded to some of our recommendations regarding the Health Outcomes Survey (HOS), including addressing the need for more comprehensive case-mix adjustment factors for the longitudinal measures (maintaining mental or physical health status), and increasing the sample size from 30 to 100 individuals. We support the movement of these two measures to the Display page for 2024 and 2025 and the re-weighting of the measures to "1" in the 2026 Star Ratings.

The HOS instrument and methods of data collection are long overdue for upgrades or replacement. We offered extensive analysis via our HOS White Paper in 2018 HOS White Paper SNP Alliance-Paone. It would be ideal if a replacement for these two HOS measures could be determined in the

next two years while the measures are held out of Star Ratings—although this probably too short a time window for this to happen.

In the meantime, we're encouraged that CMS is exploring new person-reported outcome measures (PROMs) and alternative instruments and methods to eventually replace HOS. It is time to invest in this pursuit. We hope the dually-eligible and diverse population will be central in the development, testing, and review of new PROMs.

The SNP Alliance sits on two important technical groups and will bring the focus on special needs populations forward in these discussions. The SNP Alliance joins with other experts to work on technical issues with the MA Star measures and rating system through the RAND/CMS Technical Expert Panel on MA Stars (For example the latest meeting materials can be found at: RAND Technical Expert Panel MA Stars July 22, 2020 Mtg) and to work on patient-reported outcome measures through the National Quality Forum Patient-Reported Outcome Performance Measures (PRO-PM) Roadmap Technical Expert Panel (TEP) NQF: PROM TEP 2021.

Physical Functioning Activities of Daily Living (PFADL) (Page 191; 5921of the *Federal Register*)

CMS briefly discusses the Physical Functioning Activities of Daily Living (PFADL) measure in the Final Rule. They state:

In the 2021 Advance Notice, we stated that we planned to post the longitudinal Physical Functioning Activities of Daily Living (PFADL) change measure on the 2021 and 2022 display pages and that we may consider that PFADL measure for the Star Ratings in the future, pending rulemaking. Prior to potentially proposing this measure through future rulemaking, CMS would submit this measure through the Measures Under Consideration process to be reviewed by the Measure Applications Partnership which is a multi-stakeholder partnership that provides recommendations to HHS on the selection of quality and efficiency measures for CMS programs, as required by Section 3014 of the Affordable Care Act. The 2021 Advance Notice also stated that given the complexities of the existing HOS measures, CMS is committed to exploring alternative PROs to replace the existing HOS outcome measures. We are particularly interested in replacements that would be simpler and more direct for plans to use and to focus their quality improvement efforts. If we propose to add the PFADL measure to the Star Ratings in future rulemaking, we will consider using it to replace existing measures.

As stated, CMS will continue to post the PFADL measure on the 2021 and 2022 Display page and "may consider" the measure for Star Ratings in the future, pending rulemaking. They state they would first submit the measure through the Measures Under Consideration process to be reviewed by the Measure Application Partnership (NQF staffs this group).

SNP ALLIANCE ANALYSIS & POSITION:

Background on the measure - The Physical Functioning Activities of Daily Living (PFADL) is a longitudinal change measure derived from HOS. It measures, at the contract level, the change over two years in the physical functioning of beneficiaries enrolled in MA contracts. The PFADL scale

combines two physical functioning questions (limitations in moderate activities and climbing stairs) with the six activities of daily living questions to create a Likert-type scale. PFADL scale scores are created from responses to the baseline and the two-year follow-up questions. Contract-level change scores are on a 0-100 scale, with 100 equivalent to all MA beneficiaries retaining 100% of baseline function over two years and 0 corresponding to every beneficiary in the MA contract experiencing maximum decline. In contrast to HEDIS measures, the PFADL change measure score for an MA contract is its mean change score rather than the proportion of individuals passing the measure.

CMS has indicated they will use a methodology to correct population characteristic differences by grouping PFADL scores into four baseline groups from lowest to highest and comparing the average scores for each group two years later. They will use a case-mix linear regression model that sets predictive rates for the second PFADL score.

