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Kaiser Foundation Health Plan
Program Offices

March 5, 2018

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. 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 Call Letter***

Dear Administrator Verma:

Kaiser Permanente appreciates the opportunity to provide comments in response to the Advance Notice and draft Call Letter for CY 2019. As the largest private integrated healthcare delivery system in the U.S., Kaiser Permanente delivers health care to approximately 12 million members in eight states and the District of Columbia. Kaiser Foundation Health Plan, Inc., the nation's largest not-for-profit health plan, and all of our health plan subsidiaries either are Medicare Advantage Organizations (MAOs) or offer Section 1876 Cost plans, serving a total of more than 1.5 million Medicare beneficiaries.

I. GENERAL COMMENTS

In the following sections, organized in the order of the Advance Notice and draft Call Letter, we provide comments on a number of CMS' proposals. We would like to highlight a few key points:

- **Calculation of Fee-for-Service Cost:** Kaiser Permanente encourages CMS to adopt the Medicare Payment Advisory Commission's (MedPAC) recommendation to calculate MA benchmarks using fee-for-service (FFS) spending data only for those beneficiaries enrolled in both Medicare Part A and Medicare Part B. At present, CMS' approach results in distorted and inequitable payment rates across geographies and does not accurately reflect the costs of Part C coverage.

- **Revised CMS-HCC Risk Adjustment Model:** Kaiser Permanente prefers the Payment Condition Count model to the All-Condition Count model but we are concerned that only a small percentage of members, generally those with four or more HCCs, will have a condition count that results in a new positive risk score value, which does not seem consistent with the intent of the 21st Century Cures Act. We also believe the revised model should be calibrated using more recent data based on ICD-10 diagnoses.

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- **ESRD Rates and Risk Adjustment Model:** Given the likely increase in ESRD individuals enrolling in MA plans beginning with contract year 2021, we ask that CMS undertake an evaluation of the ESRD benchmarks and risk adjustment model to ensure plans are prepared to provide care for this high-need population.

- **Normalization Factors:** We request that CMS reevaluate the normalization factors and share with MAOs further explanation regarding what factors are driving the higher risk scores from 2015 to 2016. If CMS finds that the ICD-10 transition contributed to the large increase in the normalization factors, we recommend that CMS use additional data years to smooth the impact for 2019 and help maintain payment stability.

We appreciate CMS' consideration of these points and our more detailed comments below.

II. COMMENTS ON THE 2019 ADVANCE NOTICE

Attachment II. Changes in the Part C Payment Methodology for CY 2019

Calculation of Fee-for-Service Cost (Section B)

Kaiser Permanente supports the Medicare Payment Advisory Commission's (MedPAC) 2017 recommendation that CMS should calculate MA benchmarks using fee-for-service (FFS) spending data only for those beneficiaries enrolled in both Medicare Part A and Medicare Part B. Different areas of the country have different Original Medicare enrollment patterns, resulting in material distortions in the payment levels across geographies. The ultimate effect of not recognizing regional variation is to disadvantage the MA enrollees in the areas that have had and will continue to have lower local benchmarks due to the lower proportion of FFS beneficiaries in those areas who are enrolled in both Parts A and B.

For example, while the expected impact nationally of calculating FFS cost based on beneficiaries with both Parts A and B (as opposed to Part A only) is an increase in FFS per capita costs of 5.1 percent, certain states would experience significantly higher changes. Hawaii's average FFS cost would be expected to increase by more than double the national average (10.3 percent); Washington DC's FFS cost would be expected to increase 9.3 percent; Rhode Island's would increase by 8.4 percent.[1] Under CMS' current methodology, the FFS costs in these areas and others are significantly understated. At the county level, the differences would be even more inequitable. If CMS has not already undertaken an analysis of these disparities at the state or county levels, we encourage the agency to do so in order to fully understand the current inequity underlying the need to adjust the calculation methodology.

Basing the payment benchmarks for MA enrollees, who are enrolled in both Parts A and B, on the costs of those FFS enrollees who are enrolled in both Parts A and B is more accurate, more reasonable and *more equitable* than CMS' current methodology. CMS appears to agree that doing so would be more accurate for determining MA payments, given that the agency has undertaken

[1] Based on an analysis shared with CMS on October 19, 2017.

this approach for Puerto Rico for the last several years and notes that it was done "to produce a more accurate projection of FFS costs per capita."

ESRD Rates (Section D)

With the 21st Century Cures Act's repeal of the prohibition on beneficiaries with ESRD enrolling in MA, we believe it is likely that enrollment of ESRD individuals in MA plans will increase significantly beginning in 2021. While we believe MAOs are in a good position to provide ESRD individuals with high quality, coordinated care, we have concerns about the sufficiency of the ESRD benchmarks to cover MAOs' costs for this population and the potential for adverse selection. We request that CMS take steps to assist MAOs in preparing for higher ESRD enrollment, including evaluating the ESRD rates against dialysis provider payments in the commercial and MA markets and sharing as much data as feasible with MAOs to assist with bid development.

CMS-HCC Risk Adjustment Model for CY 2019 (Section H)

Kaiser Permanente appreciates CMS' consideration of options for implementing the 21st Century Cures Act requirement to take into account an enrollee's total number of diseases or conditions, but we have concerns about both options presented. We request that CMS share the other alternatives the agency considered for incorporating condition counts into the model, and their expected impact. Should CMS proceed with one of the options included in the Advance Notice, however, we believe the Payment Condition Count (PCC) model is preferable to the All-Condition Count option: the PCC model focuses on the most clinically relevant HCCs while the All-Condition model encourages increased coding of less clinically relevant conditions.

Under the Payment Condition Count model, we are concerned that only a small percentage of members will have an HCC count that results in a new positive risk score value – generally those with four or more HCCs – while risk scores will decrease for many enrollees with one, two or three HCCs. We do not believe this is the intent of the 21st Century Cures Act provision. Rather, the provision is intended to ensure more appropriate risk adjustment for individuals with progressively greater health needs given that the CMS-HCC model has historically underpaid for the most complex individuals.

Kaiser Permanente supports the reintroduction of Chronic Kidney Disease (CKD) level 3 and the addition of the chronic and care-intensive mental health and substance use conditions to the model, as these are clinically important conditions with impacts on the costs of care and management. As we noted in our comments on the 2014 CMS-HCC model, CKD is a chronic disease that requires close follow-up and clinical management and is also an indicator of future morbidity. CKD level 3 requires close attention to the use of certain medications and radiographic dye that may worsen kidney function, so there are increased costs of disease management and integrated care management activities that should certainly be reflected in the risk adjustment model. We believe the addition of CKD level 3 and the new mental health HCCs and substance abuse HCC will help improve the accuracy of payment under the CMS-HCC model.

Regarding the implementation date, we agree that CMS could use 2019 as an opportunity to test and gather feedback on the revised model. If CMS does this and chooses to make the model

permanent going forward, we recommend that CMS calibrate the model using a full year of ICD-10 diagnosis data for the 2020 payment year and beyond. CMS notes that the proposed model was calibrated using 2014 data predicting 2015 FFS costs because the transition to ICD-10 in 2015 would cause the coding in 2015 to be unstable for use in calibrating the model. Using ICD-10 based diagnosis data to calibrate the new model would allow for greater differentiation among conditions in the model due to the more precise nature of ICD-10 codes. Overall, better specificity in the codes will result in improved coding of clinically relevant codes and therefore improved predictive costs.

ESRD Risk Adjustment Model for CY 2019 (Section I)

Consistent with our comments regarding the ESRD benchmarks, we believe it is important that CMS ensure appropriate risk adjustment for the ESRD population given the likely inflow of ESRD beneficiaries to MA plans beginning in 2021. We request that CMS share as much information as possible about the ESRD model and trends to assist MAOs in preparing for this policy change, including sharing the regression model and CMS' rationale for inclusion of some conditions and not others.

For example, we find it inconsistent that CMS has not proposed to make adjustments to the ESRD model similar to those proposed for the CMS-HCC model to account for multiple HCCs and to include the new HCCs for mental health and substance abuse. The ESRD population is among the highest-need patient populations and has some of the highest health care costs. We expect that the HCCs that drive costs in the community model would also stand out in the ESRD model regression results and believe CMS should consider incorporating similar methodological and HCC changes.

