

January 16, 2018

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

Submitted electronically to: [www.regulations.gov](http://www.regulations.gov)

***RE: Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program [CMS-4182-P]***

Dear Administrator Verma:

Kaiser Permanente offers the following comments on the above-captioned Proposed Rule.<sup>1</sup>

The Kaiser Permanente Medical Care Program<sup>2</sup> is the largest private integrated health care delivery system in the U.S., with more than 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 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. Kaiser Permanente's mission is to provide high-quality, affordable health care services and to improve the health of our members and the communities we serve.

We appreciate the opportunity to provide comments on a variety of important issues discussed in the Proposed Rule. We highlight a few key issues here and provide detailed comments on these and other provisions in the following sections.

- Kaiser Permanente conceptually supports CMS' proposals to provide more flexibility in the Uniformity of Benefits and meaningful difference requirements, but we ask that CMS implement these proposals thoughtfully to prevent undue administrative burdens on MAOs and beneficiary confusion.
- Kaiser Permanente strongly supports the Star Ratings system and appreciate CMS' ongoing work to promote quality improvement and enrollees' ability to compare health

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<sup>1</sup> Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program, 82 Fed. Reg. 56336 (Nov. 28, 2017) (hereinafter, "Proposed Rule").

<sup>2</sup> Kaiser Permanente comprises Kaiser Foundation Health Plan, Inc., the nation's largest not-for-profit health plan, and its health plan subsidiaries outside California and Hawaii; the not-for-profit Kaiser Foundation Hospitals, which operates 39 hospitals and over 650 other clinical facilities; and the Permanente Medical Groups, independent physician group practices that contract with Kaiser Foundation Health Plan to meet the health needs of Kaiser Permanente's members.

and drug plans. We have concerns, however, about continued contract consolidation activity and the codification of the Categorical Adjustment Index into regulation.

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

## **SECTION A. SUPPORTING INNOVATIVE APPROACHES TO IMPROVING QUALITY, ACCESSIBILITY, AND AFFORDABILITY**

### **A.1. Implementation of the Comprehensive Addiction and Recovery Act of 2016 (CARA) Provisions: Medicare Part D Drug Management Programs**

Kaiser Permanente is committed to working with CMS to address the opioid epidemic and seeking to expand evidence-based strategies that have potential for the greatest impact. Indeed, prevention, treatment, research, and effective responses to opioid overdoses are critical to fighting the epidemic. We have therefore implemented policies and clinical practice interventions to improve care quality and patient safety with respect to opioid prescribing. Our four-pronged approach was described in testimony given by Dr. Edward Ellison before the President's Commission on Combating Drug Addiction and the Opioid Crisis in October 2017.<sup>3</sup>

Kaiser Permanente greatly appreciates CMS' goal of addressing the opioid epidemic through the establishment of drug management programs. As discussed below, we recommend that CMS permit plans greater flexibility and discretion in implementing the programs. For example, we suggest that plans maintain the ability to implement claims edits to limit concurrent prescriptions of opioids and benzodiazepines or muscle relaxants. We also recommend that plans be able to implement lock-in restrictions more quickly than six months and that integrated delivery systems be allowed to utilize certain processes rather than the ones proposed by CMS. We believe by allowing plans greater latitude in establishing and operationalizing these programs, these programs will have a greater likelihood of success.

#### *Definition of Frequently Abused Drug*

Kaiser Permanente supports CMS' definition of "frequently abused drug" and the proposal to define such drugs as opioids for plan year 2019. However, we also support allowing sponsors to continue to implement the current policy for non-opioid medications, such as benzodiazepines and muscle relaxants, which permits Part D plan sponsors to address concurrent use of these drugs during case management and apply beneficiary-specific claims edits.

The 2016 CDC Guideline for Prescribing Opioids for Chronic Pain states that concurrent use of opioids and benzodiazepines may increase the risk of overdose and death.<sup>4</sup> On August 31, 2016, the FDA issued a Drug Safety Communication indicating that "the combined use of opioid medications with benzodiazepines or other drugs that depress the central nervous system (CNS)

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<sup>3</sup> See PBS NewsHour, "America Addicted" (Oct. 9, 2017). Available at: <https://www.youtube.com/watch?v=LNioiRHq8vY&app=desktop>

<sup>4</sup> CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016, Deborah Dowell, MD, Tamara M. Haegerich, PhD, Roger Chou, MD, Division of Unintentional Injury Prevention, National Center for Injury Prevention and Control, CDC, Atlanta, Georgia, published in *Morbidity and Mortality Weekly Report*, Vol. 65 (March 18, 2016).

has resulted in serious side effects, including slowed or difficult breathing and deaths.”<sup>5</sup> The FDA action included the issuance of new or revised patient Medication Guides, labelling changes, and Boxed Warnings for opioid analgesics and opioid cough medications to highlight the risk of concomitant use with other CNS depressants. Given the heightened risk associated with this dangerous drug combination, plan sponsors need latitude to implement beneficiary-specific claim edits for benzodiazepines and other drugs, as appropriate, to protect at-risk beneficiaries.

#### *Definition of Clinical Guidelines and Program Size*

With respect to defining the clinical guidelines to be used in identifying at-risk beneficiaries, CMS is proposing a high dose threshold of 90 morphine milligram equivalents (MME) or greater for any duration during the most recent six months; and either four or more opioid prescribers plus four or more opioid dispensing pharmacies, or six or more opioid prescribers, regardless of the number of opioid dispensing pharmacies.

We propose modifying “for any duration” to permit beneficiaries a reasonable overlap time to refill medications. Beneficiaries generally need a few days to pick up a new prescription prior to exhausting their supply of the preceding prescription. We propose that CMS set a reasonable overlap period of no more than three days for the purposes of identifying potential at-risk beneficiaries; however, plan sponsors should also have the discretion to reduce the overlap periods by utilizing beneficiary-specific claim edits as determined by case management.

We support CMS’ proposal 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. Kaiser Permanente, as an integrated delivery system, uses a team-based care approach in which multiple providers from the same group practice may care for the same patient, and all patient data, including prescriptions, is maintained in the member’s electronic health record (EHR). Further, Kaiser Permanente owns and operates the pharmacies through which the vast majority of member prescriptions are filled. In our system, therefore, it would not be uncommon for a patient to see multiple providers or visit multiple pharmacy locations (including receiving prescriptions by mail order, if permitted under controlled substance scheduling). As all the member’s visits and fills at Kaiser Permanente locations are recorded in the EHR, the member’s experience is equivalent to visiting a single provider or pharmacy.

