March 5, 2018

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Submitted via www.regulations.gov

Re: Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 Draft Call Letter (CMS-2017-0163)

Dear Administrator Verma:

The Alliance of Community Health Plans (ACHP) appreciates the opportunity to comment on the 2019 Advance Notice and Call Letter.

ACHP is a national leadership organization bringing together health plans and provider organizations that are among America's best at delivering affordable, high-quality coverage and care. Members are non-profit plans active in 30 states and the District of Columbia, providing both private and public coverage to more than 19 million Americans, including 2.3 million Medicare beneficiaries. Six of the 14 5-star MA/PD plans are ACHP member plans, in addition to two 5-star, MA-only plans. Eighty-five percent of enrollment in 5-star plans is in plans offered by ACHP members.

We greatly appreciate CMS' commitment to providing regulatory flexibility and relief from outdated or burdensome requirements in this Advance Notice and Call Letter and in the previously proposed rule for MA and Part D. Proposals in both documents reflect recommendations that ACHP has previously offered and will facilitate the ability of plan sponsors to strengthen benefits that reflect the needs of their enrollees and administer coverage efficiently.

Summary

Before presenting detailed comments, we wish to highlight several issues and recommendations in the 2019 Advance Notice and Call Letter:

- **Restoring Quality Payments:** ACHP urges CMS to pay full quality bonuses created by Congress to ensure seniors receive the highest possible quality of care. Including quality payments in only

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the post-ACA benchmark calculation has reduced or eliminated quality incentive payments in half of all counties, affecting some 2.5 million seniors. The unintended consequence of the benchmark cap provision has been to undermine value-based care, disincentivize quality and diminish benefits to seniors worth tens of millions of dollars. In some areas, 4- and 5-star MA plans may receive the same payment as a 3-star plan, contrary to CMS' goal of paying for value. We continue to believe that the statute allows the Secretary discretion to exclude the quality payments from the benchmark cap calculation, as is done in other Medicare programs.

- **Improving Accuracy of the Benchmark Calculation:** While the issue is not directly addressed in the Advance Notice, ACHP urges CMS to revise its calculation of FFS costs. As the Medicare Payment Advisory Commission (MedPAC) has documented, Part A-only FFS beneficiaries have very different utilization and cost patterns from those who enroll in both A and B – and they are a growing segment of the FFS population. The result is that county MA benchmarks, driven by FFS costs, are lower than they would be if the appropriate comparison group were used – i.e., A/B enrollees. In addition, the current and proposed risk adjustment models are calibrated with FFS beneficiaries enrolled in Parts A and B. We believe that risk adjustment and MA payment rates should be based on the same population. ACHP asks that CMS recalculate the USPCCs, including ESRD USPCCs, and county benchmarks and state ESRD rates using A/B enrollees only.

- **Improving Drug Utilization Review Controls for Opioid Overuse/Misuse:** We applaud CMS' commitment to using its authority to address the nationwide opioid epidemic. ACHP is working with member plans to capture and disseminate best practices in prescribing and other approaches that can reduce inappropriate utilization. We will continue to work with the administration on this deadly crisis. We strongly support the proposal to incorporate a 7-day limit on opioid prescriptions for first-time opioid users – a practice already adopted by many ACHP plans in Medicaid and commercial coverage. We recommend that cumulative daily dosage edits at the point of sale would be more effective if plan sponsors are permitted to require that specific criteria are met before a hard edit may be overridden, beyond simply having the provider attest to the prescription's medical necessity.

- **Health-Related Supplemental Benefits**: ACHP supports the additional flexibility proposed in allowing health-related services to be covered as supplemental benefits. The expanded definition of supplemental benefits strengthens the ability of health plans to address the home environment and other factors affecting health status and provide care tailored to individual needs.

- **Star Ratings**: We appreciate CMS' commitment to quality improvement and the star ratings and welcome the plan to establish a Technical Expert Panel for future consultation on the ratings. Given our members' long commitment to superior performance, we ask that ACHP be invited to participate in the panel. We urge CMS to discontinue use of the improvement measures which distort the star ratings and are unnecessary given that the entire purpose of the ratings is to incentivize improvement. We support use of the Categorical Adjustment Index as an interim solution to address socioeconomic disparities but identify two problems that could be addressed by stratifying rates.

  Proposed Part C Risk Adjustment Model: ACHP appreciates development of the Payment Condition Count CMS-HCC model but recommends delay until 2020, in order for CMS and plan sponsors to analyze its potential effects and adjust to the revised HCC model. We recommend that the Part C risk adjustment models be updated with 2015 diagnoses and 2016 costs.

- **Employer Group Waiver Plans (EGWPs):** ACHP recommends that CMS continue to phase-in use of the individual bid-to-benchmark ratio to calculate the Part C base payment for EGWPs for the 2019 MA EGWP payment rates. Given the magnitude of the change, we recommend retaining the 50/50 blend of individual and EGWP bids for 2019, 75% individual/25% EGWP bids in 2020 and full transition in 2021.

- **Coding Intensity Adjustment:** ACHP is pleased that CMS will not increase the coding intensity adjustment beyond the statutory minimum of -5.91 percent. We recommend that future adjustments differentiate among plans according to coding patterns as MedPAC has proposed.

- **Normalization Factor:** ACHP encourages CMS to calibrate the Part C risk adjustment models with 2015 diagnoses and 2016 costs so that the FFS normalization factor is 1.000 for the year 2016 rather than 1.000 for 2015, resulting in a more accurate forecast of the normalization factor.

Section-by-Section Comments

Our comments are organized in the order that issues appear in the Advance Notice and Call Letter. We would be happy to answer any questions or provide assistance.

Attachment I. Preliminary Estimate of the National Per Capita Growth Percentage and National Medicare Fee-for-Service Growth Percentage for Calendar Year 2019

Sections A and B. MA Growth Percentage and FFS Growth Percentage (p. 6)

Develop USPCCs Using the Costs of FFS Beneficiaries Enrolled in Parts A and B**:** ***ACHP recommends that the USPCCs (aged plus disabled) that determine the MA growth percentage and the FFS growth percentage should use only the costs of the FFS beneficiaries enrolled in both Medicare Parts A and B***. As MedPAC has documented, including the A-only FFS population in the USPCC distorts these estimates because of this population's lower utilization and costs.[1] Because MA enrollees all receive both Part A and B services, we believe that the USPCCs used to determine the MA payment rates should be an apples-to-apples comparison to FFS enrollees. We believe that CMS should be consistent in its calculations of costs for the FFS population: the Part C risk adjustment models are constructed using FFS enrollees in both A and B. ACHP also recommends that the ESRD USPCCs that determine the ESRD payment rates should use only costs of the FFS beneficiaries enrolled in both Medicare Parts A and B. (We also address this issue under Section B, related to FFS costs.)

Attachment II. Changes in the Part C Payment Methodology for CY 2018

Section A.3. Quality Bonus Payment Percentage: Contract Consolidations and QBP (p. 12)

ACHP appreciates that CMS addressed the issue of contract consolidation in the proposed rule (CMS-4182-P) and that Congress has directed CMS to implement a solution. The effects of consolidation are particularly egregious when contracts are in distinct geographic areas and have different star ratings. This practice not only costs the Medicare program, it reduces plan comparability related to quality and

[1] Medicare Payment Advisory Commission, http://medpac.gov/docs/default-source/reports/mar17_entirereport224610adfa9c665e80adff00009edf9c.pdf?sfvrsn=0, ch. 13

undermines the quality system by sending inaccurate signals to beneficiaries when they choose plans. Contract consolidation has made it increasingly difficult for community-based health plans to benchmark their performance against competitors and differentiate to consumers their sustained and superior performance.