The SNP Alliance has long supported a focus on functional status as an important characteristic of people with complex chronic, behavioral, and long-term care needs. Understanding a person's functional status is an important piece of the puzzle in crafting a tailored response to care.

The PFADL measure derives from HOS using the questions about abilities such as moving tables, or hobbies such as bowling or playing golf. We have frequently discussed the problems with this wording. The wording of questions in HOS such as these is sometimes considered insensitive or lacking relatability to cultural/ethnic diverse or disabled individuals, and is potentially confusing.

Furthermore, the PFADL measure is based on a small sample. It will compare two snapshots of functional status at two-year intervals for a small sample of people enrolled in the plan. Health plan contracts with a large proportion of members who are frail, have complex chronic, degenerative, progressive conditions, have high social risk factors and other life events that impact their physical health and their ability to perform activities of daily living –are much more likely to have a random sample of members (HOS sample) with poor physical functioning in ADLs. It is predictable given the characteristics of the population.

We are most concerned that this measure misses a very important point: If a health plan serves primarily functionally-impaired or disabled individuals--*the opportunity to demonstrate improvement on this measure will not be present or severely hampered.* This is because of the wording of the questions. The wording may set up a pre-emptive bias against plans/providers who care for people who already have substantial limitations and cannot perform these ADLs *without help*. The way the question about six ADLs is worded reads:

Because of a health or physical problem, do you have any difficulty doing the following activities ***without special equipment or help from another person****?* (bathing, dressing, eating, getting in and out of chairs, walking and using the toilet)

A person responding who is already permanently disabled or has substantial ADL limitations and cannot perform one or more of these ADLs without help starts at the lowest end of the scale ("Unable to do").

If the person is in a SNP or other health plan that provides long term services and supports, adaptive equipment, puts in grab bars, provides a shower bench, lift chair for the stairwell, special shoe-horn,

button-hole tool, personal care assistant for ADL assistance—it can result in change where the person is able to perform some of these functions *with help*. However, the HOS question asks the person about performing the task "without special equipment or help from another person"—so two years later that individual would again say "Unable to do."

Even though this person would have improved in ADLs with assistance - where his or her level of function in bathing, dressing, eating or moving is better *with help*—the measure would not capture this change. The point is not that the individual still can't do the task alone – but that the person can now do something they couldn't before *because they now receive help*.

This is really important. The difference between being unable to dress or bathe alone and being able to do some of these daily activities with the help of a personal care assistant, shower bench, grab bar, or special shoe-horn—can be life changing.

We are concerned that the PFADL measure specification using the wording of the HOS questions may close the door to showing improvement in function – among people who have substantial limitations—as these individuals use assistance.

It will not really matter that the HOS sample average PFADL scores is separated into four groups based on functioning at baseline. If the person cannot perform ADLs without help, or if decline occurs from baseline to 2 years later—the average for that group falls and the health plan would be rated lower (negatively) on performance of the PFADL measure. This would be the case even if the groups actually improve in functional ability *with help.* This is counter-productive and may be a dis-incentive for health plans to invest in adaptive equipment, innovations such as home visits that help change the home environment or add home support services to the individual's care plan and service package—since these things will not be "counted" when the PFADL questions are asked of the respondent. We do not believe this is CMS' intent.

Another point with the current HOS question is that there are only three response options in the Likert scale around ADLs ("No, I do not have any difficulty;" "Yes, I have difficulty," or "I am unable to do this activity") this limits the opportunity to mark improvement. A five-point or seven-point scale would show more change.

An alternative self-report measure on ADL functional change achieved *with help*--and how the health plan actions helped to bring this change to effect—is necessary. There are other measures, instruments and methods focusing on function which may be better suited to the purpose of performance evaluation. We urge CMS to consider these alternatives and to include achievement of functional status improvement with or without help as an important focus for performance evaluation.