#### *Definition of Exempted Beneficiary*

CMS is proposing to define an exempted beneficiary as an enrollee who (1) has elected to receive hospice care; (2) is a resident of long-term care facility or of another facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy; or (3) has a cancer diagnosis.

We support CMS’ recommendation to classify LTC patients as “exempted beneficiaries” but also recommend that plan sponsors be allowed to implement beneficiary-specific claim edits as

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<sup>5</sup> Available at: <https://www.fda.gov/downloads/Drugs/DrugSafety/UCM518672.pdf>.

determined by case management if a plan sponsor independently identifies an at-risk beneficiary in long-term care.

#### *Case Management/Clinical Contact/Prescriber Verification*

CMS is proposing that plan sponsors communicate or attempt to communicate with prescribers who have prescribed frequently abused drugs regarding whether prescribed medications are appropriate for such beneficiary's medical conditions. The initial communication would be in writing, but in instances where the prescribers are non-responsive, plan sponsors would have to make reasonable attempts to communicate telephonically. Kaiser Permanente has an efficient internal communication tool built into our integrated EHR system. We therefore recommend that CMS permit outreach attempts to be conducted telephonically *or* by other communication tools available to contact prescribers within an integrated delivery system.

CMS proposes that plan sponsors must make three outreach attempts within 10 business days before concluding that a prescriber is unresponsive to case management. Within our integrated delivery system, we have internal escalation policies and processes to ensure that a prescriber responds. These processes are generally more effective than repeated telephonic attempts to the prescriber. Therefore, we recommend that CMS permit integrated systems (and other systems with such processes in place) to use internal escalation policies to elicit a response from the prescriber in lieu of the three attempts within 10 business day requirement.

#### *Requirements for Limiting Access to Coverage for Frequently Abused Drugs*

CMS is proposing that before a Part D plan sponsor can limit access of an at-risk beneficiary to coverage for frequently abused drugs, the sponsor must obtain the agreement of the prescribers of the frequently abused drugs with the limitation, unless the prescribers were unresponsive to prior outreach for case management.

Kaiser Permanente supports the lock-in proposal but recommends that the Part D sponsor be able to implement lock-in without first obtaining approval from all prescribers. First, plan sponsors will have already coordinated with the prescribers during case management, at which time the sponsor will have determined the appropriateness of the medication and verified with the prescriber that the beneficiary is at risk. Obtaining formal approval of the lock-in will only serve to delay initiating the lock-in. We therefore recommend that CMS require approval only from the primary prescriber, as determined by case management. Second, a given prescriber may be contributing to the overutilization, in which case his or her approval may not be obtained.

In addition, we recommend that plan sponsors be allowed to consider opioid utilization information from external sources during case management, including state-based controlled substance prescription registries. Many opioid drugs are generic and at-risk beneficiaries may choose to pay cash for their prescriptions to avoid plan point-of-sale safety edits.

#### *Beneficiary Notices*

CMS proposes that plan sponsors send an initial notice to the beneficiary, alerting the beneficiary that he/she has been identified as at-risk. CMS is mandating certain elements of this notice, including "contact information for other organizations that can provide the beneficiary with

assistance regarding the sponsor's drug management program." We are unsure of CMS' intent in including this element, as we would not expect an outside organization to be knowledgeable about a sponsor's own drug management program. We ask that CMS provide clarification regarding the purpose of this element and how plan sponsors should meet this requirement.

*Limitations on Access to Coverage of Frequently Abused Drugs to Selected Pharmacies and Prescribers*

CMS is proposing that a Part D plan sponsor may not limit an at-risk beneficiary's access to coverage of frequently abused drugs to a selected prescriber(s) until at least six months have passed from the date the beneficiary is first identified as a potential at-risk beneficiary. CMS notes that it expects the six-month waiting period will provide the sponsor additional time to assess whether case management or another tool has failed to resolve the beneficiary's overutilization of frequently abused drugs.

Kaiser Permanente recommends that plans be given more discretion on the timing, particularly as six months may be too long if there are significant safety concerns for a beneficiary. In the Proposed Rule, CMS notes that sponsors indicated in prior comments that the case management process can take between three and six months. If a plan is able to conduct its case management in a shorter timeframe than six months, it should be able to initiate lock-in. Moreover, in cases where the beneficiary's prescriber is contributing to the at-risk behavior, plans should have the ability to effectuate lock-in without being bound by a six-month waiting period. We recommend that plan sponsors be allowed to expedite implementation of a point-of-sale edit in cases of egregious and dangerous overutilization in order to protect the health and well-being of the beneficiary.

*Confirmation of Pharmacy and Prescriber Selection*

CMS proposes that plan sponsors obtain a confirmation from the network pharmacy that it will serve as the at-risk beneficiary's selected pharmacy. CMS proposes an exception for the confirmation requirement if the pharmacy has agreed in advance in its network agreement with the sponsor to accept all such selections and the agreement specifies how the pharmacy will be notified by the sponsor of its selection. We propose a second exception for plans sponsors that own or operate their own pharmacies, such as Kaiser Permanente. Such confirmation would be unnecessary given that the pharmacy would already be known to be confirmed, as part of our integrated system.

**A.2. Flexibility in the Medicare Advantage Uniformity Requirements**

Kaiser Permanente supports the policy direction of CMS' proposal permitting Medicare Advantage plans flexibility in offering supplemental benefits, reduced cost sharing or deductibles to enrollees with certain disease states and/or health conditions. We agree 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.

While supportive of this proposal, we believe implementation of this policy could be operationally challenging and could lead to enrollee confusion. Below, we describe a few examples that CMS should address in future guidance:

- Under the proposal, plans can offer lower cost shares for certain designated services provided to enrollees with a particular health condition. CMS will therefore need to enhance the Plan Finder tool to ensure it clearly reflects the differentiated cost sharing. In its current form, the Plan Finder displays out-of-pocket costs based on the lowest cost share in each service category. Reducing cost share for select services could result in a range of cost sharing being published on the Plan Finder, in which case the lowest cost might be used for valuing all services in that category. Beneficiaries could be misled about their likely cost sharing under different plans, which could result in their making misinformed enrollment decisions.
- 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 understand CMS intends to publish additional guidance related to this policy change in the 2019 Call Letter. We urge CMS to do so, including providing further detail and operational/implementation guidance with respect to the issues we have described above. It is important that plans have a meaningful opportunity to evaluate and provide feedback on additional parameters and CMS' expectations regarding implementation of the policy.