ACHP supports the now mandated approach to assign ratings based on the enrollment-weighted mean of the measure scores of the surviving and the consumed contract(s), for the first two years after consolidation. This will provide a more accurate picture of the performance of the underlying contracts both for beneficiaries when they evaluate choices and for the calculation of quality incentive payments. If CMS has flexibility in the future, we suggest as an alternative MedPAC's proposal to calculate star ratings based on the pre-consolidation configuration.[2] In a sense, the MedPAC approach is more conservative; it would "freeze" star ratings of consolidated contracts at the rating of each contract before they were combined, whereas CMS' model could potentially change star ratings, depending on the results of averaging.

Section A.5. Cap on Benchmarks (p. 13)**:**

ACHP urges CMS to reverse the substantial losses affecting 2.5 million seniors from implementation of the benchmark cap that has reduced or eliminated quality incentive payments. The unintended consequence of the benchmark cap provision has been to undermine value-based care, disincentivize quality and diminish benefits to seniors worth tens of millions of dollars.

The previous administration interpreted the law in a way that is contrary to Congressional intent, denying Medicare benefits to seniors who enrolled in high quality plans specifically so they could take advantage of enhanced benefits. This decision has reduced or eliminated quality payments to plans in about half the nation's counties, affecting 2.5 million beneficiaries. In some areas, 4- and 5-star MA plans may receive the same payment as a 3-star plan, contrary to CMS' goal of paying for value. According to MedPAC's March 2016 Report to Congress, the cap reduced county benchmarks by an average of $480 annually – and that figure increases annually.[3] The benchmark cap interpretation has also limited the effects of CMS' initiative to account for the effects of high enrollment of dual eligibles on star ratings, as achieving a 4-star rating will do little if the plan with high numbers of dual eligibles is in a capped county.

We believe that the statute allows the Secretary discretion to exclude the quality payments from the benchmark cap calculation, as is done in other Medicare programs. Please note that we do not support elimination of the benchmark cap, but rather removing the quality payments from the calculation in which pre-ACA benchmarks are compared to post-ACA benchmarks. We have previously shared our legal analysis with CMS and would be glad to provide another copy.

Section B. Calculation of the Fee for Service Cost (p. 15)

County benchmarks should be calculated based on the costs of the FFS beneficiaries enrolled in Medicare Parts A and B. ACHP supports excluding the costs of the Part A-only FFS beneficiaries from the county benchmark calculation. MedPAC notes that Part A-only enrollees currently represent 12

[2] Medicare Payment Advisory Commission, staff presentation for pending Report to Congress, http://medpac.gov/docs/default-source/default-document-library/ma_jan-2018-rev-public.pdf?sfvrsn=0
[3] Medicare Payment Advisory Commission, http://medpac.gov/docs/default-source/reports/march-2016-report-to-the-congress-medicare-payment-policy.pdf?sfvrsn=0, ch. 12

percent of the FFS beneficiaries and that this population is increasing. The share of A-only FFS beneficiaries varies by county, especially in counties with large numbers of federal retirees, and could have a large impact on a county's benchmark. Given continuing growth in MA enrollment, there are increasing numbers of counties in which MA penetration is greater than 50 percent or will soon reach that level. As MA penetration continues to increase, the FFS costs in those counties will be based upon a disproportionate share of Part A-only beneficiaries. As a result, without a correction, the county benchmark calculation will be distorted in representing FFS costs used for payment to MA plans that include enrollees who must be covered for both Parts A and B services.

We believe that the county benchmarks should be based on a population with similar characteristics to that of the MA population. CMS handles risk adjustment in this manner. CMS excludes Part A-only FFS beneficiaries from the calibration of the risk adjustment models because of their different utilization and costs from the A&B population. The county benchmarks used in the MA payment formula are risk adjusted by a RA model incorporating the diagnoses and costs of Parts A and B FFS beneficiaries. We believe these two components of the payment formula should be handled consistently.

ACHP recognizes there are several issues that CMS will have to consider. Among them are: whether to recalculate the geographic indices of the past five years based on the new methodology; whether or not to phase-in the change and, if so, over what time period; the effect on the benchmark quartile into which the county falls; and the effect on "double bonus" counties.

Release of the 2016 FFS cost data by county to be used in the development of the 2019 ratebook. ACHP appreciates the release of the 2016 FFS cost data by county at the time of the Advance Notice. This will provide significant assistance to MA plans in forecasting the impact of rebasing.

We recommend that CMS/OACT take this data release one-step further. We request that CMS calculate 2019 county FFS cost benchmarks using this 2016 county FFS cost data and preliminary update of the USPCCs at the time of the Advance Notice. CMS would make it clear that these are early estimates of the county benchmarks and have not been updated with the latest 2019 adjustments to the historical FFS costs. Also, the county's AGA would be adjusted by the current risk score model, not any proposed updated RA model. We recognize that these numbers could still change significantly from the Advance to the Final Notice, but the preliminary estimates would assist plans in forecasting contract year revenues and facilitate development of premiums and benefits for the bid at a much earlier stage than in the past.

Rebasing Frequency. We suggest that CMS consider not rebasing every year. Stability and predictability of payment are important attributes of any payment system. This is of particular importance for more highly integrated systems, such as many ACHP member health plans, given the capital requirements for medical centers and physician practices. After a year in which CMS does not rebase, OACT could use a 6-year (instead of a 5-year) average of the geographic adjusters to reduce the instability of the county benchmarks. When there are material changes after re-basing, we suggest that CMS use a phase-in approach.

Section B1. AGA Methodology for 2019 (p. 19)

CMS notes: "As in prior years…the average of the five year geographic indices, based on the adjusted claims data, will be divided by the county's average five-year risk score from the 2019 risk adjustment model in order to develop the AGA for the county."

When CMS recalibrates or proposes new Part C risk adjustment models, ACHP recommends that CMS provide information on the changes in county FFS risk scores as a result of these new models. For 2019, CMS proposes a blend using 75 percent of an updated 2017 CMS-HCC model and 25 percent of the 2019 Payment Condition Count CMS-HCC model. It would be very helpful if CMS would address questions including: How much county FFS risk score variation occurs if this blend is implemented, e.g., a range of -10 percent to +5 percent? Do most counties see only minor change in risk scores from the change? How large a change in county risk scores occurs where there is large MA membership? What is the average impact to county risk scores if 100 percent of the county's risk score is calculated with the 2019 Payment Condition Count CMS-HCC model and the other HCC models?

Section G. MA Employer Group Waiver Plans (p. 25)**:**

Given the significant impact of fully implementing the individual bid-to-benchmark ratio, we recommend that CMS lengthen the transition. We suggest that the 50/50 blend of the individual and EGWP bid-to-benchmark ratios remain in place for 2019. This would recognize that EGWP plans must meet current contract requirements with employers. It would also allow for implementation of CMS' proposal, which we support, to determine the bid-to-benchmark ratios to account for the proportion of EGWP members that are enrolled in HMOs and PPOs. We also support CMS' proposal to continue to waive the requirement for MA EGWPs to allocate rebate dollars to any specific purpose for 2019.

Section H. CMS-HCC Risk Adjustment Model for CY 2019 (p. 30 and from Advance Notice Part 1)

Provisions of the 21st Century Cures Act affect the risk adjustment model by directing CMS to incorporate more diagnoses for chronic diseases in the Medicare population. ACHP supports this direction and recommends that CMS consider additional modifications. For example, pancreatic cancer and other cancers involve high costs in the treatment year but much lower costs in subsequent years, so that they are not accounted for in the current model. Treatment for substance use disorders may follow this pathway as well. Another challenge to the model is reflecting the health risks of new enrollees; their risk scores are excluded from the HCC model because of its prospective nature. We suggest that both of these challenges should be addressed through a hybrid concurrent and prospective model that better accounts for high-cost, but limited duration treatments and the health risks of the age-in enrollees.