Proposed Measure Additions - New Part C Measures starts on Page 5921 of *Federal Register*)

HEDIS Transitions of Care (Pages 192-209 of 894 of the advance copy; 5921-5924 of *Federal Register*)

The Transitions of Care (TRC) measure is a composite measure made up of four parts focusing on the transfer of information and specific documentation. The measure looks at the percentage of

discharges for members 18 years of age and older who had each of the following: 1) notification of admission and post-discharge: 2) receipt of discharge information, 3) patient engagement, and 4) medication reconciliation. It was first placed on the Display page of Star ratings in 2020.

In this Final Rule CMS adopts the NCQA (measure steward for TRC measure) specification changes which the Agency considers non-substantive, including:

(1) broaden the form of communication from "one outpatient medical record" to other forms of communication, such as admission, discharge, and transfer record feeds, health information exchanges, and shared electronic medical records;
(2) change the required notification of receipt of records from "one the day of admission or discharge" to "on the day of admission or discharge or within the following two calendar days;"
(3) change the wording on one of six criteria around the Receipt of Discharge information from "instructions to the primary care providers or ongoing care provider for patient care," to "instructions for patient care post-discharge."

CMS responded to many comments. Those interested in this measure should review pages 5921 through 5924.

The Agency indicates that the measure does allow for a variety of providers to take action to meet the intent of the indicator—though the information must be "documented in the outpatient record that is accessible by the PCP or ongoing care provider." This is "the practitioner who assumes responsibility for the member's care."

The Agency notes that currently the measure only focuses on notification of admission and discharge going to the PCP or ongoing provider, not to the health plan. They note that the plan will "determine the provider that meets the intent of the measure (which may include Medicaid providers treating dually eligible enrollees).

CMS notes that the measure will be displayed on the Medicare Plan Finder.

This TRC measure will be included in the 2024 Star ratings – CMS will delay by one year for inclusion into Stars (formerly was supposed to be in 2023 Star ratings).

HEDIS Follow-up after Emergency Department Visit for People with Multiple High-Risk Chronic Conditions (Pages 192 – 209 of 894 and page 5924 of the *Federal Register*)

Follow-up after Emergency Department Visit for People with Multiple High-Risk Chronic Conditions is a process measure that looks at the percentage of emergency department (ED) visits for members 18 years and older who have multiple high-risk chronic conditions who had a follow-up service within 7 days of the ED visit. Eligible members must have two or more of the following chronic conditions: COPD and asthma; Alzheimer's disease and related disorders; chronic kidney disease; depression; heart failure; acute myocardial infarction; atrial fibrillation; and stroke and transient ischemic attack.

The following meet the criteria to qualify as a follow-up service for purposes of the measure: an outpatient visit (with or without telehealth modifier); a behavioral health visit; a telephone visit; transitional care management services; case management visits; and complex care management.

CMS notes this measure is based on the number of ED visits, not the number of members.

CMS responded to a number of comments, including the concern that the 7-day window is too short. They explained that it can take more than 7 days to process and submit an ED claim to the health plan—and the PCP is only notified once the plan receives the claim. Furthermore, plans are not always informed by facilities of ED visits, particularly by out-of-network or out-of-area facilities. Sending such notification to the receiving setting or provider is under the control of the facility. CMS maintains that this is a vulnerable population and they are staying with the 7-day window. They state that they believe health plans are "in a critical position" to help coordinate the care of their members and improve the timeliness of communications that occur between EDs, inpatient facilities, and outpatient providers.

As with the TRC measure, CMS indicates it is proceeding to add this measure to Star Ratings beginning in 2024, delaying by one year that action (the measure is on the Display page one more year).

These are NCQA measures to be added to the HEDIS measure set. NCQA and CMS considers them an important part of evaluating how plans are managing chronic conditions. CMS will include this measure in the CAI measure set.