#### **A.4. and A.5. MOOP and Cost Sharing Limits for Medicare Parts A and B Services**

CMS proposes to clarify the agency's authority to use Medicare Fee-for-Service (FFS) data to annually establish maximum out of pocket (MOOP) and cost sharing limits. CMS also intends to use MA encounter data to establish cost sharing standards and thresholds and requests comments regarding the use of MA encounter data to inform the setting of MOOP limits.

Kaiser Permanente is 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, as we expect it would add a level of complexity that could lead to volatility in the calculation of the MOOP levels. It is unclear from the proposal how CMS expects to use the 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 Call Letter in order to more fully understand the potential impact on individual MA plans.

#### **A.6. Meaningful Difference**

Similar to our comments on the proposed flexibility in the Uniformity of Benefits rule, Kaiser Permanente conceptually supports the additional flexibility that comes with eliminating the MA meaningful difference requirement, but we have concerns about the implementation of this policy change and the potential for enrollee confusion with the likely increase in the 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 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 their 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 questions and examples and provide further guidance in the 2019 Call Letter. 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 focuses on individuals with diabetes and therefore develops a network with primary and specialty providers with expertise in treating and monitoring diabetes. Would CMS approve plans that are distinguished on the basis of such network differences? Would such designs conflict with the non-discrimination provisions in the regulations?

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

#### **A.7. Coordination of Enrollment and Disenrollment Through MA Organizations and Effective Dates of Coverage and Change of Coverage**

CMS is proposing to resume the practice of seamless conversion for those plans that offer both D-SNPs and Medicaid managed care plans. We support CMS' proposal to default enrollments for dual eligible beneficiaries, but we recommend that CMS adopt another limitation in addition to the five limitations specified in the Proposed Rule: the provider network for the MA plan should not be substantially narrower than the provider network of the Medicaid managed care plan in which the individual is currently enrolled. This will help ensure that the member's default enrollment does not result in enrollment in a plan that does not offer, at a minimum, an equivalent provider network.

Kaiser Permanente also strongly supports the proposal of an "opt in" election process that would allow MAOs to convert eligible enrollees from an existing non-Medicare plan to an MA plan offered by the same organization. However, there is a need to minimize the number of data elements required to complete such elections. Sometimes the need to collect various data elements can make a process that is otherwise meant to be simple, more cumbersome. For example, we recommend that CMS waive the need for beneficiaries to provide information that would typically be required on enrollment forms given the fact that the MA plan already possesses this information to process the enrollment request (e.g., ERSD status, language preference, authorized representative contact information). In turn, this would make it easier for



beneficiaries to take advantage of this election process and minimize the potential for beneficiary confusion and processing delays (due to incomplete enrollment requests).

We also wish to raise the question of whether it is necessary to limit this opt-in process to individuals that are in their Initial Coverage Election Period (ICEP). Our experience has shown there are circumstances outside of the ICEP in which members in commercial or Medicaid plans wish to convert to MA plans, and thus would greatly benefit from being able to utilize the opt-in process to do so. For example, those members who are currently on commercial coverage and have recently retired or are about to retire, and are reevaluating their plan options, may also want to take advantage of this simplified opt-in process.

Finally, we request that CMS provide more detail about how the opt-in election process would work for newly-eligible commercial members. In particular, with the limitations on the ability to obtain and confirm the identity of the individual while using the new Medicare Beneficiary Identifier instead of the Health Insurance Claim Number (HICN), we have concerns about how the opt-in process would be operationalized.

#### **A.10. Establishing Limitations for the Part D Special Election Period (SEP) for Dually Eligible Beneficiaries**

CMS is proposing to limit the availability of SEPs to once annually for duals and LIS recipients. We note that it may be difficult for plan sponsors to determine whether the SEP has already been utilized by a given enrollee. We therefore request that CMS provide a mechanism by which to determine such SEP utilization, and make this viewable on MARx. We also request that CMS clarify whether the once-per-year SEP falls outside of the Annual Enrollment Period (AEP), or whether the SEP also applies during this same AEP timeframe. Plan sponsors will also need a mechanism by which to determine if the enrollment prior to the enrollee's SEP request was assigned by the CMS or the State.

#### **A.11. MA and Part D Star Ratings**

The Medicare Star Ratings system continues to lead the way in providing crucial information on health plan performance to Medicare beneficiaries and the public. We support CMS' ongoing efforts to enhance the quality of the reporting system as a whole, and we look forward to continuing to partner with CMS on these efforts. Our specific comments in response to the provisions of the Proposed Rule are below. Most important to highlight are our concerns about the practice of contract consolidation (with appreciation that CMS has begun to address this issue) and the codification of the Categorical Adjustment Index, which was intended to be an interim adjustment.

##### *Guiding Principles*

CMS articulates and requests feedback on a number of "guiding principles" that the agency says have been used in the past to make enhancements to the Star Ratings system. Kaiser Permanente is generally supportive of the guiding principles, but offers comments on the following principles:

- Principle: Measures developed by consensus-based organizations are used as much as possible.

We have concerns about the use of the term “consensus-based” rather than “evidence-based.” The term “consensus-based” has a specific meaning in the context of measure development. Measures developed by consensus have the lowest rating in terms of the strength and quality of the evidence used to create and specify the measure. Quality measures should have the strongest underlying evidence, not the weakest. Any specialty society may develop a consensus-based quality measure which might materially advantage their practitioners, but may have weak supporting evidence. Kaiser Permanente would not support using such measures in the Star Ratings system.

While we recognize that the guiding principles are broadly designed to address ratings and scoring methodologies, rather than the individual measures used in creating the ratings, we would still suggest that this principle be replaced with wording underscoring the importance of evidence behind the measures. Below is suggested alternative wording for the second guiding principle that encompasses the idea of evidence based medical practice and patient care:

Measures in the quality rating system should have a strong underlying evidence basis, and at a minimum should meet the criteria for validity and reliability established by independent evaluation organizations such as the National Quality Forum.