Payment Condition Count CMS-HCC Model
ACHP appreciates development of the Payment Condition Count CMS-HCC model given the greater stability this model provides over the All Condition Count model. While the All Condition Count model may improve the accuracy of risk scores of MA members with more than 5 conditions, it comes at the expense of improving the accuracy of MA members with 5 or fewer conditions – a much larger segment of the MA population. The Payment Condition Count model focuses on the most clinically relevant HCCS. However, it appears that the model will increase risk scores for only a small proportion of enrollees – generally those with four or more HCCS – and decrease scores for individuals with fewer HCCs. There is also concern about the impact on risk scores of dually eligible beneficiaries.

We suggest that CMS begin phased implementation in 2020 to provide time for additional analysis of the model's impact by CMS and plan sponsors and allow MA plans time to adjust to other changes in the EDS model and continued improvement in EDS-reported data. We also recommend that the model should be calibrated using a full year of ICD-10 data; the more precise of ICD-10 diagnoses will allow greater differentiation of conditions in the model, improved coding, and more accurate predictive costs.

Use of More Current Data for Calibrating Part C Risk Adjustment Models
ACHP supports updating the 2017 model with more current data but, if time permits, we suggest that CMS use the most current data for the recalibration of all the models – 2015 diagnoses and 2016 costs. This issue is discussed further in Section I. Normalization Factors.

Adding New HCCs: Mental Health, Substance Abuse, Chronic Kidney Disease
ACHP supports addition of the condition categories for:

- Drug abuse, uncomplicated, except cannabis (HCC 56)
- Reactive and unspecified psychosis (HCC 58)
- Personality disorders (HCC 60)

We suggest that CMS consider the complication of potential legal limitations on information availability. State regulations regarding disclosure of information on mental health and substance abuse diagnoses may impose a disadvantage on MA plans with populations in states with more stringent requirements.

As noted above, drug abuse may fall into those diagnoses for which the largest treatment cost is in the year of diagnosis, with costs falling off in subsequent years. We support inclusion of HCC 56 in the model but suggest that CMS use a "concurrent" model for these types of conditions that would more appropriately recognize the pattern of costs.

ACHP recommends that CMS consider the inclusion of diagnoses for depression and Alzheimer's disease in future risk adjustment models. These are conditions that have a significant effect on the Medicare population and carry increased risk for other chronic conditions. Depression is associated with an increased risk of mortality from suicide and other causes such as heart disease and with other mental disorders (anxiety, substance use, eating disorders). Depression may also affect whether individuals adhere to treatment regimens for other conditions.

We support inclusion in the model of HCC 138, Chronic Kidney Disease, Moderate (Stage 3) but encourage CMS to study questions about the associated costs. The data below, from the US Renal Data System, indicate that Per Person Per Year expenditures for Stage 3 are more closely aligned with Stages 1 and 2, which are excluded from the model. Significant cost increases occur at later stages of the disease.

Figure 6.2
Overall per person per year spending for beneficiaries aged 65 and older, by CKD stage, and year, 2012-2015

	(a) Medicare fee-for service		(b) Medicare advantage		(c) Commercial	
Year	CKD stage	PPPY expenditures ($,in thousands)	CKD stage	PPPY expenditures ($,in thousands)	CKD stage	PPPY expenditures ($,in thousands)
2012	Stages 1-2	20	Stages 1-2	20	Stages 1-2	19
2012	Stage 3	21	Stage 3	21	Stage 3	21
2012	Stages 4-5	28	Stages 4-5	36	Stages 4-5	30
2013	Stages 1-2	20	Stages 1-2	20	Stages 1-2	17
2013	Stage 3	21	Stage 3	22	Stage 3	21
2013	Stages 4-5	28	Stages 4-5	38	Stages 4-5	30
2014	Stages 1-2	19	Stages 1-2	18	Stages 1-2	16
2014	Stage 3	21	Stage 3	20	Stage 3	19
2014	Stages 4-5	29	Stages 4-5	34	Stages 4-5	31
2015	Stages 1-2	19	Stages 1-2	17	Stages 1-2	18
2015	Stage 3	22	Stage 3	19	Stage 3	20
2015	Stages 4-5	29	Stages 4-5	31	Stages 4-5	33

Data Source: Medicare 5% sample and Clinformatics™. Abbreviations: CKD, chronic kidney disease.

As CMS points out, patients with CKD Stage 3b have more advanced illness, require more aggressive treatment, and are likely to incur significantly higher costs than patients with Stage 3a. However, there is no HCC that distinguishes between the two stages to allow differentiation in the risk adjustment model.

Section I. ESRD Risk Adjustment Model for CY 2019 (p. 30):

ACHP recommends the recalibration of the ESRD risk adjustment model in light of provisions in the 21st Century Cures Act allowing all Medicare beneficiaries with ESRD to enroll in MA plans beginning in 2021. An important component of the ESRD RA model that is missing from the proposed calibration is an update to the methodology that accounts for the costs of first-year ESRD MA members. We suggest that CMS develop a concurrent RA model rather than a simple demographic model for risk adjusting new ESRD MA members. These high-cost ESRD members often have multiple conditions in their first year of eligibility for ESRD or when newly enrolling in a MA plan. A demographic model poorly predicts the high costs of these first-year members, and it can take only a few incorrect payments for this very high-cost population to affect the overall financial results of a MA plan. This is another reason why we urge CMS to develop a hybrid concurrent/prospective model rather than rely only on the prospective model.

Section K. Medicare Advantage Coding Pattern Adjustment (p. 35):

ACHP supports updating the coding intensity adjustment by no more than the statutory minimum.

CMS has asked for feedback on three potential approaches to developing a coding intensity adjustment. As an overall guideline, we ask that CMS treat coding adjustment differentially across contracts rather than applying a single adjustment to all. As MedPAC pointed out in its March 2016 Report to Congress:

> Our finding that coding intensity varies across MA contracts is consistent with other research. Given this variation, CMS's across-the-board adjustment for coding intensity, which reduces all MA risk scores by the same amount, generates inequity across contracts by disadvantaging plans with lower coding intensity and allowing other plans to retain a significant amount of revenue from higher coding intensity.[4]

We believe that MA plans that code conservatively should not be penalized for the coding practices of other plans. Whether it is the MedPAC proposal of dividing coding intensity into high, medium and low categories or another approach, ***we recommend that CMS implement an adjustment that differentiates among plans according to past coding experience***. If CMS were to apply the coding factor at the parent organization level rather than at the contract level, especially for initial implementation, it would reduce volatility in the coding adjustment from year to year.

In the normalization section of the 2019 Advance Notice, CMS released historical FFS risk scores for 2011 to 2017 under the 2017 CMS HCC model and the Payment Condition Count model. The FFS risk score trend seems to be increasing significantly in 2016 and 2017. We encourage CMS to study this phenomenon to better understand the coding differences between FFS and MA and why FFS risk scores are increasing at a faster rate than MA risk scores. We also note the potential decrease in MA risk scores from implementation of the EDS. ***We urge CMS not to calculate a new coding intensity adjuster until***

[4] Medicare Payment Advisory Commission, http://medpac.gov/docs/default-source/reports/mar17_entirereport224610adfa9c665e80adff00009edf9c.pdf?sfvrsn=0, ch. 13

there are more years of data and the FFS risk score trend, and FFS/MA differences, are better understood.