Table D1 on page 209 of the advance copy and page 5926 of the *Federal Register* provides detail on these measures and notes the following: NQF endorsement is not available (not yet endorsed) and each is a process measure with a weight of "1."

SNP ALLIANCE ANALYSIS & POSITION:

Transitions of Care - We previously provided extensive comment on the Transitions of Care measure while the measure was under development and to the National Quality Forum which reviewed the rigor of the measure and its specifications. We appreciated NCQA's modifications to the measure specifications which CMS has now adopted.

CMS reminds the industry that the intent of the TRC measure is "to improve the quality of care transitions from an inpatient setting to home," with individuals in hospice excluded. It is based on the number of discharges, not the number of members—so individuals who experience multiple discharges within the measurement period will show up more than once in the measurement data.

TRC & ED Follow up measures - We hold to the view that these measures focus on transfer of information between providers/facilities and documentation of that in a record that can be accessed by the PCP or ongoing primary provider.

We agree that this transfer of information is very important and that providers and facilities should be encouraged to make this exchange more quickly, especially for these vulnerable groups; however, the health plan has little influence or control on these provider actions. If these measures could be

wrapped into a clinical, hospital, or nursing facility measurement set, this could expedite improvement. We do believe that starting with these measures to evaluate provider processes of care is warranted, though we urge attention to provider burden.

The measure focuses on processes of information exchange between providers/facilities and how well information is being documented—that is what is being evaluated. The burden on providers/facilities serving a high proportion of these individuals could be substantial—requiring labor-intensive chart review for many people.

We urge NCQA and CMS to take the time to determine if the measure results indicate there are unintended negative consequences on provider, facilities, or plans that serve a high proportion of high risk individuals.

We appreciate the one-year delay by CMS in moving this to Stars Ratings—especially given the challenges still faced by providers during this pandemic. Chart review is particularly difficult as it often requires the reviewer to be in-person within a building and/or adds to the clinic burden for locating records. Sometimes documentation is in progress notes which is very time consuming to comb through and find. This burden will more often be borne by providers and plans that serve a high proportion of people with multiple chronic conditions at a time when clinicians and healthcare facilities are already very stressed.

We continue to hope that NCQA will be open to identifying potential solutions to the current challenges in these measures such as the practical issues raised in the comments.

[Table D1 – New and Revised Star Rating Measures – Beginning on or After January 1, 2022 – found on page 209 of 894 and 5926 of the *Federal Register]*

Extreme and Uncontrollable Circumstances (§§ 422.166(i), 423.186(i)) [page 211-217 and 5926-5929 of Federal Register]

CMS modifies §§ 422.166(i)(8) and 423.186(i)(6) to clarify the rules for how the adjustment for extreme and uncontrollable circumstances would apply where there are missing data, including data missing because of a data integrity issue as defined at §§ 422.164(g)(1) and 423.184(g)(1).

CMS reminds readers that they finalized in the April 2019 final rule a policy effective for the 2022 Star Ratings for contracts with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas that were affected by different disasters for 2 consecutive years. Such multiple year-affected contracts will receive the higher of the current year's Star Rating or what the previous year's Star Rating would have been in the absence of any adjustments that took into account the effects of the previous year's disaster for each measure.

CMS responded to commenters that advocated for multi-year look back as follows: Carrying forward very old data into the Star Ratings for many years, especially in situations where large numbers of contracts are impacted by disasters in a given year or in areas that are more prone to disasters, could erode incentives for plans to provide high quality care for their beneficiaries even in the face of a disaster. Further, using a multi-year lookback for contracts affected by disasters would

be operationally very complex since for each contract we could be comparing to a different year of data that is unaffected, in particular in areas that are prone to disasters, and could put CMS at risk of not producing Star Ratings in time for open enrollment and be confusing or misleading to beneficiaries. CMS states it has "an obligation to ensure that Star Ratings data are useful for providing comparative plan information to beneficiaries because part of the purpose and authority for the Star Ratings is to provide comparative information to beneficiaries under sections 1851(d) and 1869D-1(c) of the Act."

