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December 19, 2018

Seema Verma, MPH  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
200 Independence Avenue, SW  
Washington DC, 20201

**RE: CMS-4185-P**

Dear Ms. Verma:

The Medicare Payment Advisory Commission (MedPAC) welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) notice of proposed rulemaking entitled “Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care Programs for Years 2020 and 2021,” published in the *Federal Register*, vol. 83, no. 212, pages 54982 to 55088. We appreciate your staff’s work on the notice, particularly considering the competing demands on the agency.

This proposed rule includes several provisions that would revise regulations for the Medicare Advantage (MA) program (Part C) and the Prescription Drug Benefit program (Part D). Our comments focus on the following provisions:

- Requirements for MA plans offering additional telehealth benefits
- Dual eligible special needs plan (D-SNP) provisions
- Modifications to the MA quality bonus program
- MA risk adjustment data validation provisions

**Requirements for MA plans offering additional telehealth benefits**

The Secretary is proposing to implement provisions in the Bipartisan Budget Act of 2018 that allow MA plans to voluntarily provide additional telehealth benefits and treat them as basic benefits in the bidding process. The proposal defines “additional telehealth benefits” as Part B services (e.g., primary care visits, routine or specialty consultations, dermatological examinations, behavioral health counseling) that are clinically appropriate to furnish through electronic exchange (e.g., secure messaging, store and forward technologies, telephone, videoconferencing, and other internet-enabled technologies). The proposal would allow plans to determine clinical appropriateness of each additional telehealth benefit, based on existing professional standards.

This category of telehealth benefits is distinguished from other categories of telehealth coverage in MA:

- telehealth benefits covered under original Medicare: must be included in the basic benefit for each plan's bid
- telehealth benefits not covered under original Medicare or meeting the additional telehealth benefit definition (e.g., remote access technology and telemonitoring): may be provided as a supplemental benefit in a plan's bid.

The Secretary's proposal would allow plans to offer different cost sharing for a Part B service based on whether it is provided in person or via telehealth (assuming clinical appropriateness for telehealth); would require plans to disclose telehealth benefits, including applicable conditions and limitations, premiums and cost sharing, and any other conditions of use in the Evidence of Coverage (EOC); and would require plans to identify providers offering telehealth services in the provider directory. The Secretary requests comment on two additional proposals: whether telehealth benefits could be used to fulfill network adequacy requirements, and whether a proposal to require that telehealth providers have a contract with an MA plan should be applied differently by plan type (e.g., HMO, PPO).

#### *Comment*

Additional telehealth benefits can provide value to MA enrollees, but we strongly believe that offering these voluntary benefits should not affect the beneficiary's access to the original Medicare benefit, particularly for in-person services. This standard drives our comments about network adequacy, differential cost sharing, and disclosure of additional telehealth benefits in the EOC and of providers offering telehealth services in the provider directory.

- Additional telehealth benefits should not be used to fulfill network adequacy requirements. MA plans are required to maintain appropriate coverage of providers in their network for all Part B benefits, including in-person services. Network adequacy for providers of in-person services requires a minimum number of providers in a specific geographic area. Telehealth services do not require co-location of provider and patient, and do not have a geographic limitation on the supply of providers. Because network adequacy requirements rely on a geographic component that is not relevant for telehealth services, and because the network adequacy requirement for providers of in-person services is applied independent of whether plans voluntarily offer additional telehealth benefits, the network adequacy requirement should continue to be based only on providers offering in-person services.
- It may be appropriate to allow plans to offer different cost sharing for certain Part B services offered in person and via telehealth, but CMS should ensure that access to in-person services is not made prohibitive by the differential cost sharing. When a telehealth option is available, differential cost sharing can be discriminatory if it imposes an undue financial burden on beneficiaries who choose to receive care on an in-person basis rather than through telehealth. The agency could identify discriminatory cost sharing by evaluating the change in cost sharing amounts over time. For example, in-person cost

sharing could be discriminatory if there is a large increase from one year to the next that coincides with the addition of a telehealth benefit for the same service, or if in-person cost sharing increases while telehealth cost sharing decreases for the same service over time.