Medicare Advantage Coding Pattern Adjustment (Section K)

Kaiser Permanente supports CMS' proposal to apply the statutory minimum coding intensity adjustment factor for 2019. We would have concerns about CMS implementing one of the alternative approaches given the lack of detail provided in the Advance Notice.

We find MedPAC's suggestion of applying the coding intensity adjustment stratified by low, medium and high coders interesting, but without details to model, is difficult to understand the impacts at the plan level. Regarding the option presented in the 2016 Advance Notice, we commented in 2015 that we believe it is inappropriate to cap MA plan payments based on demographic factors (age, gender, Medicaid, and institutional status), as would occur if CMS pursued that option. Under section 1853(a)(3)(C) of the Social Security Act, CMS is required to use a risk adjustment methodology that accounts for enrollees' health status. By adjusting payments using demographic-only factors, CMS would effectively be removing health status from the determination of plans' risk scores.

Given the complexity of the risk adjustment changes in the 2019 Advance Notice, we recommend that CMS maintain the minimum coding intensity adjustment required by law.

Normalization Factors (Section L)

Kaiser Permanente has reviewed the risk score trends over the last five years and we have concerns about the calculation of the normalization factors. We see that the 2016 FFS data point represents

an unusual change from 2015 – an increase of 1.4 percent – which is well outside the range of the year-to-year risk score changes from the last five years, ranging from -0.2 to +0.8. This large change from 2015 to 2016 is causing normalization factors for Part C and ESRD to be higher than we had expected as modeled using the linear model. We also share concerns raised by AHIP that the transition from ICD-9 to ICD-10 from 2015 to 2016 is a contributing factor not accounted for in CMS' calculation of the normalization factors. We request that CMS revisit and validate the data and calculation methodology, and provide further explanation regarding what factors are driving the higher risk scores. If CMS finds that the ICD-10 transition contributed to the large increase in the normalization factors, we recommend that CMS use additional data years to smooth the impact for 2019 and help maintain payment stability.

We also request that CMS provide transparency into the principles and guardrails used to guide the development of the normalization factors so that plan sponsors can better predict risk scores. For example, it would be helpful to understand more of the reasoning and technical factors behind CMS' selection of certain data years and calculation methodologies over others. We also request clarification regarding which HCC model and diagnosis-to-HCC mapping for both ICD-09 and ICD-10 are used to calculate the historical FFS risk scores. Providing insight into these factors will allow plan sponsors to better predict the potential impact of the normalization factors and help maintain stability in plan benefit design from year to year.

Encounter Data as a Diagnosis Source for 2019 (Section N)

Kaiser Permanente appreciates CMS' efforts to work with MAOs to remediate challenges with encounter data submissions (EDS). However, we remain concerned about increasing reliance on EDS while CMS is unable to close out past data submission years due to challenges with the MAO-004 reports and concerns about the accuracy of the EDS data. CMS also has observed a discrepancy between EDS and Risk Adjustment Processing System (RAPS) submissions of inpatient encounters. Given these ongoing challenges, we continue to believe that it is premature for CMS to base risk scores and, consequently, payments on EDS data.

Adding further complexity is CMS' proposal to phase in the new CMS-HCC model through the gradual incorporation of EDS data submitted under the new model. While we appreciate CMS' attempts at improving the risk adjustment model, adding more operational complexity so soon after transitioning to the six community segment model will be particularly burdensome. We also believe it will be very complex to add inpatient diagnosis from RAPS to enhance the inpatient diagnosis data store for EDS-based risk scores. With the significant complexity and instability in the risk model and its data sources, MAOs will have great difficulty projecting their risk scores to support their 2019 plan bids.

We request that CMS maintain the current blend of EDS and RAPS data and not take further steps to phase in EDS until the operational challenges have been resolved.

III. COMMENTS ON THE DRAFT CY 2019 CALL LETTER (Attachment VI)

Section I – Parts C and D

Enhancements to the 2019 Star Ratings and Future Measurement Concepts (pp. 106-157)

Changes to Measures for 2019

Medication Adherence for Cholesterol (Part D)

CMS proposes to concatenate consecutive stays to create a single admission and discharge date for the proportion of days covered, or PDC adjustment. While CMS is considering this change to the metric, we recommend that CMS also improve the metric by setting an upper limit of 75 years of age (to exclude ages 76 and up). This age cutoff would then align with the evidence and national guidelines on which statin recommendations are based. The current NCQA metric for statin use and statin adherence in persons with cardiovascular disease is through age 75 and does not include age 76 and up, with a similar age range for statin use/adherence in persons with diabetes. These metrics are based on American College of Cardiology (ACC) and American Heart Association (AHA) guidelines on treatment of blood cholesterol, which has strong statin recommendations through age 75 for four statin benefit groups.[2] In addition, the statin recommendations of the U.S. Preventive Services Task Force apply up to age 75, and not beyond, for statin recommendations in primary prevention.[3]

Members Choosing to Leave the Plan (Part C & D)

The CMS proposal suggests adding two additional exclusions meeting two specific Service Area Reduction (SAR) scenarios:

- The area reduced is part of non-Special Needs Plan (SNP) PBPs and the only PBPs remaining in the contract that cover the area are SNP PBPs.
- The area reduced is part of a SNP PBP and there are no non-SNP PBPs or another SNP PBP within the contract of the same SNP type that cover the area.

The 2018 Technical Notes already exclude "Members affected by a contract service area reduction" and we understand that exclusion to mean that all beneficiaries disenrolled due to any SAR should be excluded from the measure. We request that CMS clarify the intent of the new exclusions and provide information about their impact.

Data Integrity

With respect to Data Validation audit findings, we request that CMS provide detailed information in terms of which standards/sub-standards could potentially impact the star rating for the Special Needs Plan (SNP) Care Management Measure and the Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Reviews (CMR), and to limit the potential star ratings impact to those findings that are specifically related to the accuracy and quality of the SNP Care Management and MTM Completion Rate for CMR data reported.

[2] Stone, NJ et al, 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risks in Adults.
[3] See:https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/statin-use-in-adults-preventive-medication1

Because the scope of Data Validation audits covers the end to end reporting process, there are Data Validation audit standards (for all reporting measures) that address areas that do not directly impact the accuracy or quality of the data reported. For example, there are standards that focus on document headers and footnotes. It would be unreasonable for CMS to consider decreasing the performance on a star measure based on auditor feedback regarding document headers, footnotes, labels, etc. A finding based on such non-data accuracy standards does not necessarily imply a true data integrity issue (i.e., the underlying data reported may still be accurate).

We urge CMS to limit the stars impact to those data validation audit standards on which findings would correlate to a direct impact on the accuracy or quality of data reported to CMS. Moreover, given the complexity of the data validation standards and scoring methodology, it is critical that CMS be fully transparent regarding its intentions in advance of the audits commencing for the upcoming Data Validation cycle.

New 2019 Display Measure

Plan Makes Timely Decisions about Appeals (Part C)

Kaiser Permanente supports the introduction of a revised Part C Timely Decisions about Appeals measure with the inclusion of cases dismissed. CMS proposes including cases dismissed by the Independent Review Entity (IRE) in instances when the plan sponsor has subsequently approved coverage/payment. We urge CMS to include all dismissals and not differentiate between cases dismissed for subsequent approval versus cases dismissed for other reasons. By limiting the inclusion to only cases dismissed for subsequent approval, CMS would only be including untimely dismissals in both the numerator and denominator. This would only negatively impact contract performance. By including all dismissals, it would allow both timely and untimely dismissals to be included which would be a more accurate and more fair representation of appeal timeliness.

Changes to Existing Display Measures

Use of Opioids from Multiple Providers and/or at High Dosage in Persons without Cancer (Part D)

We understand that due to the timing of the Pharmacy Quality Alliance (PQA) measure development and the NQF endorsement process, the PQA has not yet revised their Measure 3: Use of Opioids at High Dosage and from Multiple Providers in Persons without Cancer (OHDMP). We have raised and will continue to raise our concerns with PQA about how multiple providers and multiple pharmacies would be counted for this measure. We support CMS' proposal in the *Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2019* (the "Proposed Rule"), to count pharmacies that share real-time electronic data as one pharmacy under the clinical guidelines. We also support CMS' proposal to count prescribers associated with the same Tax Identification Number (TIN) as a single prescriber, but recommend requiring the prescribers to share real-time electronic data. While we support the CMS proposal to add only the OHDMP measure to the Part D Display Page, given that the metric has not yet been revised, we recommend that CMS wait until the OHDMP measure has been tested and refined before adding the measure to the Medicare Stars Display page.