CMS finalized the rules as proposed. The changes are applicable to the 2022 measurement year and 2024 Star Ratings. They do not believe additional rules are necessary to address the impact of the PHE. They will continue to monitor the impact of COVID-19 on the healthcare system and Part C and D plans.

SNP ALLIANCE POSITION:

We do not have any comment on this provision in the Final rule other than our request to examine the results of these rules on SNP and MMP contracts and encourage CMS to review and be transparent about the Agency's analysis to confirm that the methods were equitable across plan types and there were no unintended biases.

Quality Bonus Payment Rules - §§ 422.162, 422.164, 422.166, 422.252, 423.182, 423.184, and 423.186; (Pages 218 – 227 of advance copy of the Final Rule and page 5929-5931 of the *Federal Register*)

CMS proposed several amendments to §§ 422.162(b)(4) and 422.166(d)(2)(vi) to codify current policies for using the Star Ratings to calculate quality bonus payment percentage increases (QBPs) and determine beneficiary rebates for MA organizations.

In the proposed rule (Feb 2020) CMS indicated that if a contract does not have sufficient data to calculate and assign Star Ratings for a given year because it is a new MA plan or low enrollment contract, § 422.166(d)(2)(v) provides the rules for assigning a QBP rating. That regulation references the definitions at § 422.252.

CMS amended the definition at § 422.252 for new MA plans by clarifying how the definition is applied, indicating that any new contract under an existing parent organization that has other MA contracts with numeric Star Ratings in November would be assigned the enrollment-weighted average of the highest Star Rating of all other MA contracts under the parent organization that will be active as of April the following year.

CMS added at § 422.166(d)(2)(vi)(B) that if a new contract is under a parent organization that does not have any other MA contracts with numeric Star Ratings in November, CMS would look at the MA Star Ratings for the previous 3 years. The QBP rating would be the enrollment-weighted average of the MA contracts' highest-level Star Ratings from the most recent year that had been rated for that parent organization.

CMS finalizes this methodology to calculate the QBP ratings as proposed with that slight revision to clarify that the enrollment figures used in the enrollment-weighted QBP rating calculations are the November enrollment in the year the Star ratings are released (Page 226).

CMS does not believe that a change to the ratings used for QBP purposes is appropriate at this time and, even if it did, asserts that such a significant change from current practice as suggested by some commenters should be subject to additional analysis and the opportunity for public comment via the rulemaking process. Further, they state that their current Part C and D Star Ratings contractor, RAND Corporation, is soliciting input from their Technical Expert Panel on suggested potential changes to the mix and number of measures included in the Star Ratings program for consideration in the future.

SNP ALLIANCE POSITION:

The SNP Alliance sits on this MA Star Rating Technical Expert Panel facilitated by RAND and we will bring the focus on special needs populations forward in these discussions.

Other technical changes

MA Application - Page 465 of advance copy and pages 5999-6000 of the Federal Register– CMS modified the criterion where there is only one year of poor prior contract performance ("one year of low Star rating") as a basis for denial of a MA application. CMS considers this a contract compliance failing, but not on par with the other two criteria (enrollment sanctions and financial insolvency) for denying an application. Therefore CMS states: *We are removing the references to Star Ratings as a basis for denial at paragraph (B) of §§ 422.502(b)(1)(i) and 423.503(b)(1)(i)* [page 6003 of the *Federal Register*.]

SNPs Evidence-based Model of Care - See pages 629 to 633 of the advance copy and 6094 - of the Federal Register on MOC provisions previously enumerated with reinforcement on CMS' expectations regarding review and approval (they mention CMS audits). This includes review of:

- the plan's HRA tool which must cover specific domains, must be completed upon enrollment and annually for every individual enrolled in the SNP;
- assurance that information on assessed needs from the HRAT is addressed in the individual's plan of care (ICP required for every SNP member);
- that an interdisciplinary care team (ICT) with demonstrated expertise and training is involved in treatment and care management for every SNP member;
- that there is at least one face to face encounter within the first 12 months of enrollment ("as feasible and with the individual's consent") for every SNP member for the:
    - delivery of health care or care management, or care coordination services
    - be between each enrollee and a member of the ICT or the plan's care management and coordination staff or contracted plan healthcare providers
    - be in-person or through a visual, real time interactive telehealth encounter

This section also describes the NCQA review and approval process previously described.