- As proposed, CMS should require plans to disclose additional telehealth benefits through the EOC and to differentiate providers offering in-person and telehealth services in its provider directory. It is important for plan enrollees to fully understand the scope of all benefits and to maintain access to in-person services covered under the original Medicare benefit.

Finally, CMS should require all MA plans to have a contract with telehealth providers, and to use the contract to enforce provider selection and credentialing requirements, as well as state licensing requirements. Without a contract, it is unclear exactly how these requirements could be enforced or how a plan could ensure that an enrollee receives appropriate care through out-of-network telehealth. Furthermore, we do not believe the Medicare program should pay for services (directly or through MA plans) without ensuring that the appropriate requirements are met. These concerns do not vary by plan type, and thus we believe contracts should be required equally for all MA plans.

### **D–SNP provisions**

D–SNPs are MA plans that are intended to meet the distinctive care needs of beneficiaries who qualify for both Medicare and Medicaid (dual eligibles). D–SNPs differ from standard MA plans because they must limit their enrollment to dual eligibles, follow an evidence-based model of care that has been approved by the National Committee for Quality Assurance, and have state Medicaid contracts that meet certain minimum requirements.

### ***Integration requirements for D–SNPs***

The proposed rule would implement section 50311 of the Bipartisan Budget Act of 2018, which requires D–SNPs to meet additional standards for Medicaid integration starting in 2021. The legislation requires D–SNPs to meet one or more of the following three standards:

- *First standard:* The plan meets additional requirements (to be determined by the Secretary) to coordinate the delivery of long-term services and supports (LTSS), behavioral health services, or both. Under the proposed rule, these D–SNPs must notify states of admissions to inpatient hospitals and skilled nursing facilities (SNFs) for at least one group of high-risk enrollees, which will be specified by the state.
- *Second standard:* The plan either (a) meets the requirements of a fully integrated D–SNP (FIDE SNP) or (b) has a capitated Medicaid contract to provide LTSS, behavioral health services, or both. Under the proposed rule, the latter subset of D–SNPs would be defined as highly integrated D–SNPs (HIDE SNPs). Both FIDE SNPs and HIDE SNPs would have capitated Medicaid contracts, but the scope of those contracts would differ. FIDE SNPs must have contracts that cover a broad range of Medicaid services such as acute care,

primary care, and LTSS. The contracts for HIDE SNPs would be more limited: At a minimum, they would include coverage of LTSS or behavioral health services, but the range of services provided would not be as broad as for FIDE SNPs.

- *Third standard:* The plan belongs to a parent organization that sponsors a Medicaid managed care plan that provides LTSS or behavioral health, and the parent organization assumes “clinical and financial responsibility” for individuals who are enrolled in both plans. Under the proposed rule, plans would meet this standard if they are FIDE SNPs or HIDE SNPs and use aligned enrollment, which means that beneficiaries cannot enroll in the D–SNP unless they are enrolled in its companion Medicaid plan. The use of aligned enrollment ensures that all D–SNP enrollees receive their Medicare and Medicaid benefits from the same parent organization.

### *Comment*

The Commission supports the development of managed care plans that provide both Medicare and Medicaid services as a way to provide better-coordinated care to dual eligibles. However, we have long been concerned about the relatively low level of integration in many D–SNPs. In 2013, we recommended that Congress permanently reauthorize D–SNPs with high levels of integration while letting the authorization for all other D–SNPs expire.<sup>1</sup>

We recognize that CMS is obligated to implement the BBA provisions, but we believe that the proposed rule will do little to promote greater integration. In particular, we believe that the first of the new standards for integration—requiring D–SNPs to share information on inpatient and SNF admissions—will have a very limited impact. States can already require D–SNPs to provide this information, but it is our understanding that very few, if any, states do so. As a result, we believe that most states are unlikely to use the information to improve care coordination.

In addition, we believe that the use of aligned enrollment should be a requirement for D–SNPs that meet either the second or third standards for integration. The BBA’s first standard for integration should apply to plans that do not have capitated Medicaid contracts and thus do not provide any Medicaid services themselves, or perhaps have contracts that cover a very limited set of services, such as coverage of Medicare cost sharing. The statutory language for this standard thus focuses on ways that these D–SNPs can provide more information to the Medicaid program, instead of providing more Medicaid services themselves.