Because we believe that any 2019 or future MA coding intensity adjustment be based on the most current risk adjustment models and data available, we have significant concerns about the three models CMS is considering:

1. 2010 Advance Notice Proposal for MA Coding Adjustment

- The supporting data and details of the methodology used were not made available. This makes it impossible for plans to verify the findings as presented in the 2010 Advance Notice and to conduct independent analysis and validation of coding pattern differences. Given the substantial impact of the proposed adjustment on plan payments, we believe that these data should be shared well in advance of any adjustment to permit review and analysis by MA plans.

- The policy set forth in the 2010 Advance Notice represented a reversal of the treatment of the coding intensity issue described in both the Advance Notice for 2009 and the announcement of MA capitation rates and payment policies. In the 2009 final notice issued in April 2008, CMS concluded that "…we did not have available comprehensive information from medical records to support our hypothesis that risk score differences were driven by coding pattern differences, rather than by the health status of MA enrollees." At that time, CMS indicated that for 2010, the results from MA plan audits would be used to further inform the analysis of coding pattern differences, along with additional utilization data that would be collected. We assume that CMS did not move forward with this proposal because RADV audits and the collection of valid/reliable MA utilization data have been more difficult and resource-intensive than the agency originally anticipated.

- In the coding adjustment methodology, we note that CMS counts enrollees who were enrolled for at least 7 months in the prior year in the calculation of the Enrollment Duration Factor (EDF). ACHP believes a 12-month standard should be used for calculation of the EDF as a more accurate measure of "stayers."

- In the 2010 Advance Notice, CMS proposed to apply a three-year adjustment all in a single payment year, because no coding adjustment was made to payments in 2008 and 2009. We assume that any new calculation for future years would be a single year payment adjustment unlike what was proposed in the 2010 notice.

- If CMS were to undertake this methodology, it is imperative to incorporate 2016 and 2017 FFS data, given the unusual increase in risk scores during the past two years.

2. 2016 Advance Notice Proposal for MA Coding Adjustment

In the 2016 notice, CMS considered use of the old demographic variables of the AAPCC formula prior to 2000 to calculate a demographic factor for MA relative to FFS; that would have been compared to the ratio of risk scores between MA and FFS. ACHP's concerns with developing an MA coding adjustment based on the proposal in the 2016 Advance Notice are as follows:

- Significant questions would have to be addressed about the methodology CMS considered for computing a coding intensity adjustment. CMS indicated that payments "would be no greater

than the level of payment that would have been made if we were still using the variables in the adjusted average per capita cost (AAPCC) payment system that was in effect prior to 2000." This appears to place a cap on MA payments that is not authorized by the statute.

- The demographic factors used in the 2000 AAPCC formula are now, in 2018, outdated. CMS would have to update and develop a new risk adjustment model that is based solely on new demographic factors with no HCCs.

- CMS assumes that the difference between risk scores reported by a demographic model and by a diagnosis-based model is solely due to coding differences. But these two risk adjustment models each reflect inevitable inaccuracies in measuring the risk profile of different populations. In other words, "noise" may account for the risk score differences rather than coding

- If one were to eliminate the comparison between the demographic model and the HCC model and simply calculate an MA and FFS risk score under the same HCC model and compute the MA-to-FFS risk score ratio, what would the approach be measuring? Is it measuring coding intensity differences between these two populations or the *health status differences* between the two populations? Under the 2016 CMS proposed methodology, it is impossible to determine that the difference in risk scores is attributable to differences in coding intensity or in the health status of the two populations.

We have the following additional comments on factors considered by CMS in the 2016 Advance Notice::

- *Self-reported health status:* For patients in the traditional FFS program, and particularly in rural areas where access to providers may be a problem, chronic conditions may be underreported. With generally lower cost sharing in MA than in FFS, patients are more likely to access the health plan and be aware of their chronic conditions than do their FFS counterparts. Also, smaller practices in rural areas may not have implemented an electronic medical record; in MA and other settings where there is more likely to be an EMR, patients' understanding of their chronic conditions, and their self-reported health status, is likely to be better.

- *Mortality Rates:* Comparison of mortality rates is a flawed means to compare the overall illness burden of two populations for risk adjustment purposes. The overall purpose of risk adjustment is to predict the expected costs of different populations with different health status. The illness burden of a population is much more than simply the "mortality" rate of that population.

- *Part D Drug Information:* Prescription drug data have been used as a risk adjustment measure in commercial lines of business, but the data must be used in combination with other information. The accuracy of prescription drug RA models is greatly improved when inpatient and outpatient diagnoses are supplemented to predict future health care costs of a population. The problem of using drug information by itself is that the RA result would be skewed by use of brand name drugs. That is, a drug-only model would yield results suggesting that a patient using brand name drugs is at a higher acuity level than a patient with the same illness but using a generic drug. The problem is exacerbated by the fact that MD-PD plans have higher generic use rates than stand-alone Part D plans. Assuming a similar population between an MA-PD plan and a stand-alone plan, use of drug-only information would incorrectly result in a lower risk profile for the MA-PD plan due to the latter's higher use of generics.

3. MedPAC's March 2017 Report to Congress: Medicare Payment Policy Proposal for MA Coding Adjuster

We believe there is promise in the three recommendations from MedPAC to account for the impact of coding differences and improve the equity of the adjustment across MA contracts.[5] More detail would have to be provided in order to model the impact of the proposed changes.

- Develop a risk adjustment model that uses two years of FFS and MA diagnostic data. This would help to account for enrollees with high cost but short-term diagnoses for whom treatment costs may be high for a relatively short period and then decline significantly. It would also ameliorate the problem of capturing accurate risk scores for enrollees aging into Medicare, which currently are calculated using demographic factors alone.

- Exclude diagnoses in both FFS and MA coding that are documented only through health risk assessments (HRAs). We support efforts to reduce use of HRAs when there is no associated follow-up clinical care in person or via phone or other technology, as appropriate. When excluding diagnoses from health risk assessments, CMS will have to be cautious to ensure that none of the procedure codes on the claim indicate a medically necessary service equivalent to an evaluation and management (E&M) office visit. CMS should consider the following:
  - Claims and medical encounters with HRAs should not be excluded if they had a concurrent problem-based visit. A study in the *Journal of the American Medical Association* found that 44 percent of annual wellness visits had a billable concurrent procedure code on the same claim.[6]
  - Some MA plans provide annual physical exams (with no beneficiary cost sharing) in place of annual wellness visits.
  - E&M home visits should not be excluded unless there is clear evidence that (1) only one home visit was provided to the beneficiary during the year and (2) a health risk assessment or wellness visit may have been the only service provided. Medically necessary E&M home visits often focus on high-risk and older beneficiaries. Frequently, multiple E&M home visits occur for these beneficiaries during the year. In Medicare fee-for-service, stringent documentation is necessary to bill for these services and their diagnoses should rarely be excluded.

- Apply a coding adjustment that fully and equitably accounts for the remaining differences in coding between FFS and MA. MedPAC proposes grouping contracts into categories of high, medium, and low coding intensity and applying a codling adjuster based on the average level for each group. This approach reflects our recommendation above that CMS implement an adjustment that differentiates among plans according to past coding experience.

Section L. Normalization Factors (p. 36):

ACHP recommends that CMS include more years of historical FFS risk score data to smooth out the forecasted increase in FFS risk scores for 2019. It is possible that the large increase in the FFS risk scores for the two latest years is, in part, due to the conversion of ICD-9 to ICD-10, a one-time event. It is also possible that the introduction of MIPs-related payment under MACRA has an effect on FFS coding.