Safe disposal of controlled substances-Member education is required when conducing in-home HRAs – This is discussed on pages 643 and 644 of the advance copy and pages 5891-5894 and 6095 of the *Federal Register*

CMS discusses the statutory new requirement that will primarily impact SNPs that perform an in-home health risk assessment – requiring (as part of this assessment) the provision of information and

educational materials to the member regarding safe disposal of certain prescription drugs that are controlled substances.

Specifically, CMS states (page 5891 of the *Federal Register*):

With the exception of MA SNP plans, all other MA plans are required under § 422.112(b)(4)(i) to make a best effort to conduct an HRA annually and generally do so as part of an enrollee's covered annual wellness visit (see 42 CFR 410.15), but there is no requirement that the HRA be conducted in-home. We note that MA special needs plans (SNPs), as part of their model of care, are required to conduct annual HRAs for their enrollees (42 CFR 422.101(f)(1)(i), but are also not required to conduct in-home HRAs.

SNP ALLIANCE ANALYSIS

This could be a substantial burden to SNPs more than general MA plans, however it is a statutory requirement if in-home risk assessments are done.

We have some basic questions such as: Will the HRA in-home assessor know in advance of the visit if the member has been prescribed controlled substances? Should the SNP provide the information about safe disposal to all members receiving an in-home visit just in case?

The SNP Alliance seeks input from plan members on the expected cost of this requirement and if or how this may impact their ability to conduct in-home HRAs for purposes of care management or treatment. We would like to know if providing this information has impacted the rest of the HRA completion or in-home activities--which are the primary reason for the in-home visit. We are interested in hearing from health plans that have found successful ways to ensure this safe disposal information is provided when indicated. What are practical considerations and are there any best practices around this?

2022 RATE ANNOUNCEMENT

Announcement of Calendar Year (CY) 2022 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ISSUED: January 15, 2021.

NOTE: This summary is for the Performance Evaluation/Quality Leadership Group of the SNP Alliance and therefore only focuses on the following areas:

- ***Quality Bonus Payments***
- ***Part C and D Star Ratings and Future Measurement Concepts***
- ***Extreme and Uncontrollable Circumstances***
- ***Frailty Adjustment for FIDE-SNPs***

SELECTED SECTIONS

Section B. MA Benchmark, Quality Bonus Payments, and Rebate (focus is on QBP for this document; Pages 35-37)

CMS changed the definition of a "new MA plan" in the regulations at § 422.252 for the 2022 quality bonus payments (QBPs) only. For 2022 only, a "new MA plan" means an MA contract offered by a parent organization that has not had another MA contract in the previous four years, a change from the prior three-year requirement, which affects new contracts that started in 2019. With this change, new plans started in 2019 will continue to be considered new in 2022 and receive the 3.5 percent QBP.

In the CY 2022 Advance Notice Part II, CMS finalized this modification to the definition of "new MA plan" in the regulations at § 422.252 for the 2022 QBPs only (see the Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency Interim Final Rule (CMS-1744-IFC) (85 FR 19269–19275)). As explained in the IFC, this change was necessary because the CAHPS and HEDIS data that would otherwise be used for the 2021 Star Ratings for a new MA plan that started in 2019 is not available because we eliminated the requirement to submit those CAHPS and HEDIS data. (85 FR 19275). The change to the definition of "new MA plan" is limited to the 2021 Star Ratings (and therefore, the 2022 QBPs) only.