In contrast, the second and third standards for integration should apply to D–SNPs that also provide significant Medicaid services. The distinction between these standards would be based on the structure of their capitated Medicaid contracts. The second standard should apply to plans where states have signed capitated Medicaid contracts directly with D–SNPs and the D–SNPs provide Medicaid services. The third standard should apply to situations where states sign capitated Medicaid contracts with another legal entity (a Medicaid managed care plan) that is part

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<sup>1</sup> Medicare Payment Advisory Commission. 2013. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

of the same parent organization as the D–SNP. Under this arrangement, the D–SNP itself does not provide any Medicaid services, but another part of the plan’s parent organization does. This approach has become increasingly popular as more states develop Medicaid managed care programs for disabled and elderly individuals and require their Medicaid plans to offer companion D–SNPs.

We believe that the second and third standards describe D–SNPs with higher levels of integration than D–SNPs that meet the first standard. However, this greater integration only occurs if enrollees also receive their Medicaid services from the D–SNP or a companion Medicaid plan offered by the same parent organization. As a result, we believe that the use of aligned enrollment should be a requirement for both the second and third standards for integration. However, we agree with CMS that the use of aligned enrollment should be limited to situations that involve comprehensive Medicaid managed care plans (plans that Medicaid defines as managed care organizations instead of plans that provide more limited services and are defined as prepaid inpatient health plans or prepaid ambulatory health plans).

### ***Eligibility of partial-benefit dual eligibles for D–SNPs***

Partial-benefit dual eligibles are a subset of dual eligibles whose Medicaid coverage is limited to assistance with the Part B premium and, in some cases, Medicare cost sharing.<sup>2</sup> Partial-benefit dual eligibles can enroll in a D–SNP if the state authorizes it in its Medicaid contract with the plan, and 36 states (including the District of Columbia) currently allow it. In the proposed rule, CMS considered limiting the enrollment of partial-benefit dual eligibles in D–SNPs “since there are no Medicaid services that the D–SNP is integrating or coordinating on their behalf.” CMS decided against limiting enrollment for these beneficiaries but has asked for comments on this issue.

### ***Comment***

The Commission believes that D–SNPs can do little to promote greater integration for partial-benefit dual eligibles, and our analysis of person-level quality data from the Healthcare Effectiveness Data and Information Set<sup>®</sup> suggests that D–SNPs perform about the same as regular MA plans for this population. However, we have also found that D–SNPs are more likely than regular MA plans to provide extra benefits such as coverage of dental, hearing, and vision services. These extra benefits may be attractive for some partial-benefit dual eligibles, particularly those who are qualified Medicare beneficiaries and already have their Part A and Part B cost sharing covered by Medicaid.

The Commission examined the eligibility of partial-benefit dual eligibles for D–SNPs in its June 2018 report to the Congress and at its November 2018 meeting. The Commission discussed two potential ways of addressing this issue: (1) limit enrollment in D–SNPs to dual eligibles who qualify for full Medicaid benefits or (2) require MA plan sponsors to have separate D–SNPs (distinct plan benefit packages) for full-benefit and partial-benefit dual eligibles. Both options

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<sup>2</sup> Medicaid also pays the Part A premium for some partial-benefit dual eligibles who do not have enough work history to qualify for premium-free Part A coverage.

would make it easier to pursue greater levels of integration for dual eligibles who qualify for full Medicaid benefits, but the second option would enable partial-benefit dual eligibles to enroll in MA plans with the distinctive package of extra benefits that D-SNPs typically offer.

### **Modifications to the MA quality bonus program**

The notice proposes changes to the star rating system that determines eligibility for bonuses under the MA quality bonus program (QBP). The changes would affect how to determine cut points for the different star levels on the 5-star scale (that is, the threshold levels for assigning a star rating to a given measure result—for example, establishing a rate of 89 percent or higher as the cut point for a 5-star rating), and the degree to which cut points could change from year to year. The proposal includes revisions to some measures and announces the addition of other measures. The proposal also outlines the way in which special treatment will be accorded in the determination of star ratings for plans affected by “extreme and uncontrollable circumstances such as natural disasters.”