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[5] http://medpac.gov/docs/default-source/reports/mar17_entirereport224610adfa9c665e80adff00009edf9c.pdf?sfvrsn=0, ch. 13
[6] https://jamanetwork.com/journals/jama/fullarticle/2622010

We hope that CMS will re-analyze the data and provide information on factors that are driving the risk scores, and whether they are indicative only of short-term anomalies. Given the difficulty of predicting any significant trend change, use of additional years of data is warranted until CMS has more data to gauge the trend of FFS risk score increases.

ACHP encourages CMS to recalibrate the Part C risk adjustment models with the most current data available, 2015 diagnoses and 2016 costs. CMS suggests that the transition from ICD-9 to ICD-10 in 2015 has made data from that year unreliable. Our member plans believe the transition to ICD-10 generally went smoothly. Any drawbacks of using 2015 are more than offset by having more recent data in the new Part C risk adjustment models, so that the denominator year would be 2016 at 1.000 rather than 2015 as proposed in the Advance Notice. With a 1.000 normalization factor in 2016, one less year is needed to trend off the 1.000 factor, resulting in a smaller normalization factor for 2019. It is especially important that the forecast of the contract year's normalization factors be as up to date as possible because CMS does not correct for past years' forecasting errors.

If the timing is too late to recalibrate the 2019 Part C models with 2015 diagnosis/2016 cost data, ACHP encourages CMS to recalibrate the 2020 models so that the denominator year would be the year 2017. We prefer CMS update the Part C models every year going forward with the most current data until the Part C FFS normalization factor trend is further explained and understood.

Attachment VI. Draft CY 2019 Call Letter

Section I – Parts C and D

Enhancements to the 2019 Star Ratings and Future Measurement Concepts (p. 106)

ACHP appreciates CMS' commitment to quality improvement and the star ratings. We welcome CMS' plan to establish a Technical Expert Panel to provide feedback on the ratings framework, measures and methodology. As the organization that originally developed HEDIS measures and whose members have long been committed to superior performance, ACHP asks that we participate in this panel.

ACHP submitted extensive comments on star ratings issues included in the proposed rule for MA and Part D (CMS-4182-P). We offer the following additional comments on specific proposals in the call letter:

New Measures for 2019 Star Ratings

Statin Use in Persons with Diabetes (Part D)
We recommend that CMS treat this measure as a process measure with a weight of 1 after the initial year, rather than 3 as proposed. Compliance with the measure reflects on a single prescription fill and does not indicate ongoing adherence that would be necessary to reach clinical goals. The measure specifications for this and the Part C cardiovascular measure are very similar, and CMS indicates that the latter will be considered a process measure.

Statin Therapy for Patients with Cardiovascular Disease (Part C)
We note that this HEDIS measure is not based on medical record review, as indicated in the call letter, but on claims, and it focuses on medications dispensed, not prescribed. We agree with the treatment of this measure as a process measure, weighted at 1, but suggest that CMS consider keeping it as a display measure for another year to better understand performance on the measure.

Changes to Measures

Improvement Measures (Parts C and D)
ACHP addressed this issue in our comments on the proposed MA/Part D rule. ***We urge CMS to reconsider use of the improvement measures which are unnecessary and distort the star ratings for both health plans and consumers***. The entire thrust of the star ratings system and the quality payments is to incentivize improvement. A separate measure of improvement blurs the distinction between high-performing plans and others. Consistency and stability in performance over time should be rewarded more than improvement in any given year. ACHP believes that star ratings are more appropriately based on performance across the entire range of clinical, patient experience and administrative/compliance measures.

If the improvement measures are retained, we strongly recommend that they be reassigned a weight of no higher than 3. The "super weighting" of 5 that CMS created for these 2 measures alone introduces significant distortion in the weightings. We urge CMS to weight all measures within the 1/1.5/3 weighting system that it originally established.

MPF Price Accuracy (Part D)
CMS proposes to retain the current MPF measure in the 2019 star ratings and include the enhancements outlined in the call letter in the display measures for 2020 and 2021. We appreciate this approach and recommend that CMS incorporate sufficient leeway for sudden changes in drug prices – a common occurrence – that cannot be immediately updated in the plan finder.

Members Choosing to Leave the Plan (Parts C and D)
ACHP supports the additional exclusion to this measure for service area reductions that result in plan benefit packages (PBPs) becoming unavailable to eligible beneficiaries. ***We recommend that CMS add another exclusion to the measure: beneficiaries switching contracts within the same sponsoring organization***. These actions may not reflect negatively on the plan sponsor and, in fact, are likely to be the result of decisions that better meet the coverage needs of beneficiaries. As both the competitive landscape and seniors' needs and expectations change, plan sponsors develop new products to meet market demands. We believe that a beneficiary who switches between contracts may well be expressing a vote of confidence in the plan sponsor. Without knowledge of the individual circumstances, this action should not adversely affect star ratings.

Removal of Measures from Star Ratings

Beneficiary Access and Performance Problems (BAPP) (Parts C and D)
We appreciate that CMS has responded to recommendations that we and others have made on the BAPP measure and support its removal from the 2019 star ratings.

Data Integrity and Proposed Scaled Reductions for Appeals of IRE Data Completeness Issues
(p. 113 & 114)

ACHP recognizes the importance of accurate and reliable data for measures reported in the star ratings. We believe, however, that CMS' approach duplicates HEDIS auditing of measures. If a sponsor meets HEDIS requirements for accuracy of reported data, we do not think it necessary for CMS to duplicate the review of the same data reporting.

We also suggest that reductions in star ratings for data integrity errors blur the distinctions between quality measurement and compliance and audit activities. Compliance issues are already a component of the star ratings metrics. We believe that CMS' approach to data integrity reductions exposes MA plans to the double jeopardy of being penalized through audits and penalized again through the star ratings. CMS should maintain the focus of the star ratings on clinical quality and beneficiary satisfaction.

ACHP appreciates the proposal to scale the reductions for Part C and D appeals measures. Instead of an automatic reduction to 1 star, data from the Timeliness Monitoring Project and audits would be used to determine the scaled reductions, from 1 to 4 stars, and calculated separately for Parts C and D. We recommend that CMS makes its review and calculations available to plan sponsors so that they can better understand the findings.

2019 Star Ratings Program and the Categorical Adjustment Index (p. 122)

ACHP appreciates CMS' commitment to addressing the challenges faced by Special Needs Plans and plans with high enrollment of dual-eligibles in achieving high star ratings. We supported implementation of the Categorical Adjustment Index (CAI) in the 2017 plan year. CMS indicated at the time that it saw the CAI as an interim solution to the within-contract disparities in care that exist for the low-income subsidy (LIS) population and persons with disabilities (i.e., disabled beneficiaries). The CAI is separately applied to a contract's overall rating and Part C and D ratings – the magnitude of the CAI differs for each of these three adjustments. However, the index does not address which contracts actually provided better care to the LIS and disabled populations.

CMS has acknowledged that the index has resulted in a "modest movement" of the star ratings. However, the magnitude of the adjustment both positive and negative is expected to be about twice as large in 2019 as it is in 2018 and it could cause more contracts to lose star ratings. CMS has indicated its intent to work with measure stewards to update technical specifications so that star ratings measures reflect health needs of the SNP population. We are aware that PQA is considering risk adjustment for the three medication adherence measures and that NCQA is considering stratified reporting of four measures. We believe these and other longer-term efforts represent the fairest and most transparent path to achieving appropriate measures across the Medicare Advantage population. We urge CMS to continue to consider the CAI as an *interim* solution and work with stakeholders on more satisfactory options.

