To Whom It May Concern:

Re: CY 2019 Draft Call Letter – Comments

On behalf of Providence Health Assurance I would like to thank you for the opportunity to provide comments on the CY 2019 Draft Call Letter.

PHA has concerns regarding methodology for New Measure: Statin Use in Persons with Diabetes (SUPD):

Providence Health Assurance (PHA) supports the addition of a quality metric monitoring the use of statins in patients with diabetes since this has a significant population health impact on outcomes. PHA would also support an increase in weight on this clinical measure. We would respectfully ask CMS to provide a thoughtful explanation for not selecting the Part C HEDIS measure of Statin Therapy in Patients with Diabetes (NCQA measure), which had also been under consideration. The NCQA measure includes more robust clinical considerations for patient eligibility and thus appropriateness of statin use.

Specifically, many patients are intolerant to statin therapy, and PHA would be unable to exclude patients based on pharmacy claims data alone. PHA data shows that 3.8% of the patients in the denominator have associated diagnosis codes for myalgia, myositis, myopathy, or rhabdomyolysis and would be ineligible for statin therapy. This is likely an underestimate of all patients that would be considered intolerant to statins. In addition, the Part C HEDIS measure would be excluding patients with cirrhosis, which is again, unable to be determined through pharmacy claims. PHA data supports that 1.8% of patients within the denominator have an associated diagnosis of cirrhosis and would be ineligible for statin therapy.

Additionally, PHA proposes that CMS include more therapeutic options for this measure, as only including statins is clinically narrow. This measure is intended to ensure that patients with diabetes are using therapies that reduce their risk of atherosclerotic cardiovascular disease (ASCVD). According to the recently updated American College of Cardiology guidelines for the use of non-statin therapies[1] and the American Diabetes Association standards of care for diabetes[2], ezetimibe, proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitors (e.g. evolocumab and alirocumab) and bile-acid sequestrants (e.g., cholestyramine) may be considered in patients that are unable to tolerate statins, or do not reach therapeutic goals. PHA data supports that this would capture an

References:
Buono, EW et. al. Coming full circle in the measurement of medication adherence: opportunities and implications for health care. Dovepress. 2 June 2017
Fairman, K and Motheral, B. Evaluating Medication Adherence: Which Measure is Right for your Program? J Managed Care Pharm 2000: 499-504.

additional 3.6% of patients in the numerator; therefore, capturing patients that are receiving quality care as this measure intends.

PHA has significant concerns with Improvement Measures (Part C & D):
The Part C and Part D improvement measures are the highest weighted measures in the Stars program. This high weighting sends a clear message that improvement is rewarded in the Stars program. While PHA agrees with this objective, we disagree that that objective is achieved through the current policy. We find that improvement measures explicitly advantage low-performing Medicare Advantage Organizations (MAOs); however, the picture is different for high performing health plans. We feel that at best, the improvement measures create uncertainty and complexity for high performing MAOs; and at worst, the measures inappropriately penalize high performing health plans.

In its current form, the improvement measure methodology is very complex to understand and seemingly impossible to predict. These are undesirable attributes in a performance program that is otherwise fairly concrete.

In addition, we feel that the methodology creates a "double jeopardy" by factoring national performance changes and statistical significance. National MAO performance is already accounted for in the calculation of star measure cut-points, and including this factor in the improvement measure is duplicative. As a specific example, over 2017 and 2018, PHA consistently achieved 83% on the Breast Cancer Screening measure. In 2017 Stars, this performance was significantly above the 5 Star cut point; however due to broader MAO performance, the 5 star threshold moved up to 84%. The result was that our steady performance of 83% only earned a rating of 4 stars in 2018, a decline from the year prior. Our objection lies with how this was evaluated within the improvement measure scoring: in 2018 Stars, PHA was assessed a score of "Significant decline" on the Breast Cancer Screening measure, despite steady and strong absolute performance in the prior year. We can accept that we narrowly missed the 5 star threshold in an ever-competitive program, but feel this should not be assessed as a "significant decline" in the improvement scoring methodology.

In addition, we feel that the hold harmless provision proved to be inadequate. As the math played out in the 2018 Stars Second Plan Preview for PHA, under the current methodology it is seemingly possible for a plan to be in the top 96th percentile of performance nationwide, but still disadvantaged in the improvement measure scoring, irrespective of the hold harmless provision.

These results are not consistent with the intent of the improvement measure and illustrate why the methodology should be changed.

Where possible, we suggest that CMS aim to reduce complexity and unpredictability in the Stars program because such factors undermine the larger aims of continuous improvement and competition. Therefore, we recommend that CMS evaluate improvement relative to the MAO's absolute prior performance on the measure. Such an approach would add clarity and reinforce the value of continuous improvement for MAOs.