- Principle: Ratings are a true reflection of plan quality and enrollee experience; the methodology minimizes risk of misclassification.

Kaiser Permanente recommends that CMS put a process in place to reduce misclassification due to problems when cut points do not represent meaningful and substantive differences in plan performance.

When plan sponsors’ scores are tightly clustered, the differences between cut points can be quite small. For example, several CAHPS measures have cut points that may be only 1 or 2 points apart. These do not represent substantively meaningful differences in performance. In such cases, assigning different stars levels results in greatly increased risk of misclassification. Moreover, the survey-based CAHPS and HOS measures are particularly subject to issues of statistical precision around the scores. This issue is also a concern for some HEDIS measures, especially for smaller plans. There are cases where the small differences between cut points are smaller than the statistical confidence intervals around a measure. In those cases, a small and statistically insignificant difference in scores can result in contracts being misclassified by 1 or 2 star levels.

We recommend that CMS consider:

- (1) Dropping a measure if it does not adequately distinguish performance between contracts;
- (2) Revising the measure to see if it can be improved; and/or
- (3) Testing alternative methodologies for assigning star levels for tightly clustered measures. (For tightly clustered CAHPS measures, for example, CMS could consider methods other than basing cut points on the national distribution ( $\geq 15$ th to  $< 30$ th percentile,  $\geq 30$ th to  $< 60$ th percentile, etc.), such as reasonable predetermined cut points.)

Having adequate differences between cut points, ones that reflect meaningful performance differences, is important to the industry, important to the validity and acceptability of the star ratings, and consistent with the language of the principle.

### *Feedback on Existing Measures*

CMS solicits feedback from stakeholders on how well the existing stars measures create meaningful quality improvement incentives and differentiate plans based on quality.

- Additional opportunities to improve measures so that they further reflect the quality of health outcomes under the rated plans.

Kaiser Permanente urges CMS to consider adopting into the Medicare Star Ratings program only those measures that have met all the following criteria:

1. National Quality Forum (NQF) endorsed;
2. Publicly reported by NCQA (or the measure steward) for at least one measurement period; and
3. Reported on the CMS Display Page for at least one measurement period.

Regarding criterion 3 above, Kaiser Permanente strongly recommends that CMS not report new (first year) measures (HEDIS or otherwise) on the Display Page. First-year measures are designated by the National Committee for Quality Assurance (NCQA) as inappropriate for public reporting. They are collected and submitted to NCQA to ensure that plan sponsors do not experience unanticipated data collection challenges, and to identify and accommodate technical specification refinements that may be necessary prior to public reporting in the second year. Only after a measure has been reported in the second year should it be eligible for inclusion on the Display Page.

Using all three criteria will assure Medicare beneficiaries, plan sponsors and CMS that the Stars measures are as accurate as an “assignment of overall and Part C and D Summary Star Ratings” as possible. In addition, adoption of only fully vetted measures, whose validity and reliability have been broadly tested, and whose results have been audited, will permit CMS to reach another of its stated goals, namely, ensuring the system creates incentives for Quality Improvement.

Below are several examples where changes could be made to improve incentives for quality improvement and/or differentiate plans based on quality:

- Medication Adherence Measures

For the three Medication Adherence measures, D11, D12, and D13, (Diabetes, Hypertension, Cholesterol) Kaiser Permanente recommends that CMS and the measure steward, Pharmacy Quality Alliance (PQA) consider excluding beneficiary prescriptions from these measures that are documented as “discontinued” by the prescriber. While it may be challenging for plan sponsors to reliably report such data, given the current measure specifications, including such discontinued prescriptions in the calculations makes it erroneously appear that beneficiaries with discontinued medications are non-adherent.

- HOS Measures

The relatively small size of the Health Outcomes Survey (HOS) sample makes it difficult to identify meaningful changes in plan sponsors' performance on two key HOS measures—Improving or Maintaining Physical Health and Improving or Maintaining Mental Health. Given the importance of these two HOS outcome measures, each with a weight of 3, we recommend that CMS require larger sample sizes. Unlike with Medicare CAHPS, CMS does not give plan sponsors the options of oversampling. We recommend that CMS either increase the required sample size of the HOS survey, or allow plan sponsors to oversample.

- Display Page Measures

As stated above and in prior comments, Kaiser Permanente urges CMS to not report new (first year) measures (HEDIS or otherwise) on the Display Page. First-year measures are designated by NCQA as inappropriate for public reporting. They are collected and submitted to NCQA to ensure that plan sponsors do not experience unanticipated data collection challenges, and to identify and accommodate technical specification refinements that may be necessary prior to public reporting in the second year. Only after a measure has been reported in the second year should it be eligible for inclusion on the Display Page.

- Whether CMS' current process for establishing the cut points for Star Rating can be simplified, and if the relative performance as reflected by the existing cut points accurately reflects plan quality.

The rating system methodology should be designed to ensure that a plan sponsor's performance, both on individual measures and summary/overall measures, translates into equitable ratings.

Kaiser Permanente supports providing increased stability of cut points from year to year. We continue to advocate for benchmarking the upcoming Star Rating year's performance, utilizing cut points derived from the prior rating year's data. We assert that prior knowledge of measure cut points versus their revelation at the close of the Star Ratings season better serves the MA-PD community's efforts for improvement. This approach would also allow the thresholds to change over time, with a one year lag, reflecting the change in the overall performance of plan sponsors. Additionally, it would provide CMS enough time to compute ratings for their inclusion in the "Medicare and You" handbook, thereby making ratings more available and rendering them more useful to Medicare beneficiaries making vital health coverage choices.

- Adding measures that evaluate quality from the perspective of adopting new technology (for example, the percent of beneficiaries enrolled through online brokers or the use of telemedicine) or improving the ease, simplicity, and satisfaction of the beneficiary experience in a plan.

Kaiser Permanente agrees with the need to consider new and emerging technologies, and the need to modify technical measurement specifications to accommodate these technologies when appropriate, especially those affecting care delivery. Specifications should be modified as technology becomes available and measures incorporating the specifications are demonstrated to

be reliable and valid. Moreover, all measures should be periodically evaluated and specifications should be adjusted to accommodate new and emerging technology.