Potential Problems with CAI
As the CAI continues to grow, we have identified two potential issues with its application that we recommend CMS address:

1. The CAI assumes that the within-contract disparities for LIS and disabled enrollees are the same for all contracts. However, an MA contract with a relatively small percentage of LIS and disabled enrollees may provide better care to those enrollees than an MA contract with a relatively high percentage of LIS and disabled enrollees. In the hypothetical example in Table 1 below, Contract A has (1) better quality of care for the LIS and disabled population and (2) lower within-contract disparities. Nevertheless, the CAI penalizes Contract A and rewards Contract B.

Table 1. Hypothetical Example of the CAI Rewarding a Contract for Lower LIS/Disabled Scores and Larger Within-Contract Disparity

MA Contract	Population	Enrollment	Quality Scores			CAI Adjustment on Overall MA-PD Rating
			Annual Flu Vaccine	Diabetes Care: Blood Sugar Controlled	Readmission Rate (Reversed)	
Contract A	LIS or Disabled Population	2,000	0.89	0.92	0.91	−0.041117
	Non-LIS; Non-Disabled	8,000	0.91	0.92	0.92	Not Applicable
Contract B	LIS or Disabled Population	8,000	0.79	0.81	0.87	+0.113869
	Non-LIS; Non-Disabled	2,000	0.89	0.90	0.90	Not Applicable

2. As the CAI grows, it allows for more inconsistency among a contract's overall star rating and Part C and D ratings. While the current star rating measurement weights are intended to assign about two-thirds of the weighting to Part C measures, the application of the CAI now leaves greater possibility for overall ratings that were not intended to be mathematically possible (see Table 2 below). In the most extreme cases, the CAI can now reduce a contract's overall star rating from 4.0 to 3.5 but leave the contract's separate Part C and D ratings at 4.0. Conversely, the CAI can also increase a contract's overall star rating from 3.5 to 4.0 while its Part C and Part D ratings remain at 3.5.

Table 2. Hypothetical Example of CAI Misalignment of Part C, Part D, and Overall Rating

Contract	Rating Type	Pre-CAI Rating	CAI Adjustment	Post-CAI Rating
Contract A	Part C Rating	4	-0.041117	4
	Part D Rating	3.36	-0.017642	3
	Overall Rating	**3.78**	-0.031272	**3.5**
	Part C and D Weighted Average	**3.78**	--	**4**

ACHP Recommendation

ACHP supports measure-level adjustments to address the within-contract disparities for the LIS and disabled population. Rather than being measured based on the percentage of enrollees that are LIS or disabled, MA contracts should be measured on the relative quality of care provided. As a potential solution to addressing the within-contract differences in care for the LIS and disabled population, we recommend that CMS leverage NCQA's recommendation of stratifying rates of LIS and disabled beneficiaries separately from other beneficiaries. For measures with meaningful disparities, one

possibility is to create two ratings for these measures: (1) a rating for enrollees that are either LIS or disabled, and (2) a rating for all other enrollees. If a MA contract has enough enrollees in the measure denominator to calculate a rating for both populations, the final measure rating would be an enrollee-weighted average (see example in Table 3 below).

Other possibilities to address socioeconomic effects include expanding the number of strata to separate LIS and disabled beneficiaries into mutually exclusive categories. We believe stratification would create an incentive for MA plans to increase enrollment of the LIS and disabled population and spur competition to provide better care among those populations. In the short term, we ask that CMS align the CAI adjustments so that the overall rating is mathematically comparable to the Part C and D ratings.

Table 3. Hypothetical Example of LIS/Disabled Stratified Star Ratings

MA Contract	Population	Enrollment	Readmission Star Rating	Overall Readmission Star Rating
Contract X	LIS or Disabled Population	2,000	4.5	4
	Non-LIS; Non-Disabled	8,000	4	
Contract Y	LIS or Disabled Population	8,000	5	5
	Non-LIS; Non-Disabled	2,000	4	
Contract Z	LIS or Disabled Population	2,000	4	4
	Non-LIS; Non-Disabled	50	N/A	

Validation Audits (p. 159)

ACHP appreciates and supports the proposed improvements to the validation audit process.

Plan Finder Civil Monetary Penalty (CMP) Icon or Other Type of Notice (p. 164)

ACHP does not support use of an icon or other notification of civil monetary penalty in the Medicare plan finder. We believe the plan finder should be used by beneficiaries to consider options based on cost and star ratings – and the star ratings already reflect a number of measures reflecting compliance with administrative requirements. Imposition of CMPs reflects the contractual relationship between CMS and MA plans, while the plan finder should help beneficiaries choose plans based on cost and quality Our concerns about use of an icon in the plan finder include:

- CMP's are often imposed in cases in which there have been limited instances of non-compliance. Often these instances of non-compliance have been corrected, or can easily be corrected, by the time the CMP has been imposed. An icon for CMPs would not distinguish between minor penalty amounts and significant penalties and could have a negative effect on a plan that is disproportionate to the underlying penalty they received.
- A typical beneficiary will not have the knowledge base to understand the background and implications of a CMS enforcement action. The icon could cause them not to consider and utilize information that provides a much more comprehensive view of the plan's quality.
- Displaying a CMP icon will disproportionately penalize plans selected for a Program Audit, given

that the majority of CMPs are issued as a result of audit findings.
- The icon is unnecessary as CMS posts audit results and enforcement action on its website where information related to plan performance can be accessed.

Audit of the Sponsoring Organization's Compliance Program Effectiveness (p. 165)

CMS is considering allowing plan sponsors that have undergone a program audit to treat that audit as meeting the annual compliance program audit requirements for one year from the date of the CMS program audit. ***ACHP appreciates CMS' responsiveness to concerns we and others have raised about the burden of multiple audits and encourages CMS to adopt this change***.

Section II – Part C

Meaningful Difference (Substantially Duplicative Plan Offerings) (p. 170):

CMS proposes to eliminate the meaningful difference requirement which requires that sponsors offering more than one plan in a given service area must ensure the plans are substantially different. The purpose of the requirement is to help beneficiaries identify differences among plans in order to determine which option provides the highest value at the lowest cost to address their needs.

ACHP supports retaining the meaningful difference requirement but recommends that CMS consider alternatives to relying on out-of-pocket costs for determining differences. We believe the requirement has served to clarify choices and reduce confusion. It acts to discourage potential gaming when a sponsor for example, eliminates a zero premium plan facing the need for a premium increase only to introduce a new, substantially similar zero premium plan.

Clarifying options for consumers is in the best interest of a competitively viable and strong MA market. One approach may be to allow MA sponsors to provide an actuarial attestation on the difference in actuarial value among choices. If the meaningful difference requirement is eliminated, we ask CMS to issue guidance as soon as possible for 2019 bids.

Total Beneficiary Cost (p. 171):

ACHP supports the proposed increase in the Total Beneficiary Cost (TBC) limit from $34 pmpm to $36 pmpm for 2019. The TBC limit may be an effective check where there is limited competition in the MA market. In response to CMS' request for comments for future years, we suggest that CMS consider elimination of the TBC limit in highly competitive markets, e.g., with 3 or more MA plans. In those areas, competitive market forces are likely to limit any MA plan from imposing significant premium increases or benefit reductions. For example, experience suggests that, in competitive markets, MA plans are highly reluctant to be the first to eliminate a zero premium plan.

Maximum Out-of-Pocket (MOOP) Limits (p. 174)

ACHP recognizes that a lower voluntary MOOP benefit helps the frailest and highest cost members. ***We encourage CMS to continue to incentivize MA plans to offer the lower voluntary MOOP***.