Attachment VI. Updates for Part C and D Star Ratings (Page 84)

- CMS announces that ***June 30, 2021*** is the deadline for contracts to make requests for review of the 2022 Star Rating appeals and CTM measure data. (Page 85)

- The ***Part C & D Improvement measures*** that will be used to calculate the 2022 Star Ratings are listed in Table VI-I. As stated in §§ 422.164(f)(4)(i) and 423.184(f)(4)(i), CMS will only

include measures at the contract level if numeric value scores are available for both the current and prior years. (Page 85-86)

- The ***Categorical Adjustment Index*** measure set and CAI values for minimum, median, and maximum within-contract variation for LIS/DE differences is posted. As finalized at §§ 422.166(f)(2) and 423.186(f)(2), all measures identified as candidate measures are included in the determination of the 2022 CAI values. A summary of the analysis of the candidate measure set that includes the minimum, median, and maximum values for the within-contract variation for the low-income subsidy (LIS)/dual eligible (DE) differences is posted with the 2022 CAI values at https://go.cms.gov/partcanddstarratings. (Page 87)

  CMS' response to comments around working toward a longer-term solution that more fully accounts for the impact of socioeconomic factors on the Star Ratings, was to say they are:

  > *reviewing the ASPE recommendations, exploring additional options to account for differences in within-contract performance across different social risk factors, and investigating the feasibility of adding additional social risk factors to the CAI or alternative methodologies.*

- CMS reiterates its policy for ***Extreme and Uncontrollable Circumstances***. For the 2020 measurement period with the COVID-19 pandemic, most MA and Part D contracts qualify for the disaster adjustments finalized in the CY 2020 Final Rule, published in the Federal Register on April 16, 2019 (84 FR 15830–31). (Page 87)

  Specifically, for the 2022 Star Ratings, CMS will not exclude the numeric values (that is, the performance data) for affected contracts with 60 percent or more of their enrollees in FEMA-designated Individual Assistance areas during the 2020 performance and measurement period from either:
  - (1) the clustering algorithms; or
  - (2) the determination of the performance summary and variance thresholds for the Reward Factor.

  This means that CMS will use the performance scores for all contracts for the 2020 performance and measurement period to establish cut points for non-CAHPS measures and determine thresholds for the Reward Factor for the 2022 Star Ratings, subject to the other rules in the Star Ratings methodology, including the specific rules adopted in the March 31, 2020 COVID-19 IFC.

  Application of the 25 percent rule for FEMA-designated Individual Assistance areas means that contracts with at least 25 percent of their service area in a FEMA-designated Individual Assistance area in 2020 will receive the higher of their measure-level rating from the current and prior Star Ratings years for purposes of calculating the 2022 Star Ratings. The Agency says that most commenters' supported this policy. Table VI-3 on pages 90-91 provides a complete list of the Individual Assistance FEMA Major Disaster Areas declared.

- CMS notes that it will continue to solicit feedback on new measure concepts, updates to measures and provide advance notice regarding measures being considered for implementation for future Star Ratings (page 91). CMS lists the following changes to existing Star Ratings measures in 2022 (Page 91):

    - Medicare Plan Finder (MPF) Price Accuracy moves to the 2022 Star Ratings with a process measure weight of "1"

    - Controlling Blood Pressure – A non-substantive update by the measure steward, NCQA was announced in the HEDIS Volume 2 Technical Specifications for use in measurement years 2020 and 2021 which now allows for patient self-report blood pressure readings, as well as telephone and e-visit encounters to be recognized in the data capture for this measure (Page 92).