CMS suggests, as an example of incorporating new technologies into the Star Ratings system, that the percent of beneficiaries enrolled through online brokers could be included. We do not support the use of a measure for enrollment through use of online brokers, as the suggested metric is not a quality measure, but rather is a business management function that would not be appropriate for Star Ratings data capture. Kaiser Permanente does support, however, a modification to include the use of telemedicine into the Star Ratings, via CAHPS measures data collection. 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.

As an example, in reviewing use of online or phone methods to communicate with doctors, internal focus group data show that unless respondents are specifically asked about these non-traditional ways of having an appointment with their doctor, they will not consider these instances when thinking about their care in the last 6 months (as the CAHPS instrument requests). Telephone appointments, video appointments, and email communication with physician offices are alternative modes in which beneficiaries can, and often do, access care. Nevertheless, these telehealth appointments are not 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. As always, once items are identified, further testing must be conducted to measure reliability and validity.

- Including survey measures of physicians' experiences. (Currently, we measure beneficiaries' experiences with their health and drug plans through the CAHPS survey.) Physicians also interact with health and drug plans on a daily basis on behalf of their patients. We are considering developing a survey tool for collecting standardized information on physicians' experiences with health and drug plans and their services, and we would welcome comments.

Although important, physician experience with health plan sponsors is not a critical component of safe, effective, efficient, timely, patient-centered, or equitable care – the focus points for CMS. We question whether physician experience with a health plan would help inform a beneficiary's choice of a plan. Moreover, physician experience measures could potentially highlight conflicts of interest between physicians' business interactions and reported experiences that might influence patient care. Given other Star Rating priorities, physician satisfaction with health plans should not take the place of developing more outcome, clinical and experience measures for the Quality Rating System.

While this CMS proposal should be a low priority given the need to develop better outcome, clinical and experience measures that truly focus on healthcare quality, we also have methodologic reservations about survey measures of physician experiences. For example, how would providers who are part of networks of multiple health plan sponsors be sampled and queried? How could CMS control for physicians' experience with one plan sponsor affecting their responses for another?

### *Contract Ratings*

Kaiser Permanente supports the CMS proposal to continue the practice of calculating the Star Ratings at the contract level permitting all plan benefit packages (PBPs) under the same contract to have the same overall and/or summary ratings. We agree that reporting at the plan level would significantly increase plan sponsor burden for data reporting. Moreover, reporting at the PBP level rather than the contract level would significantly reduce sample sizes for the various Star Rating metrics.

### *Contract Consolidations*

CMS proposes a change in how contract-level Star Ratings are assigned in the case of contract consolidations, noting that there has been a continued increase in the number of enrollees being moved from lower Star Rating contracts that do not receive a Quality Bonus Payment (QBP) to higher Star Rating contracts that do receive a QBP. CMS expressed concern in the preamble that this practice results in masking low quality plans under higher rated surviving contracts and does not provide beneficiaries with accurate and reliable information for enrollment decisions. Kaiser Permanente shares CMS' concerns and those expressed by MedPAC in its March 2016 *Report to the Congress*. Since cross-walked contracts can cause confusion and opacity to the plan performance and quality improvement of MAOs, we agree that CMS should act to reduce the impact of crosswalk activity on Star Ratings.

Kaiser Permanente supports CMS' proposal to calculate the Star Ratings for "surviving" contracts after a consolidation based on the enrollment-weighted average of the contracts' Star Ratings. We do, however, still have concerns as to how well the averaging method will address situations where the consolidated contracts cover different service areas (potentially in different states) and where the average would still result in misrepresenting the performance of a portion of the "surviving" contract. In both cases, the Star Rating for the full surviving contract will not accurately depict the quality of the portion of the contract that was consolidated into the surviving contract. MedPAC has addressed these issues in its comments on the Proposed Rule.

Overall, we applaud CMS' commitment to ensuring the integrity of the Star Ratings as a credible measure of quality improvement and as a mechanism to permit Medicare beneficiaries to have valid, reliable information with which to make important Medicare enrollment decisions. We look forward to continuing to work with CMS on this issue.

### *Adding, Updating and Removing Measures*

CMS proposes that "substantive" updates to existing measures would be added to the Star Ratings system based on future rulemaking, but that prior to such a rulemaking, CMS would announce new measures and substantive updates to existing measures and solicit feedback from the industry.

We recommend that substantive updates be clearly separated from system/process changes if both are related. For example, the recent CMS Complaints Tracking Module (CTM) system enhancements affected the C28 measure (Complaints against the Health Plan), but were not clearly identified in Call Letter or other subregulatory guidance. A CMS teleconference on the topic focused on the IT/system changes for CTM in HPMS but did not highlight how the re-

categorization of complaints would impact the Stars measure. We believe those changes were substantive but were not identified as such.

We request that CMS explain its concept of “substantive” as it relates to updates to Star measures. We further ask that CMS seek industry comment on the use of the term for each time an update is being considered. We further request that updates to existing measures that are not known at the time of the draft Call Letter should be clearly identified through measure steward notifications with enough advance notice to allow plan sponsors sufficient time to review and comment.

We recognize that CMS follows a measure review and public comment process that by design is linked to the subregulatory guidance and now rulemaking cycles. However, we have some specific concerns about a small number of measures, related in part to changes in measurement specifications and metric validity issues, and would appreciate CMS providing information as soon as possible about its intent for these measures with respect to the 2019 Star Ratings. The measures in question are as follows:

- Beneficiary Access and Performance Problems (BAPP);
- HOS Fall Prevention measures;
- Hospitalizations for Potentially Preventable Conditions (HPC);
- Statin Therapy for Patients with Cardiovascular Disease (SPC); and
- Statin Use in Persons with Diabetes (SUPD).

### *Improvement Measures*

Kaiser Permanente supports the CMS proposal to codify the special rule to hold sponsoring plans harmless when those plans have 5-star ratings for both years on a measure used for the improvement measure calculation.

### *Data Integrity*

CMS is proposing to authorize scaled reductions in Star Ratings for Part C and Part D appeal measures and says it will use statistical criteria to determine if a contract’s appeals measure-level Star Ratings would be reduced for missing IRE data. The criteria would permit CMS to use scaled reductions for the appeals measures to account for the degree to which the data are missing. CMS proposes to use multiple data sources such as the TMP (timeliness monitoring project) data or information from audits, to determine whether the data at the Independent Review Entity (IRE) are complete.