Potential Changes to Existing Measures

Controlling High Blood Pressure (Part C)

We support changes to this metric. Kaiser Permanente recommends a quality metric of <140/90 for all adults with hypertension going forward. In light of the Systolic Blood Pressure Intervention Trial (SPRINT), Health Outcomes Prevention Evaluation-3 trial (HOPE3), and the study[4] by Wei et al., the current target for systolic blood pressure of <150 is no longer appropriate. A blood pressure target of <140/90 is highly defensible, and easy to implement and report.

Plan All-Cause Readmissions (Part C)

NCQA is exploring several revisions to the measure, which may impact the definition of the denominator, numerator, and risk adjustment model for data collected in 2018. These changes are substantial and pending NCQA analysis and are prompted by new evidence regarding readmissions measurement. CMS is proposing to keep the current Plan All-Cause Readmissions (PCR) measure at triple weight in the Star Ratings through 2020, and simultaneously add the new Plan All-Cause Readmissions measure to the Display Page for 2019 and 2020 before moving it to the Star Ratings with a weight of 1 the first year and 3 thereafter.

First, Kaiser Permanente continues to strongly advocate that CMS not adopt a new measure into public reporting until the measure has been fully vetted, broadly tested, and audited to ensure the measure is valid, reliable, and appropriate for meeting the goals of the measure. Given the number of changes being considered for the PCR measure, we strongly recommend that CMS wait until NCQA has tested, refined, and added the new and expanded measure into NCQA's public reporting first before adding the expanded measure to the Medicare Stars Display page.

It is not yet clear that the proposed expanded measure would be effective in meeting the CMS stated goals of the measure. A recent study did not find evidence that changes in observation-unit stays accounted for the decrease in readmissions.[5] Some literature suggests that observation stays may be at higher risk for revisit to the Emergency Department (ED) or hospital upon discharge based on the nature of the acuity of patients in this status.[6] National experts in the field of observation medicine and published data agree that a well-functioning observation unit could still have approximately 15-20 percent of all individuals requiring initial admission. Some percentage of the remaining 80-85 percent of the discharged population could be reasonably expected to revisit the ED or hospital due to the diagnostic uncertainty at the time of discharge from observation.[7]

According to CMS' Medicare Benefit Policy Manual:

> The decision to admit a patient is a complex medical judgment which can be made only after the physician has considered a number of factors, including the patient's medical history and current medical needs, the types of facilities available to

[4] Wei et al., Effects of intensive antihypertensive treatment on Chinese hypertensive patients older than 70 years, J Clin Hypertens (Greenwich).] 2013. 15:420-7.
[5] Zuckerman et al., N Engl J Med 2016; 374:1543-1551.
[6] Dharmarajan et al., BMJ 2017;357:j2616.
[7] Wiler et al., Academic Emergency Medicine 2011; 18:959–965.

> inpatients and to outpatients, the hospital's by-laws and admissions policies, and the relative appropriateness of treatment in each setting.[8]

To begin measuring and potentially penalizing facilities for readmissions from observation could negatively impact decision making in the observation unit, prompting more patients to be admitted to the hospital when they otherwise could have safely gone home or to another venue. The impact could be significant to the hospital system and could expose patients to costlier inpatient care. Without a better understanding of the clinical consequences of this measure, as well as what readmission rates one might expect from a well-functioning observation unit, it would be premature to institute this new, expanded PCR measure into public reporting so quickly.

Second, Kaiser Permanente encourages CMS to consider removing or reducing the weight of the current PCR measure due the risk of driving inappropriate behavior. Concerns have been raised by studies that higher quality outcomes are not necessarily correlated with current measurement of readmissions. We understand that new research, described below, has shed light on the risks of current measurements of 30-day readmission rates, and that is why both CMS and NCQA are considering changing the measure. Keeping the current PCR measure triple-weighted and then adding an expanded readmissions measure would place undue emphasis on readmissions measurement and performance, an area already under significant public scrutiny and reporting; this may also detract attention and resources from other important quality of care initiatives.

Currently, there is no evidence nor consensus on how to effectively measure readmissions to drive quality improvement. Specifically, recent research on the federal Medicare Hospital Readmissions Reduction Program showed that 30-day and 1-year risk-adjusted readmissions decreased, but that the 30-day and 1-year risk-adjusted mortality increased among heart failure patients studied.[9] Heart failure accounts for the highest volume, proportion, and cost of Medicare readmissions, accounting for 24.5 per 100 readmissions.[10] These findings suggest that a focus on readmissions may have unintended consequences worthy of further study. The Gupta study builds on past studies that have found that certain hospitals have higher readmission rates (specifically, major teaching hospitals and safety-net hospitals) because of both case mix (medical complexity) and socioeconomic mix of the patient population, and that there is less evidence that the difference in readmission rates is related to measured hospital quality.[11] Rather than doubling focus on measuring readmissions while these questions remain, we recommend pausing and reassessing the evidence and the literature on these issues to ensure that measurement is meaningful in meeting quality goals.

In summary, Kaiser Permanente believes it is premature to expand the current readmissions measure to additional populations. Preliminary published studies suggest that since the initiation of reporting of Plan All-Cause Readmissions, heart failure patients are experiencing increased mortality. It is not clear this measure is driving improved hospital performance and could potentially have deleterious effects either in the form of prolonged hospitalizations that could lead to other healthcare acquired conditions, or prevent appropriate rehospitalization of patients. Until we understand that readmission measurement clearly correlates with improved clinical care and does not contribute to harm, it would be reasonable to consider whether triple weighting the

[8] Pub 100-02, Medicare Benefit Policy Manual, Ch. 1, Sec. 10, March 10, 2017.
[9] Gupta et al., JAMA Cardiology November 12, 2017.
[10] Hines et al., AHRQ H-CUP Statistical Brief #172 April 2014.
[11] Joynt & Jha, JAMA January 23/30, 2013 (309:4).

readmissions measure for health plans could also have unintended consequences. We urge CMS to consider either reducing the weight of this measure or moving it to the Display Page, as either action may lessen that effect and allow more time for further study.

Initiation and Engagement in Alcohol or Drug Dependence (AOD) Treatment (Part C)

Kaiser Permanente supports counting medication as a treatment within 14 days of the diagnosis of Alcohol or Other Drug Dependence in the numerator for this measure. CMS requests feedback to share with NCQA on the appropriateness of adding particular behavioral health diagnostic codes to this measure. CMS has suggested potential diagnostic codes including self-harm, asphyxiation, overdose, and poisoning conditions. We do not recommend adding the suggested behavioral health diagnostic codes to this measure, as these conditions do not always indicate a substance use related condition. Individuals with a diagnosis of self-harm, asphyxiation, overdose or poisoning may not have an alcohol or drug related problem at all and it would be inappropriate for those diagnoses to trigger an event requiring alcohol/drug treatment to score well on such a measure. Rather, members with the suggested potential diagnoses may require mental health services that do not involve alcohol or drug abuse treatment. Moreover, NCQA has proposed to add self-harm to the denominator for follow-up after an emergency department visit, which would address that condition in a more appropriate measure.

It would be difficult to differentiate between individuals with these behavioral diagnoses who do or do not have a substance use disorder and, therefore, we do not believe the addition of these additional diagnoses would add value to the measurement and may in fact cause confusion. Only those enrollees with substance use disorders should be included for this measure to ensure that appropriate care is being delivered.

Telehealth and Remote Access Technologies (Part C)

Kaiser Permanente strongly supports the availability of telehealth and remote access technologies as care options for our members and patients, where clinically appropriate. Telehealth helps to enable continuous, coordinated, patient-centered care through secure, reliable, real-time communication and data transfer. Technologies such as video and telephone visits have been shown to be effective modalities of care delivery with quality on par with that of care provided in traditional face-to-face settings.[12] If these and other remote access technologies are deployed in strategic and clinically appropriate ways, health care providers can optimally meet patients' care needs and preferences and enhance the overall care experience.