#### *Comment*

Because we recognize CMS’s desire to improve the star system as it is currently implemented, we have comments on specific issues in the proposal. However, we wish to reiterate the Commission’s principles with respect to quality incentive programs in Medicare, including the MA QBP.<sup>3</sup> Overall, quality measurement should be patient-oriented, encourage coordination, and promote delivery system change. The Commission asserts that Medicare quality incentive programs should use a small set of outcomes, patient experience, and resource use measures that are not unduly burdensome to report. In MA, it is also important to assess plan performance insurance functions. Medicare quality programs should give rewards based on clear, absolute, and prospectively set performance targets (as opposed to “tournament models,” under which entities are scored relative to one another). Some argue that tournament models may be necessary for new measures for which performance data do not yet exist for setting appropriate targets. However, CMS currently addresses this concern in the QBP and other quality programs by collecting and publicly reporting new measure results for a year or more before using them for payment, so historic data is available to set performance targets. The Medicare program should also take into account, as necessary, differences in an entity’s patient population, including social risk factors. Because adjusting measure results for social risk factors can mask disparities in clinical performance, Medicare should account for social risk factors by directly adjusting payment through peer grouping.

#### ***Determining cut points for existing measures and new measures***

The proposal includes various refinements to the star system to achieve “stability, predictability, attenuation of the influence of outliers, [and] restricted movement of the cut points from 1 year to the next.”

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<sup>3</sup> Medicare Payment Advisory Commission. 2018a. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.

For existing measures, CMS would use the current clustering algorithm that assigns measure results to each of the 5 star levels, but the clustering algorithm would be applied 10 times to 10 sets of contracts. Contracts would be randomly assigned to 10 equal groups. The cut point computations would be repeated 10 times, but in each iteration one of the 10 groups would be omitted. The final cut points would be the average of the 10 sets of cut points. This approach somewhat reduces the influence of outliers; for example, in at least one of the 10 iterations, the contract with the lowest result for a given measure would be excluded from the computation of cut points.

For new measures, CMS would continue to use the current “tournament” method of determining star cut points for the first three years of the measure’s use. That is, the clustering would be applied once to the measure results to determine star cut points.

CMS also proposes placing upper and lower limits (“guardrails”) on how much a star cut point can change from one year to the next. For measures that are on a 100-point scale, the limit would be 5 percentage points. For other measures, the limit would be 5 percent of a level that excludes upper-range and lower-range outliers.

#### *Comment*

As previously stated, the Commission asserts that Medicare quality programs should not use “tournament models” under which MA plans are scored relative to one another; rather, Medicare should assess plan performance relative to clear, absolute, and prospectively set targets. Plans should know ahead of time what performance they need to achieve on each measure to receive a certain payment adjustment. At the same time, rewards should be distributed based on a continuous scale (i.e., without payment “cliffs”), so that plans with similar performance will receive similar financial rewards. Based on their performance on quality metrics, plans could earn a specific number of points set by a continuous scale. This scale could stretch over almost the entire distribution of performance, giving even top-performing plans an incentive to continue to improve on a budget-neutral basis. To control for outliers, the continuous scale could be set to exclude tails of the distribution (for example, the scale is set at the 2nd percentile of plan performance (0 points) to the 98th percentile of plan performance (10 points)).

Within the existing framework of the current MA quality bonus program, from our own analyses and from discussions with the industry, we are aware of concerns about the influence of outliers on star cut points and concerns about the variability of cut points from year to year. These are issues that should be addressed to improve the system that is currently in place, as CMS is proposing. However, what CMS is proposing is complicated and only minimally resolves the outlier concern. For example, if, for a given measure, one contract has a very low rate and is the only 1-star contract under the current clustering method (as was true of the readmission measure in 2018), the low-performing contract under the proposed method would be excluded from 1 of the 10 groups. However, the low-performing contract could continue to be the sole 1-star contract in the remaining nine groups. The average value of the 1-star threshold would be the average of the extremely low rate, represented nine times, and one other rate from the clustering algorithm that

applies to the set of results that excludes the very low result. An alternative is to simply remove outliers from the measure results when applying the clustering algorithm.

With regard to the proposal to use guardrails, as stated previously, we believe that a star cut point should not be lower than it was in the preceding year.<sup>4</sup> That is, the guardrails should not be bi-directional, as proposed.