Kaiser Permanente supports the CMS approach to scaled reductions in Star Ratings for appeals measures. We agree that the validity of the data submitted to the IRE is an important aspect of accurate Star Ratings.

CMS indicates, “When applicable (for example, data from IRE, PDE, call center), CMS expects sponsoring organizations to routinely monitor their data and immediately alert CMS if errors or anomalies are identified.” We agree that an important aspect of maintaining data integrity is to

regularly review and monitor the accuracy of data being received/reported by the IRE. To successfully employ a robust internal monitoring program however, the IRE must provide plan sponsors with updated and accurate data by which they can successfully reconcile in real time. We therefore recommend that the IRE be required to include all data elements that are used for compiling the Stars scores in the IRE system and on the IRE website. This includes adding an indication of “timeliness” which is not currently available on the IRE website. By requiring the IRE to display a timeliness indicator on their website for each case, plan sponsors will be better able to reconcile and monitor data, and address discrepancies immediately and throughout the course of the monitoring period, to ensure the highest level of data integrity.

In addition to the above comments, we request that CMS provide clarification on the following issues:

1. Since TMP and audit activities occur at the parent level (the parent might hold multiple contracts), how does CMS propose to evaluate a potential reduction to the Star Ratings that are at the contract level? Will a TMP finding resulting in a star reduction be applied equally to all contracts under the parent organization, or through some other mechanism?
2. CMS references other audits as being applied to reduce Stars scores for appeals measures. We request that CMS identify which other audits may be included, and how those audits will be reviewed to determine impact on the Star Ratings. Will the outcomes of other audits have direct impact on a star rating (drop score to 1 immediately), or will they be utilized as an information source for assessing data integrity and evaluated for scaled Star reductions (like the TMP)?
3. Additionally, we request clarification on how CMS plans to utilize the Data Validation Audit (DVA). According to text in the Proposed Rule, CMS indicates that it will continue to reduce Part C and D data to 1 Star when a contract did not score at least 95 percent on the DVA.<sup>6</sup> Is the DVA considered part of the “other audits” to which CMS refers?

Since TMP or audit findings can stem from issues within one or more contracts of a parent organization, it would be inequitable to apply parent level audit outcome reductions equally to all contracts that fall within the parent’s organization. We encourage CMS to develop a fair and equitable methodology that recognizes that some scoring is derived at the parent level, and some is derived at the individual contract level.

#### *Categorical Adjustment Index Value*

In the Proposed Rule, CMS asserts that a growing body of evidence links the prevalence of beneficiary-level social risk factors with performance on measures included in MA and Part D Star Ratings. However, CMS goes on to state that through its research to date, it has seen that “administrative costs may increase as a result of enrolling significant numbers of beneficiaries with LIS/DE status or disabilities,” but “the impacts of socioeconomic status (SES) on the quality ratings are quite modest, affect only a small subset of measures, and do not always negatively impact the measures.” Kaiser Permanente therefore recommends that CMS only use risk adjustments specifically made by measure stewards. Moreover, because of the “quite

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<sup>6</sup> See 82 Fed. Reg. at 56395.



modest” impacts on quality ratings, for “only a small subset of measures,” CMS should institute a hold harmless provision on Categorical Adjustment Index scoring methodology.

Kaiser Permanente is concerned that CMS is considering codifying this interim solution that requires significant, complex changes in the calculation methodology for many measures—and corresponding increases in CMS’ and plan sponsors’ administrative burden—while CMS acknowledges that the CAI has a small, equivocal impact on Star Ratings. Given that CMS has engaged with measure developers to discuss the potential need for adjustments at the measure level, and given that CMS is working in collaboration with the Office of the Assistant Secretary for Planning and Evaluation (ASPE), we do not believe it is appropriate to codify this intentionally temporary adjustment in the Code of Federal Regulations. We recommend that CMS, ASPE and measure stewards develop fair solutions for measure-level adjustments that can be implemented and applied over the long term, based on the results of the research and evaluation currently underway.

As we have commented before, industry studies have shown that there are Star Ratings measures on which dual-eligible (DE)/low income subsidy (LIS)/disabled subgroups perform favorably compared to subgroups that are not DE/LIS/disabled. This prompts questions as to which subgroups should be adjusted for, and for which measures within those listed by CMS. Adjusting measures based on inadequate or confounding covariates would weaken the accuracy of any adjustments. Measure stewards or other entities may be able to develop evidence as to the influence of low-income and/or disability status that can be used for adjustments. The responsibility of adjusting measures to account for disparities should remain in the hands of measure stewards and not be included in regulation.

If CMS proceeds with its proposal to codify this interim solution, we believe that plan sponsors should be held harmless in the case that the adjustment reduces their Star Rating. As we have commented previously, creating fluctuations in Star Ratings due only to calculation methodology changes can cause beneficiary confusion by creating the impression that a contract’s actual performance has changed. Such confusion would diminish the credibility of the Star Ratings program.

#### *Specific Measure Comments*

Kaiser Permanente recommends that CMS retire the Diabetes Care – Kidney Disease Monitoring measure. We recommend removal of this measure from the Star Ratings because nationally, plans have historically performed well, and continue to perform well on this measure.

#### **A.17. Request for Information Regarding the Application of Manufacturer Rebates and Pharmacy Price Concessions at Point of Sale**

In this Request for Information (RFI), CMS posits that when price concessions and rebates are applied post-point-of-sale, the price concession and rebate amount accrues to the Part D plan sponsors and the government. While this post-point-of-sale application may result in some instances of higher beneficiary cost-sharing at the point of sale (POS) for the individual enrollee, it permits plan sponsors to offer lower premiums to all enrollees with Medicare Part D coverage.

Indeed, CMS has promoted the stable Part D premiums as an exemplar of Medicare Part D program efficiency and affordability.<sup>7</sup>

CMS is proposing to require plan sponsors to reflect at least a minimum percentage of manufacturer rebates and all pharmacy price concessions in prices at POS. While we agree that rebates are not the optimal way to reduce drug prices overall, the POS approach being considered by CMS would be very difficult to administer and, more importantly, it will not solve the problem of high drug prices. Kaiser Permanente believes that the issue of rebates and price concessions, and how they should benefit Part D enrollees, deserve attention, but we believe a great deal more work needs to be done by stakeholders and CMS before large policy changes can be adopted.