We appreciate CMS' continued interest in sharing feedback on telehealth measurement with NCQA. Kaiser Permanente's telehealth options, particularly telephone, secure email, and video encounters, provide alternative pathways for our members to interact with their care team toward maintaining their health and ensuring chronic conditions are well controlled. However, our use of telehealth is not currently fully captured by HEDIS measurement.

[12] McKissick et al. Journal of Pediatric Health 10.1016 22 December 2016; Sokoreli, I., et al. International Journal of Integrated Care 16.5 2016; Journal of Clinical Psychiatry 71.7 2010; Journal of Technology in Human Services, Vol. 26, No. 2.

For example, a patient with diabetes who has her A1c well controlled, has documented good blood pressure, is taking statins, and is up-to-date on eye care, interacts with her provider regularly over the phone and email since she has few or no complications. The patient is receiving regular diabetes care, but because the patient does not have two in-person encounters within 24 months, she would not be included in the HEDIS denominator. In another example, a member with Chronic Obstructive Pulmonary Disease (COPD) had a spirometry test two years ago. This member's COPD has been well controlled and the member checks in with his doctor via phone and secure email. If the member has not had an in-person visit in two years and has an exacerbation, then the current HEDIS measure treats this member as newly diagnosed with COPD because the phone and secure email encounters are not counted.

These cases exemplify the many members who are generally managing their health care conditions well and who often prefer check-ins by telehealth in between face-to-face encounters. The lack of telehealth inclusion in the current HEDIS measures overlooks important aspects of enrollees' care and could even incentivize unneeded health care services, such as a premature spirometry procedure in the case of a COPD patient.

We recommend that CMS recognize use of telehealth and remote access technologies through the Star Rating system to the extent clinically appropriate, including but not limited to telephone and video encounters, and use of remote monitoring (such as for controlling enrollees' high blood pressure).

We also recommend modifying the CAHPS measures data collection to reflect encounters and interactions done via telehealth. Technology can be used to aid multiple aspects of beneficiary interaction with health plans, e.g., How Well Doctors Communicate, Getting Care Quickly, and Getting Needed Care. Specifically, telephone appointments, video appointments, and email communication with physician offices are ways enrollees can, and often do, access care, as anecdotally illustrated above. However, internal focus group data show that unless respondents are specifically asked about these methods of having an appointment with their doctor, they will not consider these instances when thinking about their care in the last six months (as the CAHPS instrument requests). Therefore, these telehealth appointments will not be captured via CAHPS access composites. We recommend either revision of the current CAHPS access question language to encompass telehealth modalities or development of additional items that would capture telehealth encounters. As always, once items are identified, further testing must be conducted to measure reliability and validity.

Potential New Measures for 2020 and Beyond

Care Coordination Measures (Part C)

We look forward to reviewing CMS' proposals for expanded efforts to better evaluate effective care coordination through new care coordination measures. We encourage CMS to update the CAHPS survey to reflect enrollee satisfaction with healthcare as it is provided today, e.g., with more team based care and incorporation of new healthcare service delivery modes such as secure messaging, access to online medical records, telephone and telehealth/video visits. For example, Kaiser Permanente members have a very high adoption of rate of the use of telehealth services and other tools available on the member portal at KP.org. This reflects the confidence Medicare

beneficiaries have in their ability to directly influence the delivery of care and their increasing sophistication in using digital technology to obtain care and services on their own terms.

Opioid Overuse (Part C)

Managing the use of opioids is of critical importance to addressing the health and safety of our members, and we are committed to working with CMS to address the national opioid epidemic and expanding evidence-based strategies that have potential for the greatest impact.

CMS requests feedback regarding NCQA's HEDIS 2018 data collection on Use of Opioids at High Doses and Use of Opioids from Multiple Providers, which are adapted from the PQA's opioid measures, and whether to include these Part C measures on the Display Page. Given the similar Part D measures that constitute data for Patient Safety reports (which may also be reported on the Display Page), we do not believe there would be value in including these Part C measures on the Display Page. For MA plans that offer both Part C and Part D benefits, including these HEDIS measures would be redundant. Furthermore, we do not believe these measures would benefit Part C only plans because NCQA criteria for reporting on these HEDIS measures requires that a health plan offer both medical and pharmacy benefits. Therefore, regardless of whether these measures are added, they would not be applicable to Part C only plans. As such, it places an undue burden on MA plans that offer Part C and Part D benefits as they would be required to report different measures that have the same/similar purpose.

CMS also requests feedback on the HEDIS 2019 testing of a new measure concept that addresses members who were previously naïve to opioids who become long-term or "chronic" users and the potential testing of a second measure concept that addresses the concurrent prescription of opioids and central nervous system depressants, since similar measures are being or have been developed as Part D measures.

Kaiser Permanente believes that understanding the difference between "opioid naïve" and "chronic use" is beneficial to understanding and addressing prescribing and medication use patterns, especially in helping to prevent "opioid naïve" patients from becoming chronic users. Additionally, we believe MA plans that offer both Part C and Part D benefits are uniquely positioned to play a role in addressing this issue given their ability to access both medical and pharmacy data. In order to address opioid misuse, we believe a plan, at minimum, must have access to pharmacy data or must offer Part D benefits. Therefore, we believe these measures would only be applicable to Part D plans or MA-PDs.

However, as CMS notes, similar measures have already been or are being developed as Part D measures, which if adopted as part of the Star Ratings would be reported for Part D only plans and those offering Part C and D benefits. Therefore, the addition of these potential measures by NCQA for Part C is unnecessary and redundant. If both Part C and Part D measures are added, plans that offer both Part C and D benefits would essentially be measured and evaluated twice on the same thing. We believe these NCQA measures would provide more value for non-Medicare lines of business that would not be reporting on similar Part D measures. We do not see the same value for MA plans, given the existence of Part D measures.

Depression Screening and Follow-up for Adolescents and Adults (Part C)

Kaiser Permanente conceptually supports a depression screening and follow-up measure, but we have concerns about the measure as proposed. Because the outpatient requirement for this metric has been removed, the measure is effectively a universal screening rather than a measure that captures appropriate care and follow-up for depression. We do not recommend the use of this metric, as evidence shows treating already diagnosed depression into full remission is most predictive of better outcomes, reducing morbidity and mortality.[13] The effects of universal screening with 30-day follow-up is less certain. Furthermore, it is difficult to ensure appropriate follow-up if it is not based on whether the patient had an encounter with a health care provider. A patient could have a false positive screen (e.g. "just a bad day") that may be a confounding variable in depression screening or could switch insurance, and perhaps health care providers, after the screening. If, however, CMS proceeds with depression screening as part of the measure, we recommend focusing screening on high risk patients (e.g., patients diagnosed with diabetes, congestive heart failure, COPD, post-partum).

We support maintaining flexibility in selecting depression measurement tools, as there is a range of standardized and validated assessment tools available. For example, we believe that the Patient Health Questionnaire (PHQ-9) is appropriate for adults, but not for adolescents. Another tool, the Patient Reported Outcomes Measurement Information System (PROMIS), may also be used for measuring adolescent depression and outcomes, has been heavily validated, and is considered by many to be a better outcomes indicator than other available tools. The PROMIS tool also allows for both screening and outcomes review so that results can be compared over time.

Unhealthy Alcohol Use Screening and Follow-up (Part C)

Kaiser Permanente supports development of this potential new measure. We agree with the recommendation to include Alcohol Screening and Follow-up for health plan reporting, and believe that the denominator criteria (all patients aged 18 years and older seen for at least two visits or at least one preventive visit during the measurement period) are appropriate. We also agree with the requirement for brief counseling for unhealthy alcohol use. Feedback/follow-up for patients could include feedback on alcohol use and harms; education on the low-risk drinking limits; identification of high-risk situations for drinking and coping strategies; and increased motivation to reduce drinking.