### ***Changes to the hospital readmission measure***

The National Committee for Quality Assurance (NCQA) has made changes to the readmission measure to exclude “individuals with high frequency hospitalizations” and to add observation stays to the definition of inpatient admissions. In addition to these changes, CMS proposes to raise the minimum number of admissions for the denominator for this measure from 10 to 150 and to include the under-65 population in the measure. As a result of these changes, the measure will be removed as a star measure for one year but will continue to be publicly reported. For the following year it will be restored as a star measure with a weight of 1 (versus the current weight of 3), and the year after that its star measure weight will be restored to 3.

### ***Comment***

We support raising the minimum denominator for the readmissions measure. The current standard of at least 10 admissions has resulted in very high or very low star ratings assigned to contracts based on a small number of admissions (for example, the sole 1-star contract in the 2018 star ratings had only 24 admissions, and 6 readmissions). This, in turn, has had an effect on other contracts and their placement in different star categories when a tournament model is used.

We also support the inclusion of the population of Medicare beneficiaries under age 65 because the change holds plans accountable for the care provided to more of the Medicare population. We also understand that removing beneficiaries with frequent hospitalizations from the measure calculation was done because the current clinical risk-adjustment model may not accurately predict the risk of readmission for this high-needs population. However, in removing this population from the readmission measure, CMS should develop a measure or set of measures to continue to hold plans accountable for the care provided to this high-needs population to ensure they are working to improve the quality of care for this population.

### **MA risk adjustment data validation provisions**

A significant portion of payments to MA plans relies on diagnoses that plans submit to CMS. Risk adjustment data validation (RADV) audits are necessary for ensuring payment accuracy in every payment year by holding plans accountable for submitting accurate data that conform to program rules.

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<sup>4</sup> Medicare Payment Advisory Commission. 2018. Letter to Seema Verma, MPH, RE: CMS-4182-P, January 3.



The Secretary proposes to implement a method of conducting RADV audits and calculating overpayment recovery amounts that is similar to the method described in a 2012 memo.<sup>5</sup> Contract-level audits will be conducted on approximately 30 contracts per year and will use a sample of 201 enrollees with at least 1 reported hierarchical condition category (HCC) (i.e., a group of related diagnosis codes used in risk adjustment), Part B enrollment for the full data collection year, continuous enrollment in the contract for the full data collection year and January of payment year, and no ESRD or hospice status. The sample will include 67 randomly selected enrollees from each of three risk score strata (low, medium, and high). For each beneficiary, CMS will calculate a disease score (i.e., the portion of a risk score based on HCCs) error rate, which represents the share of payments that were based on diagnoses submitted for payment, but found to be unsupported by evidence in the medical record.<sup>6</sup> The payment error rate for a contract will be defined as the lower 99<sup>th</sup> percent confidence interval of beneficiary-level error rates in the sample. The overpayment recovery amount will be the payment error rate for the contract extrapolated to the total payment for the contract.

In the 2012 RADV methods memo, CMS stated it would apply a fee-for-service (FFS) adjuster to the overpayment recovery amount based on the expectation that an audit of FFS diagnoses would show downward bias on MA risk scores (i.e., if only the FFS diagnoses with medical record support (rather than all FFS diagnoses) were used to calculate HCC coefficients, MA risk scores would be larger).<sup>7</sup> If downward bias on MA risk scores existed, applying a FFS adjuster to offset the bias would reduce overpayment recovery amounts that plans would be required to return to CMS. However, CMS conducted a study of FFS diagnoses and concluded that unsupported FFS diagnoses introduce no systematic bias on MA risk scores.<sup>8</sup> In fact, the CMS study found an upward bias on MA risk scores of 0.1 percent. If CMS applied a FFS adjuster based on these findings, we would expect overpayment recovery amounts to increase by 0.1 percent.