#### *Complexity of Including Rebates and Price Concessions at the Point of Sale*

The ability to estimate the rebates and price concessions at POS is complicated by several factors, including:

1. Rebates often depend on performance (volume, market share, growth, etc.), measured *after* dispensing, and this measurement may be stratified into tiers, which are associated with varying percentage rebates.
2. Drug prices for generics are quite fluid and may increase or decrease dramatically. As such, rebates will see material changes as well.
3. Shortages and failure to supply create changes in suppliers during any given year. This may have the effect of changing or eliminating a rebate on a given drug and NDC (National Drug Code).
4. Requests for Proposals to generic manufacturers result in changes to unit cost of numerous products during the year. There are also periodic changes to the terms and levels of rebates throughout the plan year.

Due to the need to negotiate with many parties, the fact that many manufacturers sell the same generic medications, and many other factors that affect the drug market, including the items listed above, determining price concessions at POS determinations is very difficult. Even the use of an estimate introduces a subjective and complex adjustment that will add to the cost of administering Part D benefits, which could be passed on to Part D enrollees, contrary to CMS' intent to keep Part D plans affordable. Furthermore, negotiations of rebates are so complex and multi-dimensional that significant variances will result from the time a plan sponsor estimates a rebate at POS to incorporate into the negotiated price compared to the actual year end rebates reportable via annual DIR submissions. Because of all these factors, end-of-year reconciliation after including estimated rebates at POS may become very difficult.

It is also important to consider that individual enrollee cost-sharing at POS will vary as some plans utilize copayments as opposed to cost-sharing. Copayments are generally such that the

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<sup>7</sup> See e.g., CMS Press Releases "Medicare Issues Projected Drug Premiums for 2018" (Aug. 2, 2017) and "Medicare projects relatively stable average prescription drug premiums in 2017" (Jul. 29, 2016).

member copay amount would not be reduced with a reduction in drug price, while all enrollees see the benefits of rebates in the form of lower plan premiums.

Finally, plan sponsors use multiple IT systems for the complex tasks of tracking purchases and dispenses of drugs, and reporting rebates and price concessions. Each of those IT systems will need to be updated and programed for any new estimating and reporting requirements. IT system changes require time and attention to coding, implementation and testing prior to final roll-out. We therefore recommend that CMS provide adequate time for system changes, should CMS decide to make changes to rebate/price concession reporting.

#### *Direct and Indirect Remuneration (DIR) Reporting under RFI Proposals*

For any required inclusion of rebates or price concessions at POS, plan sponsors would have to estimate the rebate amount to incorporate in the negotiated price at the point of sale. Plan sponsors would maintain thorough documentation of the calculation to derive the estimated rebates and discounts and then true them up to actual DIR at the end of the year to report the net amounts of DIR in the annual reports.

When CMS or its auditors try to evaluate DIR and price concessions/rebates at POS two or three years later, they will try to “tick and tie” to account for every drug on the Prescription Drug Event (PDE) samples they choose. This accounting process will not be accurate because of the estimates used, and could lead to incorrect and unnecessary audit observations or findings. With civil money penalties (CMPs) now being assessed upon audit observations and findings, CMPs may also be incorrectly imposed.

### **SECTION B. IMPROVING THE CMS CUSTOMER EXPERIENCE**

#### **B.1. Restoration of the Medicare Advantage Open Enrollment Period (OEP)**

CMS is proposing to implement the “new OEP” pursuant to the 21<sup>st</sup> Century Cures Act. We request that CMS provide additional clarification regarding the following:

- It is unclear whether the OEP would be applicable to Cost plans. Related to this, does CMS intend to revise the current Special Enrollment Period (SEP), or provide a corresponding SEP, for Cost plans with Part D to accept new enrollees? Under one scenario, an MA enrollee may want to switch to a Cost plan that includes an optional Part D plan, and thus may need to be able to use the OEP or a SEP to be able to switch to that plan.
- It is unclear whether the OEP allows only for changes from one contract to another, or if the OEP also allows for changes within a contract (i.e., from one PBP to another PBP).

#### **B.4. Revisions to Timing and Method of Disclosure Requirements**

Kaiser Permanente supports CMS’ proposal regarding electronic delivery of documents, but we request that CMS provide additional details and clarification regarding the following issues:

- Under the proposal, the EOC can be posted online the day before the Annual Enrollment Period (AEP), and must be made available upon request. We request that CMS clarify whether this includes making available the Low-Income Subsidy (LIS) Rider that accompanies the EOC for enrollees with Extra Help.
- We support the proposal to send the Annual Notice of Change (ANOC) to beneficiaries by September 30, but it is unclear whether the ANOC online posting deadline would be the day prior to AEP, or on September 30.
- We request clarification on whether the proposal to deliver documents via electronic delivery online will be a CMS requirement, or if it will be optional.

Finally, Kaiser Permanente agrees there is a need to reflect changes in the plan via the EOC, formulary and directory, while providing an adequate description in the ANOC. Therefore, we suggest that the model ANOC be revised to allow plans to add information as needed about upcoming changes previously not supported by the ANOC model instructions. Specifically, we request that an instruction be added that allows plans to add information about changes as needed to ensure adequate disclosure of upcoming changes.

#### **B.6. Lengthening Adjudication Timeframes for Part D Payment Redeterminations and IRE Reconsiderations**

Kaiser Permanente supports the elimination of the MA Plan Notice for cases sent to the Independent Review Entity (IRE). This would help eliminate the need to send the resolution letter informing the member that their case has been forwarded to the IRE. However, this process change may create the need for additional changes in the resolution letter process, which are not detailed in the Proposed Rule. We request clarification as to whether MAOs would continue to have the full adjudication timeframe to forward the denied case to the IRE, or if the MAO's processing timeframe would be reduced to ensure the IRE issues the resolution letter to the member in accordance with the prior adjudication timeframe.

#### **B.10. and B.11. Parts C and D Preclusion Lists**

CMS proposes to eliminate the prescriber and provider enrollment requirement and compile a "Preclusion List" of individuals and entities that:

- (a) are currently revoked from Medicare, are under a reenrollment bar, and CMS determines that the underlying conduct that led to the revocation is detrimental to the best interests of the Medicare program; or
- (b) have engaged in behavior for which CMS could have revoked the individual or entity to the extent applicable if they had been enrolled in Medicare, and CMS determines that the underlying conduct that would have led to the revocation is detrimental to the best interests of the Medicare program.