We recommend that CMS make changes to the MOOP values that will strengthen the actuarial incentives for MAOs to offer the voluntary MOOP. First, CMS could change the maximum copays between the two MOOPs on those service categories that have higher utilization by Medicare beneficiaries, e.g., primary

care physician, physician specialist, emergency care, and so on. At this time, these services have the same maximum copays under each MOOP. In considering which MOOP to offer as part of their overall benefit package, MA plans will take under consideration which MOOP offers service categories that will allow the plan to charge a higher copay that will result in a larger actuarial value of copayments (utilization multiplied by copays). A plan will be more likely to offer the Voluntary MOOP if the plan can charge a higher copay, for example, on primary care physician visits under the voluntary MOOP than under the mandatory MOOP because changing that copay results in a significant actuarial value. The more service categories that CMS differentiates between the MOOPs, especially for those services with higher Medicare utilization, the more likely an MA plan will choose to offer the voluntary MOOP.

Second, CMS could move to reduce the dollar difference between the MOOPs. It has been many years since either MOOP has changed from $3,400 or $6,700. Over time, we would encourage CMS to update the voluntary MOOP to a higher value while maintaining the mandatory MOOP at $6,700; an alternative is to update the mandatory MOOP at a lower trend. There are many alternatives for trending the voluntary MOOP. OACT uses the cost distribution of Medicare beneficiaries to currently set MOOP values. To better incentivize MA plans to choose the Voluntary MOOP, we suggest updating the limit by choosing among options such as: 1) USPCC increases; 2) actuarial value of Part A and B cost sharing; or 3) Medicare fee schedules. We would encourage CMS to trend the voluntary MOOP value by also rounding to the nearest $25 and rounding the mandatory MOOP by a smaller amount to ensure the differential between the MOOPs is reduced by a larger amount.

We believe these steps would provide a strong actuarial incentive for MA plans to move to the voluntary MOOP, a benefit that best serves the frail and high cost/high utilizing member.

Health-Related Supplemental Benefits (p. 182)

ACHP supports the additional flexibility proposed in allowing health-related services to be covered as supplemental benefits. These are defined as services that:

1) Diagnose, prevent, or treat an illness or injury
2) Compensate for physician impairments
3) Ameliorate the functional/psychological impact of injuries or health conditions
4) Reduce avoidable emergency and healthcare utilization

This expanded definition of supplemental benefits will strengthen the ability of health plans to address the home environment and other factors affecting health status and provide care tailored to individual needs. We ask that CMS issue further guidance as soon as possible so that MA plans can incorporate these benefits in their 2019 bids.

Medicare Advantage Uniformity Flexibility (p. 184)

ACHP supports the flexibility, previously announced in the proposed rule for 2019 (CMS-4182-P), that will allow MA plans to reduce cost sharing for certain covered benefits, offer tailored supplemental benefits, and offer lower deductibles for enrollees that meet specific medical criteria. We believe these are important steps forward to promote high value treatments and tailor benefits to the needs of subgroups of the MA population. We also recognize and support that plans must meet non-discrimination requirements in exercising this authority.

CMS will have to address a number of questions in further guidance, including:

- Potential beneficiary confusion if the lower cost share is reflected in the plan finder without being clearly identified as applying to only certain conditions. Cost shares associated with this proposal should not be displayed with the standard cost-sharing for the same service so as to clearly reflect that the lower cost sharing is separate from the cost sharing applicable to the standard benefits offered under the PBP.
- Reporting requirements which do not impose an undue burden such as those required by the Value-Based Insurance Design (VBID) demonstration.
- Guidance and examples of flexible benefit designs that CMS would consider discretionary.
- Ability of sponsors to provide information on reduced cost-sharing amounts and supplemental benefits and market to potential new enrollees as well as existing members.

We appreciate that CMS intends to set up a mailbox for questions and urge CMS to make its answers known to all plan sponsors. ***We also support CMS' decision (p. 185) to allow MA plans to vary supplemental benefits, in addition to premium and cost-sharing, for different segments of a plan's service area***.

Rewards and Incentives for Completion of a Health Risk Assessment (p. 186)

ACHP supports the proposed inclusion of completed Health Risk Assessments (HRAs) in a sponsor's Rewards and Incentives program. Our member plans have successfully used HRAs to identify member illnesses and potential health problems and arrange for follow-up visits with primary care providers or other follow-up care as appropriate. We appreciate that CMS recognizes the role of objectively designed assessment tools in the management of MA patients.

Section III – Part D

CY 2019 Formulary Reference File (p. 193)

CMS is analyzing the Part D utilization of current Formulary Reference File (FRF) drugs and indicates it will remove drugs from the FRF based on these results. CMS intends to update the 2019 FRF in mid-to-late May, prior to the June 4 formulary submission deadline. While having an updated and accurate FRF is important, we note that the FRF is already missing several medications covered by Part D plans. Plans are accountable for paying for all Part D medications covered by definitions in Chapter 6 of the Medicare Prescription Drug Manual. Given that there are already several missing medications in the FRF and coding and maintenance are difficult challenges for plan sponsors, ***ACHP recommends against removal of medications from the FRF at this time***.

Improving Access to Part D Vaccines (p. 199)

CMS encourages Part D sponsors to offer a $0 vaccine tier or to place vaccines on a formulary tier with low cost-sharing. We agree with the goal of achieving greater vaccination rates but want to share our concern about the potential impact on the rest of the formulary. Plans are allowed only six tiers for their formularies. Using an entire tier for zero cost-sharing vaccines makes management of the rest of the tiered structure significantly more difficult. It would require a formulary management action plan to offset the costs to the plan of absorbing the vaccines' cost share amounts. Particularly for newer vaccines, costs can be substantial and Part D sponsors will have to analyze carefully the benefits and potential downside effects of CMS' recommended action.

Improving Drug Utilization Review Controls in Medicare Part D (p. 202)

We applaud CMS' commitment to using its authority to address the nationwide opioid epidemic. ACHP is working with member plans to capture and disseminate best practices in prescribing and other approaches that can reduce inappropriate utilization. We have previously shared some of these with the Department and will continue to work with the administration on this crisis. ACHP supports further changes to increase the effectiveness of tools such as utilization review and quality monitoring to reduce opioid misuse and abuse.

7-Day Limit for First Time Users

***ACHP strongly supports CMS' proposal to incorporate a 7-day limit on opioid prescriptions for first-time opioid users*.** Many ACHP members have moved ahead with appropriate prescribing strategies for the treatment of acute pain, including implementation of 7-day or similar limits in Medicaid and commercial coverage. We believe these limits can be implemented in Medicare, will help to reduce unnecessary use of opioids and can reduce excess products that find their way into the illegal drug supply. Further, because plans use similar limits across private and Medicaid products, the proposed limit would improve and increase alignment among products and enrollees.

Limits on High Cumulative Daily Dosage

***CMS should improve the effectiveness of limits on high cumulative daily dosage edits by including criteria for filling the prescription*.** ACHP has concerns with CMS' proposal to require sponsors to impose a hard edit at point-of-sale (POS) triggered when a beneficiary's cumulative daily dosage reaches or exceeds 90 mg MME. As CMS points out in the draft Call Letter, plans presently are expected to impose hard or soft edits at POS based on cumulative daily dosage. Soft edits can be at or above 90 mg per day and hard edits apply when cumulative dosage reaches or exceeds 200 mg MME per day. In its July 17, 2017 letter, CMS indicates that the Part D sponsor "only rely on prescriber attestation that the higher dosage is medically necessary to approve dosing that is higher than the hard edit when a coverage determination is requested."[7] Our plans' experience with implementing those edits has been mixed. The edits are useful for increasing awareness of potential misuse, but they have been ineffective in reducing prescribing at those high dosages.