The Secretary proposes not to apply a FFS adjuster, a departure from the method described in the 2012 memo. CMS states that the intention of the proposal is to strictly enforce program rules requiring evidence of each diagnosis in a patient's medical record, and that applying a FFS adjuster would counteract this rule. Furthermore, the agency relies on the study conclusion that

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<sup>5</sup> "Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits," February 24, 2012. <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/recovery-audit-program-parts-c-and-d/Other-Content-Types/RADV-Docs/RADV-Methodology.pdf>

<sup>6</sup> In the audit, diagnoses that were identified in the medical record, but that plans failed to submit for payment, are accounted for in the beneficiary-level error rates. Such diagnoses offset submitted diagnoses that were found to be in error (i.e., unsupported in the medical record). However, contracts cannot receive a payment as the result of an audit because contracts are required to submit diagnoses for payment. Therefore, diagnoses that are not submitted for payment, yet are discovered in the patient's medical record during an audit, cannot generate a new payment to a plan.

<sup>7</sup> The expectation that unsupported FFS diagnoses caused downward bias on MA risk scores was based on a flawed study. This study used a standard for determining errors in FFS diagnoses far stricter than the standard applied to MA plans under RADV audit. MA plans under audit are required to show beneficiary-level medical record support, meaning one medical record from any encounter with a valid provider at any time during the calendar year is sufficient.

<sup>8</sup> In the study, CMS audited FFS diagnoses, calculated new HCC coefficients based on corrected FFS diagnostic data, and compared MA risk scores based on corrected HCC coefficients with MA risk scores based on the original HCC coefficients.

there is no systematic bias on MA risk scores from unsupported FFS diagnoses. Applying a FFS adjuster based on the study results would have no overall impact on the overpayment recovery amounts calculated during RADV audits. Finally, the agency notes that even if systematic bias had been found, RADV audits would not be the appropriate venue to rectify the problem. If systematic bias existed, it would affect all MA risk scores and RADV audits only address a small number of contracts.

The agency also proposes to conduct sub-cohort audits of MA contract enrollees reported as having a certain HCC or set of related HCCs. For example, a sub-cohort audit could address all enrollees in an MA contract that were reported as having diabetes. For sub-cohort audits, the agency plans to apply a payment error rate and overpayment recovery amount method that is similar to the contract-level audits. Finally, the Secretary proposes to expand appeal rights for MA contracts under RADV audit.

### *Comment*

*Extrapolation.* We support the proposal to use extrapolation from a sample of contract enrollees because it strengthens the enforcement of data and payment accuracy. Extrapolation allows CMS to enforce accountability more broadly while limiting the burden of conducting audits for both the agency and plans. Concern about using a sample of enrollees is offset by the very high degree of certainty (i.e., a wide confidence interval around the average error rate) applied to the payment error rate for a contract, so that any overpayment recovery is based only on the portion of overpayments found to have 99 percent confidence. Furthermore, we note that extrapolation is used in audits of Medicare FFS claims, and audits of MA data should be treated similarly.

*FFS adjuster.* We support the agency's proposal not to apply a FFS adjuster to the calculation of overpayment recovery amounts and support all three agency rationales for the proposal:

1. Program rules require medical record evidence to support each HCC for risk adjustment. Applying a FFS adjuster would inappropriately weaken that requirement and would allow invalid data into payment calculations.
2. The agency found that diagnoses on FFS claims that lack medical record support (defined as an error) do not systematically bias MA risks scores. Therefore, application of a FFS adjuster would have no systematic impact on overpayment recovery amounts identified during RADV audits. Two factors highlighted by the study help in understanding the limited effect of FFS diagnostic errors on MA risk scores. First, unsupported diagnoses on FFS claims are very rare when applying a standard of medical record support similar to the RADV requirement.<sup>9</sup> MA plans under audit are required to show beneficiary-level support, meaning one medical record from any encounter with a valid provider at any time during the calendar year is sufficient. Commonly cited FFS diagnostic error rates (of 20 percent or

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<sup>9</sup> The standard of beneficiary-level medical record support that CMS applied for FFS diagnoses was stricter than the standard for MA plans. CMS looked at medical records linked specifically with claims that included a diagnosis code. MA plans can look at any medical record, linked to a risk adjustment submission or not, as long as the medical record comes from an encounter with a valid provider type.

more) are claim-level error rates, which assess only one medical record associated with the specific claim. Second, if HCC coefficients were based on corrected FFS diagnostic data (i.e., diagnoses without medical record support were deleted from the FFS claims), the risk adjustment model would attribute related Medicare spending to other variables in the model, such as demographic variables. The risk model allocates all FFS spending to variables in the model, so that removing a small number of unsupported diagnoses did not have a systematic impact on MA risk scores.