Kaiser Permanente is generally supportive of CMS' proposal to eliminate the provider enrollment requirement and to compile the "Preclusion List," which will allow CMS to focus on those providers/prescribers who have demonstrated "bad behavior." Conceptually, Kaiser

Permanente believes this will add further protections to the integrity of the Medicare program and to Medicare beneficiaries in seeking appropriate medical and prescription drug services.

As written, however, the proposal is too general to understand the level of impact it will have on health plan operations. For example, the proposal raises questions such as the availability of preclusion list data file extracts and systems compatibility; the impact on existing exclusion screening and potential duplication of exclusions with other existing watch lists; the expected volume and impact on plan resources; and increased volume of notifications to beneficiaries.

Regarding implementation, Kaiser Permanente recommends the following:

- CMS should allow industry partners, including MAOs, PDPs, and PBMs, to provide input and recommendations through sub-regulatory guidance and industry calls as CMS defines its process;
- CMS should consider implementing the Preclusion List as a pilot program; and
- With respect to the Part D program, CMS should follow the processes similar to those currently in place for exclusions. Specifically, CMS should (a) define a standard format that can be used industry-wide; (b) publish the information on a regular basis (*e.g.*, monthly); (c) publish a list that a plan's Pharmacy Benefit Managers (PBMs) can use during adjudication; and (d) allow the PBMs sufficient time to code to the lists in order to meet the expectations for point-of-sale adjudication, which is typically about 18 months in the PBM industry.

#### *Provisional Coverage/Part D*

Finally, CMS seeks comment on its Part D provisional coverage proposal. The current provisional supply rule (section 423.120(c)(6)(v)) permits a Part D sponsor or its PBM to furnish a beneficiary with a provisional supply of a drug (three-month/90-day supply) with written notice to the beneficiary that there is an issue with respect to future coverage of the drug. CMS' proposal provides for one 90-day provisional coverage period with respect to an individual on the preclusion list.

Kaiser Permanente does not support CMS' approach. We recommend that CMS instead: (a) eliminate the provisional fill altogether; (b) reject claims upon the effective date of the preclusion, as is done for Medicare excluded providers; and (c) notify beneficiaries via letter, similar to the current requirement for excluded prescribers. Plan sponsors should be given flexibility on a case-by-case basis to allow for additional refills without a specific time period requirement, similar to the current rules for transitional fills.

#### **B.13. Reducing Provider Burden—Comment Solicitation**

In the Proposed Rule, CMS states that it is exploring ways to reduce the burden on providers arising from medical record documentation requests by Medicare Advantage plans, "particularly in connection with MA requirements." As an integrated delivery system, Kaiser Permanente is sensitive to the burden that these requests can put on providers. Nevertheless, so long as the

referenced “MA requirements” remain in place, MA plans will continue to need access to medical record documentation.

Examples of the types of regulatory obligations that can lead MAOs to request medical record documentation include:

- Improving data completeness, accuracy, and truthfulness (42 CFR §422.504(l)) – MA plans, in their efforts to improve the accuracy of encounter and risk adjustment data (based on best knowledge information and belief) conduct routine audits. These audits entail medical record review to confirm that the data and diagnosis codes submitted are supported by the medical record.
- Quality of Care Provided to Medicare Beneficiaries (42 CFR §§422.152, 422.152 (f)(1)(ii)) – MA plans are under an obligation to maintain quality improvement programs to improve the reliability and completeness of information received from providers. Quality improvement programs and data integrity activities may require medical record review on a periodic basis.
- Reporting of Quality Data (HEDIS) Measures (Medicare Managed Care Manual, Chapter 5, §§30.1 & 30.1.1, 42 CFR §417.106(a)(3), 42 CFR §417.418, 42 CFR §422.152(b)(5), 42 CFR §422.152(e)(i), 42 CFR §422.516. – Each year Medicare Advantage plans are required to engage a vendor to audit data submitted to support the HEDIS measures for each CMS contract (H#s). These audits also require medical record review and depending on the measures reviewed could require auditors to review 100s of records.
- Fraud Waste and Abuse Programs & Routine Monitoring and Oversight of First Tier, Down Stream (FDR) and Related Parties (Medicare Managed Care Manual, Chapter 21, §50.6.9, 42 CFR §§422.503(b)(4)(vi)(F), 422.503(d)) – Any entity seeking to contract as an MA organization must establish and implement an effective system for routine monitoring and identification of compliance risks, which includes, as appropriate, external audits to evaluate first tier entities’ compliance with CMS requirements and the overall effectiveness of the compliance program. MA plans routinely monitor provider claim activity to improve the accuracy and integrity of claims payment. At times medical record review is required to validate accuracy of claims received.
- Responding to CMS Audits (42 CFR §422.310(e)) – CMS regularly performs Risk Adjustment Data Validation Audits. These audits require medical record review to confirm diagnosis code data relied upon to generate risk adjustment payments are accurate and supported by the medical record.

We note that CMS’ own guidance regarding monitoring of FDRs advises, “Sponsors must include in their work plan the number of first tier entities that will be audited each year and how the entities will be identified for auditing. *It is a best practice for sponsors to conduct a number of on-site audits.*”<sup>8</sup> Plans are routinely audited by CMS on the effectiveness of their compliance programs, which must include such monitoring and auditing.

Kaiser Permanente appreciates CMS’ proposal to reduce the burden placed on providers, but would expect that in doing so, CMS would similarly refine the corresponding regulatory

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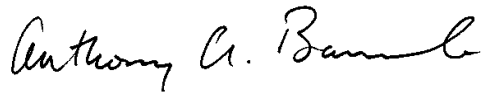
<sup>8</sup> Medicare Managed Care Manual, Ch. 21, Sec. 50.6.6.

requirements and expectations of MA plans, while still guaranteeing that plans have reasonable access to audit and monitor, among other things, claims payment and diagnosis code data submissions.

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Kaiser Permanente appreciates the opportunity to provide feedback in response to the Proposed Rule. If you have questions or concerns, please contact Anthony Barrueta at 510.271.6835 or [anthony.barrueta@kp.org](mailto:anthony.barrueta@kp.org), or Keavney Klein at 510.271.6482 or [keavney.f.klein@kp.org](mailto:keavney.f.klein@kp.org).

Sincerely,



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