Our member plans have found that these edits have dramatically increased resource needs and raised workload because of the additional staff needed to adjudicate the edits and obtain completed prior authorization forms with frustratingly little real impact on opioid prescribing. In our plans' experience, the edits rarely lead to a reduction in high-dosage prescription fills. We are concerned that imposing those edits at lower dosages under the Call Letter proposal would simply increase the administrative burden for plan sponsors without any real impact in prescribing practices.

To make those edits at POS more effective, we believe that ***plan sponsors should be permitted to require that specific criteria or requirements are met before a hard edit may be overridden***. Such processes would be considerably more effective in reducing misuse if there were criteria required of prescribers beyond simply having the provider attest to the prescription's medical necessity. Criteria could include requiring management by a pain specialist, requiring the physician and beneficiary to have a signed pain management agreement in place, having a treatment plan in place, or requiring that

[7] HPMS memo, July 7, 2017, Additional Guidance on CY 2017 Formulary-Level Cumulative Morphine Equivalent Dose (MED) Opioid Point-of-Sale (POS) Edit.

the clinician is actively monitoring the patient's use of opioids by attesting that he or she will be seeing the patient in clinic to evaluate pain needs within a set period of time (a week or a few weeks).

Other criteria could be based on CDC recommendations for prescribing opioids for individuals' chronic pain,[8] for example requiring the prescriber to attest that:

- The patient continues to need the opioid therapy because there is clinically meaningful improvement in pain and function that outweighs risks to patient safety;
- The patient is aware of the known risks and realistic benefits of continued opioid therapy at this level;[9]
- The prescribed dosage is the lowest effective dosage;
- The clinician has reviewed the patient's history of controlled substance prescriptions using the state's prescription drug monitoring program;
- The clinician is using urine drug testing to assess the patient's use of other prescribed medications as well as other controlled prescription and illicit drugs.

Challenges of Instituting Edits at Different Quantity Limits for Different Beneficiaries

CMS should prioritize edits at POS and provide guidance to plan on how to manage POS edits at different dosages. Under the proposed rules, plan sponsors would be expected to institute a hard edit at POS that would be triggered when a beneficiary's cumulative daily dosage reaches or exceeds 90 mg morphine milligram equivalent (MME). CDC guidance identifies 50 mg MME daily dose as a threshold for increased risk of overdose.[10] Some plans track use of 50 mg or more for first-time users. However, it is operationally challenging for plans to track quantity limits at multiple levels, for example – at 90 mg MME for chronic users and at 50 mg MME for new users. In light of this, we urge CMS to prioritize edits at POS and provide additional guidance to indicate how plans should manage the multiple types of edits necessary for safe and effective prescribing practices.

7-Day Temporary Supply

We recommend that CMS withdraw the 7-day transition supply component of the policy and instead allow plans to continue to apply their existing transition supply policies. We are concerned that the timeline is unlikely to be sufficient in many cases. Even though CMS has indicated that coverage determinations related to the high dosage edits meet the criteria for expedited review – which means a plan sponsor must issue a decision within 24 hours of receipt of the coverage determination request – all too often this timeline is not feasible. Sometimes prescribers respond slowly and other delays sometimes extend the timeline for a coverage determination. Many plan sponsors have a transition supply policy that is already in effect and that provides for a transition fill in excess of 7days. Plan sponsors should be permitted to retain those existing policies.

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[8] Dowell, Deborah, et. al., CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016, Centers for Disease Control and Prevention Morbidity and Mortality Weekly Report, March 18, 2016, https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm

[9] For example, the Veterans Administration requires patients to sign a consent form for long-term opioid therapy for pain. file:///C:/Users/hshapiro/Downloads/1005_D_2014-05-06.pdf. The VA also has begun publicly posting information on opioids dispensed from VA pharmacies. https://www.va.gov/opa/pressrel/pressrelease.cfm?id=3997

[10] CDC Guideline for Prescribing Opioids for Chronic Pain,

Beneficiary Notification

***ACHP recommends that beneficiaries should be notified when they become subject to a hard edit because of a high cumulative daily dosage*.** That notification should indicate why their prescription has been flagged and that they have been placed into a process requiring additional prescriber involvement. The notice should describe their rights to a temporary supply while their prescription is subject to review and should describe the timelines and the steps in the exemptions process. Notices should be clear and detailed, and should describe all the appeals options and processes to which the beneficiary has access. CMS may also consider including in such notification links to additional educational resources on opioid use and misuse.

Overutilization Monitoring System (OMS) Tracking of Potentiator Drugs

ACHP supports the proposal to begin OMS tracking of concurrent opioid and certain potentiator drugs, specifically gabapentin or pregabalin. We recommend OMS flags for other known potentiator drugs in addition to gabapentin/pregabalin: carisoprodol, zolpidem, zaleplon, and eszopiclone are also known to potentiate the effects of opioids and thus should be flagged. We also ask CMS to clarify whether it will allow sponsors to apply a restriction at the point-of-sale for potentiator drugs, including benzodiazepines.

Duplicative Long-acting Therapy and Quality Measures

ACHP supports CMS' proposals to require plan sponsors to implement a soft POS edit for duplicative long-acting opioid therapy and to incorporate a patient safety measure for concurrent use of opioids and benzodiazepines. We believe these efforts will improve prescribing and monitoring practices on opioids.

Guidance for Plan Sponsors and Provider Education Necessary

***We recommend that CMS provide guidance to plan sponsors that makes clear its expectations for managing cases of potential opioid misuse under the proposed policies and ensure that providers are educated regarding high daily dosages, duplicative prescriptions, and concurrent use of opioids with other products*.** As it has done in the past on opioids policies, CMS should provide guidance to MA/PD plan sponsors that identify its expectations for how plans should manage cases in which the new POS edits identify high dosages or duplicative long-acting opioid prescriptions, or in which OMS has detected concurrent opioid and potentiator drug use. In addition, given that clinicians are key to the successful implementation of the proposed utilization review and monitoring policies, we recommend improving provider education to ensure that all stakeholders understand the serious risk of high dosages, duplicative prescriptions and concurrent use of opioids.

Using the Best Available Information when making B vs D Coverage Determinations for Immunosuppressants and Inhalation Durable Medical Equipment (DME) Supply Drugs (p. 218)

New guidelines proposed by CMS for determining Part B coverage of a drug place the burden on Part D plans to locate information as to who covered the enrollee's transplant. Plans can be penalized if they incorrectly cover drugs that should have been covered under Part B. CMS also expects plans to default to covering immunosuppressants and Inhalation Durable Medical Equipment in instances where the plan has not received information from CMS (via MARx or otherwise) indicating that Medicare covered the transplant for the enrollee.

ACHP believes that these new guidelines have the potential to significantly shift costs from Part B to Part D and unfairly penalize Part D plans. It has been the experience of many of our plans that information concerning transplants is difficult to obtain and often incomplete. Most use of immunosuppresants has been covered by Part B. We are concerned that the new guidance will greatly increase instances of Part D covering a drug that should have been paid under Part B, with the required 20 percent cost share. This in turn will put a greater financial burden on Part D plans. ***We recommend that CMS delay implementation of this guidance*** and work with plans sponsors to better understand how plans receive information on covered transplants and develop safeguards to ensure that drugs are appropriately covered under both Parts B and D.

Thank you for consideration of ACHP's recommendations. If you have questions or require additional information, please contact Howard Shapiro, ACHP's Director of Public Policy, at hshapiro@achp.org.

Sincerely,

Ceci Connolly
President and CEO