Readmissions from Post-Acute Care (Part C)

Kaiser Permanente believes that the Plan All-Cause Readmissions (PCR) measure is itself fundamentally flawed. However, if CMS believes it is critical to implement a measure reflecting readmission of post-acute skilled nursing facility (SNF) patients to an acute care hospital, it should be a new measure, not a modified PCR measure. We could support a separate SNF readmissions measure for MA only if the risk adjustment model is modified to better capture the acuity of the patients. There are important SNF variables that affect the risk of readmission from the SNF that should be considered, such as tracheostomy (subacute patient), stage 4 pressure ulcer (marker of frailty), and eating dependence (marker of advanced illness). These are just a few of the risk factors

[13] TEAMcare: An Integrated Multicondition Collaborative Care Program for Chronic Illnesses and Depression, McGregor, M; Lin, E; Katon, W. Journal of Amb. Care Mgt: Vol. 34, June 2011.

that would be important to capture in a valid and reliable measure reflecting readmissions from SNF to acute care.

Any risk model would have to be subjected to rigorous testing, as would all elements of the proposed measure. As always, we urge CMS not to adopt a new measure into public reporting until the measure has been fully vetted, broadly tested, and audited to ensure the measure is valid, reliable, and appropriate for meeting the goals of the measure. We strongly recommend that CMS wait until NCQA has tested, refined, and added the new and expanded measure into NCQA's public reporting (i.e. the measure is no longer a "first year measure").

Finally, we ask that CMS consider whether this proposed measure is of value in a health plan-specified SNF readmission measure. If such readmissions are truly important, we believe they are more likely due to suboptimal care in either the index hospital admission or the SNF, rather than suboptimal health plan management. We therefore encourage CMS to consider adding a readmission measure to SNF Compare, rather than to the health plan Star Ratings system.

Adult Immunization Measure (Part C)

In general, we are supportive of one (or more) adult immunization measures; however, we do not believe that this measure will be beneficial as currently constructed. One of the Kaiser Permanente regions participated in the NCQA studies for both the 2017 Pneumococcal Conjugate Vaccines (PCV) measure and the proposed 2019 adult immunizations measure. Based on that, we had the following concerns which were previously communicated to NCQA. The four vaccines included have completely different recommended start dates, administration regimens, exceptions and licensed ages. Because of these differences, it would make more sense to break these out into separate measures rather than to group them. PCV is a new measure and it may be helpful to run it for a few years before incorporating it into another measure. The shingles vaccine, Zostavax, is no longer being recommended by either the Advisory Committee on Immunization Practices (ACIP) or the Centers for Disease Control. A new vaccine, Shingrix, with a reported higher efficacy rate, is now being recommended. Given these changes and other concerns, it would be best to not adopt this new measure into public reporting until the measure has been fully vetted, broadly tested, and audited to ensure the measure is valid, reliable, and appropriate for meeting the goals of the measure.

General Comments on the Star Ratings

Topped Out Measures

We strongly encourage CMS to retire measures that have "topped out". Over the past few years, the quantity of required measures has risen significantly, whereas very few are being retired. This trend requires organizations to increase resources for measurement for public reporting, which in some cases may create competing priorities between externally required reporting and internal performance improvement. Retiring "topped out" measures is a helpful remedy.

A good indication of a measure being "topped out" is when the cutpoints are within a few percentage points of each other, meaning a statistically insignificant performance change over the prior year could result in a different Star Rating. Another indication of a measure being "topped out" is when there is little room for improvement across the clear majority of plans. Currently, the

measure that meets both of these criteria is Diabetes Care – Kidney Disease Monitoring (nephropathy) (Part C). The cutpoints are all above 90 percent and are very tightly clustered: 2 stars is 92 percent, 4 stars is 96 percent, and 5 stars is 98 percent. We strongly encourage CMS to retire this measure. If CMS is concerned that performance will decrease after retirement, then this risk could be mitigated by moving a measure to the Display Page for one year then retiring it.

Electronic Clinical Data System Measures

Kaiser Permanente has serious concerns about the use of the NCQA Electronic Clinical Data System (ECDS) measures in the CMS Star Rating program. While we recognize that this is part of NCQA's new effort to collect data using ECDS, CMS says that it may consider three ECDS measures in the Star Rating program in the future. We urge CMS to delay adding any ECDS measures to the Star Ratings program, given the comparatively small number of health plans that have submitted ECDS performance results. In addition, the ECDS measures are not audited, unlike all other HEDIS measures used for public reporting. Given the innovative methods used to produce the ECDS measures, CMS should require audited results to protect the integrity of the Star Ratings. We believe it is premature for CMS to consider incorporating those results into either the Display Page or the Star Rating metrics accountability weighting.

Validation Audits (pp. 159-164)

Threshold for Requiring an Independent Validation Audit

Kaiser Permanente supports CMS' proposed changes to the current process on when an organization must hire an independent auditor. We support excluding Compliance Program Effectiveness (CPE) from the conditions considered for hiring an independent auditor. We agree with CMS that validating the CPE requires a lower level of effort based on its customized characteristics and structure. With respect to the threshold, we believe the current threshold of five or more non-CPE conditions is reasonable and need not be changed. The current threshold has been successful in removing CMS' subjectivity on determining when a plan must hire an independent validation auditor. It has also helped put plans on equal footing with regard to hiring external auditors and has helped prepare plans for the audit's impact on resources and costs.

Required Use of CMS Validation Audit Work Plan Template

Kaiser Permanente supports CMS' proposal to adopt a validation audit workplan template that includes sections that all sponsor organizations will be required to use. We agree that such standardization will promote consistency and efficiency across all validation audits, and may potentially stabilize cost fluctuations among independent auditors.

Timeframe to Complete Validation Audits

Kaiser Permanente supports the proposal to increase the validation audit timeframe from 150 days to 180 days. However, we ask that CMS clarify whether the proposal to extend the current timeframe will impact the existing process, which allows the sponsor organization to request an extension on the 150-day timeframe. We recommend that CMS continue to permit MAOs to request an extension beyond the 180-day timeframe and submit a workplan and justification, consistent with current guidelines.

Plan Finder Civil Money Penalty (CMP) Icon or Other Type of Notice (pp. 164-165)

CMS proposes to display an icon or other type of notice on Medicare Plan Finder (MPF) for those organizations that have received a Civil Monetary Penalty (CMP). While we generally support CMS' efforts to ensure transparency with respect to audit results and enforcement actions, we strongly oppose this proposal for the reasons set forth below.

First, unlike sanctions (which indicate the existence of pervasive, repetitive, and/or egregious compliance concerns), CMPs are frequently imposed for limited instances of noncompliance where that noncompliance has already been corrected or can be promptly corrected. A CMP icon on MPF would have a negative impact on plans that is disproportionate to the underlying penalty. CMS's own Past Performance methodology, which is used to identify plans that are true compliance outliers, recognizes this distinction between CMPs and sanctions—whereas CMS assigns only one negative performance point for a CMP, it assigns up to seven negative points for a sanction.

Second, the display of a CMP icon is likely to cause beneficiary confusion and/or undue alarm. When a beneficiary explores plan enrollment options on MPF, s/he encounters numerous detailed data points regarding plan benefits, coverage, and costs—many of which may be customized based on the beneficiary's inputted personal information. Because beneficiaries are generally not well positioned to understand the intricacies and implications of CMS enforcement actions, a CMP icon is susceptible to misinterpretation and misunderstanding. As a result, a CMP icon could detract from MPF's intended goal of facilitating informed beneficiary choice by diluting the meaningfulness of other important information. For example, a beneficiary whose primary concern and priority is coverage and costs associated with needed prescription drugs might not enroll in a plan offering superior drug coverage because of the presence of a CMP icon where that icon is the result of a limited instance of noncompliance that has long been remedied.

Third, because CMPs are concentrated among plans that went through a Program Audit, displaying a CMP icon on MPF would disproportionally affect those plans that were selected for a Program Audit in that year and may be misleading to beneficiaries. In any given year, CMS audits only a small subset of all plans—for example, in 2017, only 39 plans were audited.[14] In recent years, CMS has also increasingly imposed CMPs for routine audit findings. For example, for 2016, (a) 46 percent of all plans subject to a Program Audit were issued a CMP,[15] (b) 81 percent of enforcement action referrals were related to Program Audit-identified noncompliance, and (c) 17 of 21 CMPs related to Program Audit findings.[16]

As noted above, because beneficiaries are generally not positioned to understand the intricacies of CMS audit, compliance and enforcement mechanisms, a CMP icon is susceptible to misinterpretation and misunderstanding. Displaying a CMP icon on MPF could unfairly and inaccurately imply that a plan is a compliance outlier, even when that plan's overall audit

[14] HPMS Memorandum, Civil Money Penalty Enforcement Actions for 2017 Program Audits (dated February 26, 2018).
[15] Similarly, for 2017, 47% of all plans subject to a Program Audit were issued a CMP. *Id.*
[16] CMS, 2016 Part C and Part D Program Audit and Enforcement Report, (dated May 9, 2017) *available at* https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Downloads/2016_Program_Audit_Enforcement_Report.pdf.

performance is comparatively stronger than other plans. As CMS has acknowledged, a CMP is not necessarily representative of a plan's overall audit performance—even where a plan receives an above average overall score on an audit, a CMP could be imposed.[17]

Finally, we believe an icon or other notice is not needed, as CMS already publicly posts audit results and enforcement actions on its website, making detailed information on a plan's performance readily available to beneficiaries, advocates and the general public. An option to provide further transparency might be to add a link to that information from the MPF page.