    - HEDIS Measures and Telehealth – Also announced by NCQA in July 2020 through the HEDIS Volume 2 Technical Specifications release for measurement years 2020 and 2021 were several additional non-substantive measure changes that add telehealth visits to the denominator or numerator and removes other restrictions around telehealth. All commenters appreciated the additional code added to account for telehealth visits. The measures included in this change are (see pages 92 and 93):
        - Rheumatoid Arthritis Management
        - Breast Cancer Screening
        - Care for Older Adults
        - Controlling High Blood Pressure
        - Comprehensive Diabetes Care
        - Colorectal Cancer Screening
        - Osteoporosis Management in Women Who Had a Fracture
        - Plan All-Cause Readmissions
        - Statin Therapy for Patients with Cardiovascular Disease

- ***Changes to Star Ratings measures*** for future years (Page 93)
  CMS notes that measure steward Pharmacy Quality Alliance (PQA) clarified the measure specifications for the measure "Statin Use in Persons with Diabetes." The index prescription start date for this SUPD measure should occur at least 90 days prior to the end of the measurement year. This is considered a non-substantive update. Also, the measure is re-classified as a process measure, with a weight of "1." CMS announced it will implement the updated measure specifications for the 2021 measurement year (2023 Star Ratings).

- ***Display Measures*** – include measures that are transitioned from inclusion in the Star Ratings, new or updated measures before inclusion into Stars, and information-only measures. CMS

anticipates that the 2021 Display measures will continue to be shown on CMS.gov in 2022 unless noted below (Page 95):

- Retiring measures from the 2022 Display Page:
  - Timely Receipt of Case Files for Appeals (Part D)
  - Timely Effectuation of Appeals (Part D)
  - Drug-Drug Interactions (Part D)
  - Antipsychotic Use in Persons with Dementia – Community Only Residents (Part D)
  - Use of Opioids at High Dosage and from Multiple Providers in Persons without Cancer (Part D)
  - Drug Plan Provides Current Information on Costs and Coverage for Medicare's Website (Part D)

- Measures moving forward at various timeframes (Page 96)
  - Kidney Health Evaluation for Patients with Diabetes (Part C) – Display page for 2022
  - Controlling Blood Pressure (Part C) – Display page for 2022
  - Plan All Cause Readmission (Part C) – Display page for 2022 and 2023
  - Polypharmacy: Policy/CNS and Poly/ACH – Display page for 2021

- ***Potential New Measure Concepts*** for Future Years (Page 99-100) – CMS noted it solicited comments on potential new Star Ratings as shown below. They are still exploring both measures and will take comments offered into consideration.

  - Provider Directory Accuracy (Part C) – CMS floated a possible measure about the percent of plan information in its directory is inaccurate. Most commenters were not in favor of a measure related to provider directory accuracy for several reasons including: (1) it relates more to plan compliance and oversight vs. quality performance, (2) it depends on provider data accuracy where there is not currently a standard, accurate source for validating/verifying this information.

  - COVID-19 Vaccination (Part C) – CMS floated a possible new measure around COVID-19 vaccination for publication on the Display page and potential inclusion in Star ratings. Most commenters said it was premature to develop such a measure, considering the following challenges: differing availability and distribution channels across the country, lack of sufficient testing of the efficacy and safety of the vaccination among beneficiaries with multiple chronic conditions or other high risk issues, the level of control MA plans will have over vaccination procedures/rates, cultural differences in vaccination acceptance, as well as urban/rural differences. Commenters suggested CMS consider registries.

- ***Frailty Adjustment for FIDE-SNPs*** - For CY 2022, CMS is finalizing the policy to calculate frailty scores for FIDE SNPs using updated frailty factors and the 2020 CMS-HCC model. For CY 2021, CMS will calculate 75 percent of the frailty score using the frailty factors associated with the 2020 CMS-HCC risk adjustment model and 25 percent of the frailty score using the frailty factors associated with the 2017 CMS-HCC risk adjustment model. The CY 2022 impact of transitioning to frailty scores calculated using the updated frailty factors associated with 2020 CMS-HCC model, relative to CY 2021, is a change in frailty scores of 19 percent, which represents a net impact of $30 million dollars to the Medicare Trust Funds in 2022. This impact takes into account the portion of the difference between benchmarks and bids that the government retains and the portion of the program costs covered by Part B premiums.