3. If unsupported diagnoses on FFS claims caused systematic bias for MA payments, RADV audits would not be the appropriate venue to rectify such a problem. Such bias would affect all MA risk scores, but only a small number of contracts undergo a RADV audit each year.

Finally, we note that the standard of medical record support used to assess FFS diagnoses in CMS's study considers only medical records associated with a FFS claim containing the diagnosis in question. Relying only on this set of medical records maintains a direct link from diagnostic evidence in the medical record to the related claim, as well as to the risk adjustment model. The requirement for medical record support applied to MA plans in RADV audits does not maintain a direct link. Under current MA rules, plans submit a diagnosis record that includes the date of the diagnosis and the type of provider making the diagnosis. RADV audits do not require that a diagnosis and the supporting medical record come from the same encounter (i.e., on the same date and with the same provider or provider type). For example, if a diabetes diagnosis was submitted based on an inpatient stay during the month of November, a medical record from a physician visit during January of the same calendar year could be used to support the diagnosis in a RADV audit. We suggest that CMS consider requiring medical record support for diagnoses to come from the set of risk adjustment records or encounters submitted by the plan for payment.<sup>10</sup> Such a requirement would more closely link medical record support for a diagnosis with the data used to pay MA plans.

*Sub-cohort audits.* We support the agency's plan to audit sub-cohorts of an MA contract to extend audit resources to additional contracts and to focus on HCCs with greater susceptibility to insufficient medical record support. For sub-cohort audits, we believe the agency should extrapolate from a statistically valid sample to the full sub-cohort population, but the agency should consider an alternate confidence interval formula when calculating the payment error rate. For contract-level audits, the confidence interval calculation is based on a point estimate of each beneficiary's disease score (i.e., the portion of a risk score based on HCCs) error rate. For audits of a single HCC or a hierarchy of related HCCs (of which only one can be identified for a beneficiary), the beneficiary-level error rate will be either 0 or 100 percent, as the outcome of the audit will find that the HCC was either supported or not. For sub-cohort audits, the agency should consider using the confidence interval formula for a proportion in error, rather than for a point estimate.

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<sup>10</sup> If a diagnosis was submitted several times from several different hospital and physician encounters, only one medical record from one of those encounters would be required.

The agency asked for comment regarding whether to stratify sub-cohort-level audits. We do not believe stratification is necessary as there is no variation in the extent of the audit across the sub-cohort population. Contract-level audits address disease scores, which can vary across beneficiaries. Stratifying the population in contract-level audits ensures that an equal number of low, moderate, and high disease scores are represented in the audit sample. For sub-cohorts, there would be no variation because the audit only addresses the presence of one HCC, or one of a set of related HCCs. Each beneficiary in the sub-cohort population has exactly one HCC under audit and a random sample of statistically valid size is a fair approach for this audit. Although we do not think it is necessary, the agency could consider two stratification methods if there is concern about the accuracy of sub-cohort audits due to the smaller sample size. Stratification based on the number of times the audited HCC was submitted for risk adjustment would ensure equal representation among beneficiaries with low, moderate, and high frequency of submissions. The presumption is that a beneficiary with several submissions of an HCC is more likely to have medical record support than a beneficiary with only one submission of the HCC. Alternatively, the agency could stratify by type of provider to obtain a representative sample of diagnoses from inpatient, outpatient, and physician provider types. We think either stratification method could improve the accuracy of sub-cohort audits, but we also note that the use of a wide confidence interval in determining payment error rates insulates MA contracts from overpayment recovery that is not statistically valid.

*Audit appeals.* The agency's proposal to expand audit appeal rights seems reasonable. We would support an appeal process similar to the one used in FFS overpayment recovery because the process lays out a specific timeframe and uses a third party to make a definitive determination.

## **Conclusion**

The Commission values the ongoing cooperation and collaboration between CMS and our staff on technical policy issues. We look forward to continuing this productive relationship. If you have any questions, or require clarification of our comments, please feel free to contact James E. Mathews, the Commission's Executive Director, at 202-220-3700.

Sincerely,

A handwritten signature in black ink that reads "Francis J. Crosson M.D." in a cursive script.

Francis J. Crosson, M.D.  
Chairman