For these reasons, we urge CMS to reconsider this proposal.

Audit of the Sponsoring Organization's Compliance Program Effectiveness (pp. 165-166)

CMS is proposing that MAOs that have undergone a CMS program audit will be able to treat that audit as meeting the annual requirement to perform an internal audit of compliance program effectiveness, for the 12-month period following the date of the CMS program audit.

Kaiser Permanente supports this proposal. We agree that the scope of the two audits is largely duplicative, and requiring MAOs to complete both within a year results in an additional burden on plan operations and resources. We appreciate CMS' recognition of this burden and agree that the proposal will allow plans to spend time focusing on timely remediation of any findings from the CMS program audit and audit validation efforts.

Section II – Part C

Meaningful Difference (Substantially Duplicative Plan Offerings) (pp. 170-171)

Kaiser Permanente conceptually supports the additional flexibility that comes with eliminating the Medicare Advantage (MA) meaningful difference requirement, per our comments submitted on the Proposed Rule. However, we have concerns about the implementation of this policy change and the potential for enrollee confusion with the potential increase in number and variety of plan offerings.

While we support greater flexibility in plan design and CMS' effort to encourage the development of plans that are more affordable to the Medicare population, we believe there may be a substantial increase in the number and variety of plan offerings from which enrollees may choose. As CMS notes in the preamble, research has shown that a large number of plan choices can lead to enrollee challenges with choosing a plan or switching plans. We support having a reasonable metric that compares multiple plans offered by a particular MAO and helps enrollees distinguish among the choices.

We believe that there may be alternatives to relying on the out-of-pocket costs (OOPC) model for determining whether there is a meaningful difference in plan offerings. We agree that the OOPC model does not accurately reflect plan value differences; this is due at least in part to the fact that

[17] HPMS Memorandum, Civil Money Penalty Enforcement Actions for 2016 Program Audits (dated March 1, 2017) *available at* https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Downloads/HPMS_Memo_CMPs_2016_Program_Audits.pdf.

the tool/model uses only the bottom of the range of copays of items in the category to determine member out-of-pocket costs. As an alternative to fully removing the meaningful difference requirement, CMS could allow plans to demonstrate a meaningful difference between plan offerings by providing an actuarial attestation as to the actuarial value differences. We recommend that actuaries be allowed to use a utilization profile that is representative of their population for quantifying differences in actuarial value (without impact of selection effect or risk score differential).

If CMS proceeds with removing the meaningful difference requirement entirely, rather than implementing the above alternative or another method of distinguishing among plans, we ask that CMS consider the following points and provide further guidance in the 2019 final Call Letter or a HPMS memorandum. CMS' proposal does not provide specific information about which benefit designs might "substantially discourage enrollment" in the plan by certain Medicare-eligible individuals. The proposal appears to allow for differences in provider networks to form the basis for plan differences. This suggests that an MAO could develop a network that is designed to address the care needs of a particular segment of the Medicare population. Such networks could potentially be selected based on language, ethnicity, clinical specialty, or other provider factors. For example, an MAO may wish to offer a plan that caters to Spanish-speakers and therefore develops a network of providers who speak Spanish. Or an MAO may wish to offer a plan that focused on individuals with diabetes and therefore develops a network with primary and specialty providers with expertise in treating and monitoring diabetes. It is important for MAOs to understand which plan designs CMS would consider to run afoul of the non-discrimination provisions in the regulations and which would be permissible to assist with bid development.

We appreciate CMS' efforts to extend flexibility to MAOs and request that CMS provide further guidance on the implementation of this policy in the final 2019 Call Letter.

Total Beneficiary Cost (TBC) (pp. 171-174)

Kaiser Permanente supports the proposal to increase the Total Beneficiary Cost (TBC) from $34.00 PMPM to $36.00 PMPM in CY 2019 to provide flexibility in addressing medical and pharmacy inflation. We also support the elimination of the current TBC evaluation in future years. Since the TBC includes the Part B premium and OOPC calculation, it limits a plan's ability to make benefit and premium changes. While we do acknowledge that removal of the TBC eliminates some protection afforded to the beneficiary from experiencing large cost-share increases, CMS would still reserve the right to request changes or deny a plan's bid. To alleviate some of the potential for beneficiary harm, we propose that CMS consider requiring plans with significant increases to send a letter to beneficiaries, separate from the ANOC, notifying the beneficiaries of the specific increases. The letter should also include information on other plans offered within the same service area, similar to the notice required of a plan when it makes a service area reduction.

Maximum Out-of-Pocket (MOOP) Limits (pp. 174-175)

Per previous comments submitted on the Proposed Rule, Kaiser Permanente is aware of CMS' proposal to clarify the agency's authority to use Medicare FFS data to annually establish maximum out pocket (MOOP) and cost sharing limits. It is our understanding, as provided in the Proposed

Rule, that CMS also intends to use MA encounter data to establish cost sharing standards and thresholds in setting MOOP limits.

We are concerned that significant year-to-year changes in FFS spending could cause variation in the MOOP and cost sharing limits, so we ask that CMS apply this authority thoughtfully to prevent instability in MA offerings. We also have concerns regarding the use of encounter data to calculate these thresholds (e.g., will the encounter data be used in the same way as FFS data is currently used?), whether the new approach might yield very different limits, and whether these changes will help MAOs and/or enrollees. We request that CMS provide analysis and further details in the 2019 final Call Letter in order to more fully understand the potential impact on individual MA plans.

Part C Cost Sharing Standards (pp. 176-180)

Kaiser Permanente supports CMS' proposal to consider changes to its policies related to service category cost sharing limits, but we encourage CMS to consider making such changes sooner than CY 2020. While we are in support of the increase in cost sharing limits on the Emergency Care/Post Stabilization Care category for CY 2019, we do not believe that the limit difference between the voluntary and mandatory MOOP for this category is justified. Both the voluntary and mandatory MOOP should be set at $120. The purpose of a higher cost share for use of emergency services is to encourage patients to seek care from the most appropriate source, which in most cases is not the emergency department. Reducing the inappropriate use of the emergency department leads to better continuity of care with primary providers and more efficient use of delivery system resources. In turn, such resources could instead be used to reduce premiums, other copays, or to provide additional benefits. We therefore recommend that CMS set the cost sharing limit for emergency care at $120 for both the voluntary and mandatory MOOP.

In addition, we do not agree with CMS' grouping of Post-Stabilization Care and Emergency Care in the same PBP section. Cost sharing for post-stabilization is dictated by the type of service provided to ensure a patient remains stabilized after an emergency medical condition. For example, post-stabilization care can involve admitting the patient outside the emergency department, which would result in the patient incurring a cost share for inpatient hospital care. We therefore recommend removing references to post-stabilization when referring to emergency room/department visits.

Outpatient Observation Services (p. 182)

In the Draft Call Letter, CMS states that the cost sharing for observation services will now be separately reported in PBP category B9a (outpatient hospital services). CMS indicates that it is doing so in an effort to make the cost sharing for observation services more transparent.

We appreciate CMS' effort to make cost sharing more transparent for beneficiaries, especially with respect to cost shares for observation services which can be confusing. We want to confirm that the new PBP category B9b will be limited to the cost sharing associated with observation stays where the patient is directly admitted as an outpatient for observation. However, when an individual is admitted to observation following an ER visit, or surgery, for example, we would expect that the ER or surgery cost-sharing would be entered into the appropriate PBP category,

but the lack of additional cost-sharing for the observation services would not be entered into PBP category B9b. We are concerned that if observation services with $0 cost sharing that result from another service that has cost-sharing are entered into PBP category B9b, this category could contain a range of cost sharing that could be misleading and confusing to beneficiaries.

Health Related Supplemental Benefits (p. 182)

Kaiser Permanente supports CMS' new interpretation of "primarily health related". We believe it will allow plans the flexibility to provide appropriate and more closely tailored supports to help meet members' health needs. We note that the Bipartisan Budget Act of 2018 contains a provision that will allow plans to provide supplemental benefits that are *not* primarily health-related to people with chronic illnesses. We believe that this provision does not limit CMS' interpretation of "primarily health related" for supplemental benefits generally under the Call Letter proposal.

We look forward to CMS releasing further guidance on the implementation of this policy change. Given that the 2019 bids are due in just three months, it is important that plans receive guidance as soon as possible in order to understand what items and services would be approved by CMS under the expanded definition so that they can undertake the work needed to file new supplemental benefits. As part of that guidance, it would be very helpful if CMS could provide a non-exhaustive list of items and services that would be approved.

Medicare Advantage (MA) Uniformity Flexibility (pp. 184-185)

In the Draft Call Letter, CMS reiterates its interpretation, first articulated in the Proposed Rule, that the Uniformity of Benefits provisions in the statute and regulation permit an interpretation that offering certain supplemental benefits or reduced cost sharing/deductibles to a class of similarly situated enrollees is permissible so long as those enrollees are all treated the same. As Kaiser Permanente indicated in its comments to the Proposed Rule, we support the policy direction of CMS' proposal permitting MA plans flexibility in offering supplemental benefits, reduced cost sharing or deductibles to enrollees with certain disease states and/or health conditions.

However, we continue to have concerns about the implementation, and are requesting that CMS offer clarifying guidance in either the Final Rule or the Final Call Letter. The concerns that we noted in our comments to the Proposed Rule and requested that CMS address are:

- Under the proposal, plans can offer lower cost shares for certain designated services provided to enrollees with a particular health condition[18]. The Plan is concerned about beneficiary confusion if the lower cost share is reflected in Medicare Plan Finder without being clearly identified as only applying to certain conditions. It appears from the 2019 PBP Beta version that reduced cost shares associated with this proposal will be entered separately. We would expect and recommend that the cost shares associated with this proposal will not be displayed with the standard cost-sharing for the same service so as to

[18] We note that this comment applies to lower cost shares applicable to the Uniformity of Benefits flexibility and VBID.

clearly reflect that the lower cost sharing is separate from the cost sharing applicable to the standard benefits offered under the PBP.

- We ask that CMS ensure that, should a plan elect to exercise this flexibility, it will not be subject to stringent and burdensome reporting requirements like those required under the Value Based Insurance Design (VBID) program. Under that program, plans are required to submit certain data as a condition of participation, which can include enrollee demographic information specific to affected conditions, number and types of interventions and outcomes, while illustrating financial cost-savings through the development of a bid (and submission of a bid pricing tool (BPT)). While this is reasonable in the context of a demonstration program, it would be very burdensome in the ordinary course of business and could inadvertently serve as a disincentive for health plans to create the tailored benefit designs intended by this policy change.
- We have concerns regarding the interaction of this policy change and the nondiscrimination requirements. MAOs should have the discretion to consider which health conditions are most appropriate for reduced cost sharing/additional supplemental benefits and are likely to have the most meaningful outcomes for enrollees. The desired supplemental benefits would, by their nature, make distinctions in favor of those with high needs in a certain disease category. To ensure that there is comparable reduced cost sharing across every high-cost condition may be an impossible task. Plans would be disincentivized to use the flexibility afforded by this policy if, after proposing such tailored benefits and developing bids accordingly, CMS determines later that the program is discriminatory (e.g., if the health status targeted for the program is not sufficiently a high-cost condition or if it is deemed that other high cost conditions are not sufficiently also granted reduced cost sharing). At the very least, CMS should provide additional guidance and examples of situations that would be considered discriminatory.
- To ensure that enrollees have appropriate information to make their enrollment decisions, MAOs should be able to market their programs to new and existing enrollees. Unlike the VBID CY 2017 Communications Guidelines, which prohibit the MA plan from citing participation in the VBID model to potential enrollees, CMS should allow plans to provide information about the reduced cost sharing/deductibles and supplemental benefits to prospective members so that they know how they may benefit from such plan flexibility.

We appreciate CMS' consideration of these and other possible challenges with the implementation of the flexibility in uniformity of benefits. We also appreciate that CMS will be setting up a special mailbox following issuance of the final Call Letter to answer questions about the allowability of a proposed supplemental benefit offering. However, the more transparency and guidance CMS can offer to MAOs up front, the higher the likelihood that plans will be able devise and operationalize meaningful supplemental benefits.

Special Needs Plan (SNP) – Specific Networks Research and Development (pp. 185-186)

CMS seeks stakeholder feedback regarding CMS' continued examination of the need for SNP-specific network adequacy evaluations. While we agree that it is important to ensure that MAOs offering targeted plans to vulnerable populations provide appropriate access to services that address the specific needs of those populations, we do not believe that the imposition of SNP-

specific network criteria or evaluations is necessary to accomplishing this goal. We support CMS' decision to refrain from developing SNP-specific network criteria or evaluations and allow for flexibility, particularly for dual-eligible SNPs (D-SNPs).

CMS already has the means to provide sufficient oversight of SNP provider networks through established mechanisms. Existing SNP Model of Care (MOC) requirements require SNPs to address the appropriateness of their provider networks. MOC narratives are subject to CMS review and approval, and the MOC is included as a module in the current CMS Program Audit Protocols. Accordingly, we do not believe there is added value to separately reviewing SNP networks. CMS ultimately holds SNPs accountable (and audits against) to what is outlined in the MOC.

Should CMS decide to pursue SNP-specific network adequacy evaluations, we recommend that MAOs offering D-SNPs that maintain the same provider network for both SNP and non-SNP members not be included. As an integrated delivery system committed to providing the same high quality care to all members, Kaiser Permanente does not differentiate our network based on members' source of coverage—generally, all members have access to the same networks of facilities, physicians and other practitioners. Moreover, the imposition of overly-specific network adequacy requirements runs counter to the very core structural characteristics (e.g., co-located services, a shared electronic health record, centers of clinical expertise) that facilitate our integrated system's ability to provide high quality and efficient care. For example, distributing co-located services would not only inconvenience our members, but would also impede essential care coordination. Separately assessing a provider network against SNP-specific standards where SNP and non-SNP members have access to the same providers would not only add little value, but would also negatively impact our integrated system's ability to deliver high quality care.

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

Kaiser Permanente supports the proposal to allow plans to offer a Rewards & Incentive (R&I) program tied to the completion of Health Risk Assessments (HRAs). This will allow plans to employ strategies to maximize participation in HRAs, which serve as a vital foundation for meaningful care coordination activities. Because completion of the HRA is particularly critical for SNP members, we urge CMS to allow plans to offer R&I programs targeting HRA completion only to SNP members. The current R&I guidance requires that plans offer such programs to all eligible participants, and because plans are expected to make a good faith effort to conduct HRAs for all members, a reasonable interpretation of current guidance is that a R&I program focused on HRAs may not be limited to SNP members and must be offered to all Medicare enrollees. Given the vulnerability of SNP members and the importance of HRA completion for that population, CMS should clarify the existing R&I program guidance to allow for programs targeting SNP members only.

Encounter Data Listening Forums, Monitoring and Compliance Activities (pp. 191-193)

CMS notes that is in the process of finalizing the performance and monitoring metrics and thresholds first proposed in the 2018 Call Letter and later in the November 1, 2017 HPMS memo entitled "CMS Monitoring and Compliance of Encounter Data, Performance Metrics and Thresholds – For Comment."

As Kaiser Permanente noted last year when CMS first proposed using monitoring and performance metrics, it is the nature of technology that the reporting of encounter data requires the interaction and linking of many disparate data sets and systems. These interactions and links are complex, and changes at any stage of the data collection process can have significant impact on downstream data production efforts. System upgrades, implementation of new software and hardware, system configuration changes, and unexpected production outages are common. For these reasons it is also common for there to be delays in data production. To account for these types of issues, we continue to suggest setting a high threshold for non-compliance designed to target habitual abusers as opposed to those who are experiencing "one off" or intermittent delays, resulting in timeliness or completeness issues. We also suggest implementation of a mechanism for reporting expected data production delays and deadlines for anticipated remediation, so that CMS may anticipate and account for such delays and spikes in receipt of data.

As for the nature of compliance actions, we respectfully request that CMS forgo implementing compliance actions in the first year that these metrics are implemented, and instead use these measures to educate and inform plan sponsors of deficiencies or areas requiring improvement. Once CMS implements the use of compliance actions, we suggest that such actions be designed to address habitual abusers as opposed to plans with irregular instances of submission delays. While escalation may be warranted for habitual abusers, delays in submitting data, especially due to system improvements or issues as described above, do not reflect a health plan's ability to provide high-quality care for its members and plans should not be penalized in these instances. When there are significant issues with a plan, CMS should consider a tiered compliance process, starting with a notice and then followed by a series of escalating actions, in order for a plan sponsor to have a chance to remediate.

Section III – Part D

Formulary Submissions (pp. 193-196)

CY 2019 Formulary Reference File

Kaiser Permanente supports and appreciates CMS' efforts to identify drugs that are more commonly covered under Medicare Part B and remove them from the Formulary Reference File (FRF). We note that an optimal time for CMS to provide the final contract year 2019 FRF would be the first week of May or prior to the open window, mid-May, in order to ensure enough time for plans to incorporate the updated drugs in the FRF with the submission.

Additionally, we recommend that the summer submission window not be moved to a later date as it overlaps with other activities, including printing of marketing materials. We suggest an early release of the updated FRF in order to provide enough time to finalize formulary submissions.

Finally, Kaiser Permanente agrees and supports the addition of the enhancement-only window that will occur in late fall, preferably no later than the second week of November. However, Kaiser does not support the addition of a January 2019 formulary update window as it will overlap with other significant activities in month of January such as post annual benefits go-live activities and monitoring. Currently, plan sponsors have the opportunity to make positive and maintenance

changes at any time, and negative formulary changes can be made during the February update window. Therefore, a January update window is not necessary.

Improving Drug Utilization Review Control in Medicare Part D (pp. 202-217)

Part D Opioid Overutilization Policy

Although opioid overutilization in the Part D program has been reduced through various means, CMS proposes new strategies in an effort to more effectively address the national opioid epidemic by targeting beneficiaries who are taking high levels of opioid prescriptions and beneficiaries who are opioid naïve. Kaiser Permanente's comments and recommendations to both retrospective and concurrent drug utilization review (DUR) strategies are outlined below.

Retrospective DUR

Patient Safety Reporting

Kaiser Permanente supports the proposed changes to the PQA-endorsed opioid overutilization measures in the Patient Safety reports and consideration of a new PQA measure, i.e. Concurrent Use of Opioids and Benzodiazepines. For purposes of clarity, we recommend that references to Morphine Milligram Equivalents (MME) be uniformly expressed as "MME per day," which clarifies the daily dosage calculation.

Concurrent DUR

Cumulative Morphine Milligram Equivalent Daily Dose Safety Edits for High, Chronic Prescription Opioid Users

As part of the DUR requirements, CMS notes that Part D sponsors commonly implement a point-of sale (POS) safety edit to prevent drug-to-drug interactions, therapeutic duplication, or an incorrect drug dosage. To strengthen this aspect of the current Part D opioid overutilization policy, CMS is proposing a POS formulary-level cumulative opioid safety hard edit threshold of 90 MME per day with a seven-day supply allowance.

Kaiser Permanente understands the delicate balance between the need to act quickly to address the national opioid epidemic and patients' need to access medically necessary drug regimens, particularly for those patients with existing addiction issues. But we are concerned that the proposed hard edit departs too quickly and too drastically from current requirements without giving sufficient consideration to incoming clinical data or to potentially inducing withdrawal of patients on active tapering. Based on the rationale set forth below, we support a 90 MME per day *soft edit* and a hard edit at a reasonable level above 90 MME per day (e.g., 200 MME per day) to accommodate patients who are being actively tapered.

As noted in the draft Call Letter, currently, "[p]lans may set any soft cumulative opioid claim edit MME threshold at or above 90 mg per day and any hard cumulative opioid edit at or above 200 mg per day." CMS notes that in 2017 (the first year expected for implementation of a soft and/or hard edit) and in 2018, approximately half of contracts utilized a hard edit, and of those contracts, all of them set the hard edit at 200 MME or above. Thus, CMS' proposal will significantly impact

even those plans that currently utilize a hard edit by lowering the required hard edit from 200 MME per day (or higher) to 90 MME per day.

CMS is proposing the implementation of this hard edit in 2019, irrespective of any analysis of the implementation outcomes of the MME POS edits. CMS has implemented a new 2017 Part D Reporting Requirement for "Improving Drug Utilization Review Controls," which will first be reported in February 2018 (and again in September 2018 and February 2019). This reporting is on soft and hard reject edits that were in place in 2017 and includes the number of claims rejected due to edits, the number of beneficiaries impacted, and the number of rejected claims overridden or processed through the Part D reporting requirements. Prior to requiring implementation of a 90 MME per day hard edit, it would be reasonable for CMS to first review plan sponsors' reporting data to evaluate potential beneficiary impact and access to care concerns.

Finally, we are concerned that the imposition of a 90 MME per day hard edit may induce withdrawal for patients who are being actively tapered, and that the proposed one-time seven-day supply, even coupled with the proposed exception process, will not give providers sufficient discretion to address the needs of their patients. We believe that for those patients who are being actively tapered, there must be a more effective way for both doctors and patients to proceed expeditiously and safely than the proposed exception/limited supply process. We believe that a 90 MME per day soft edit and a hard edit at a reasonable level above 90 MME per day (e.g., 200 MME per day) will accommodate patients who are being actively tapered.

Days Supply Limits for Opioid Naïve Patients

For opioid naïve patients, CMS proposes a days supply limitation on initial fills of opioid prescriptions for acute pain. We support a seven days supply limit for initial fills with or without a daily dose maximum, but recommends that plans be allowed to set this limit as a soft reject. We also recommend that the days supply limit apply to all initial fills, regardless of indication.

Kaiser Permanente further requests that CMS define the term "initial opioid prescription" for the purpose of identifying when to apply the days supply limit. We request clarification as to the following potential applications of "initial opioid prescription": (1) whether it applies to the treatment of each episode or occurrence, with specific exceptions for chronic pain or pain being treated as part of cancer care, palliative care, hospice care, or other end-of-life care; or (2) whether a prescription is deemed an "initial opioid prescription" if the beneficiary has not had a prior opioid prescription fill within a particular time period (e.g., within the prior three months).

Opioid Duplicative Therapy Safety Edits

We support CMS' proposal to implement soft POS safety edits for duplicative therapy of multiple long-acting opioids and soft POS safety edits on concurrent opioid and benzodiazepine use.

Using the Best Available Information when making B vs D Coverage Determinations for Immunosuppressants and Inhalation Durable Medical Equipment (DME) Supply Drugs (pp. 218-220)

Kaiser Permanente supports and appreciates CMS' efforts to streamline the B vs. D determination process. As noted in the Draft Call Letter, only renal transplant information is available in MARx,

thus we recommend that CMS include all covered transplant information in MARx to assist Part D sponsors in making the B vs. D determination based on information in MARx.

We also support the use of the patient residence code on pharmacy claims for determining when such inhalation drugs may be covered under Part D; we believe this is the current industry standard.

Part D Mail-Order Refill Consent Policy – Solicitation of Comments (pp. 220-222)

Kaiser Permanente agrees that the Part D mail-order refill consent policy is an additional burden on Part D sponsors and interferes with the adherence measure. We support and appreciate CMS' efforts to modify or eliminate this policy to reduce unnecessary burden.

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Kaiser Permanente appreciates the opportunity to provide feedback in response to the CY 2019 Advance Notice and draft Call Letter. If you have questions or concerns, please contact Anthony Barrueta at 510.271.6835 or anthony.barrueta@kp.org, or Keavney Klein at 510.271.6482 or keavney.f.klein@kp.org.

Sincerely,

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