We suggest that CMS also reduce the number of measures evaluated for improvement, focusing on newer measures rather than long-standing measures.

In the immediate future, we urge CMS significantly reduce the weight of the improvement measure. The 5-Star Program is now in a mature state and it has proven to be a program design that intrinsically promotes continuous quality improvement. This reality negates the need for CMS to manufacture rewards through highly weighted improvement measures.

Over time, we would also like CMS to consider removing the improvement measure entirely to simplify and streamline the Stars program.

PHA supports proposed End Stage Renal Disease (ESRD) exclusion for medication adherence.
Providence Health Assurance (PHA) supports the proposed rules on End Stage Renal Disease (ESRD) exclusion for medication adherence.

PHA has concerns regarding methodology for Medication Adherence for Diabetes Medications: We believe a 5-star diabetes adherence threshold rate of 86% – given the current definitions – is not patient-centered and does not reflect quality of care provided by the sponsor. We are concerned that the thresholds are reaching unsafe levels for this category where there will be a percentage of members, especially in the aging elderly population, who may have to discontinue or hold therapy due to hypoglycemia, which impact adherence rates. Our 2017 data shows that 2.5% of our population, who were below 80% PDC, had a diagnosis claim of hypoglycemia in their history. This change in course of therapy is clinically appropriate. While the measurement of medication adherence is an important one, it does not reflect individual level needs. Early in therapy, dosages are likely to be adjusted and tapered, and may not reflect compliance when looking at claims histories. In addition, we have seen cases where the claims look as though the member was not adherent (e.g., 30 day supply but being filled every 60 days); however, the member states their doctor changed their directions to take ½ tablet daily, where previously the instruction was once daily. Without the inclusion of supplemental data for this measure, health plans are not reporting true levels of adherence.

It should be reiterated that the claims data includes some level of inaccuracies by pharmacies, such as accidental omission of a zero for 30-day supply, which can appear as non-compliance in claims data if entered as a 3-day supply.

Finally, increasing the 5-star threshold by 3% in one year is quite significant. We have shown sustained year-over-year improvement with this measure (2016 - 82%, 2017 - 83%, and 2018 - 85%). PHA improved by 2% over last year but proceeded to drop from 5-star to 4-star. This threshold increase does not align with the prior year increases for 5-Star in relation to the national average. See table below.

Star Year	5-Star Threshold	National Average
2016	82%	77%
2017	83%	79%
2018	86%	81%

We truly appreciate your consideration for adjusting thresholds to ensure patient safety, acknowledge limitations of current measure methodology, and remain aligned with increases as they pertain to the national average.

PHA has concerns regarding methodology for Medication Adherence for Cholesterol:
We believe a 5-star statin adherence threshold rate of 85% – given the current definitions – is not patient-centered and does not reflect quality of care provided by the sponsor. Unfortunately, using the metric as a sole measure of adherence may be predictive but remains inconclusive of true

adherence. An increase in the 5-star threshold by 3% is quite significant in one year. PHA is concerned that continuing to raise thresholds may create unsafe strategies such as auto-refill, leading to unsafe use of medications (e.g., if drug was discontinued by the provider) and result in waste.

Additionally, early in therapy, dosages are likely to be adjusted and tapered, and may not reflect compliance when looking at claims histories. It should be reiterated that the claims data includes some level of inaccuracies by pharmacies, such as accidental omission of a zero for 30-day supply, which can appear as non-compliance in claims data if entered as a 3-day supply.

Finally, we have shown sustained year over year improvement with this measure (2016 - 82%, 2017 - 83%, and 2018 - 84%). PHA improved by 1% over last year but proceeded to drop from 5-star to 4-star. This threshold increase does not align with the prior year increases for 5-Star in relation to the national average. See table below.

Star Year	5-Star Threshold	National Ave
2016	79%	75%
2017	82%	77%
2018	85%	79%

We truly appreciate your consideration for adjusting thresholds to ensure patient safety, acknowledge limitations of current measure methodology, and remain aligned with increases as they pertain to the national average.

PHA has concerns regarding Medicare Plan Finder (MPF) measure methodology:
PHA opposes the continued inclusion of the MPF Price Accuracy measure under current or proposed methodology due to restrictions outside of plan control. The price accuracy index calculation does not accommodate the delay between when the MPF files are generated to when they are posted. Files uploaded through the Submission Window are posted 14 days later to MPF. Prices reported in MPF are out of date by 14 days and are therefore inaccurate if (1) an increase has been applied to the Maximum Allowable Cost (MAC) or (2) if the Average Wholesale Price (AWP) or the Wholesale Acquisition Cost (WAC) has been increased by First DataBank or Medi-Span. Files must be submitted and loaded quicker and more frequently in order to reflect accurate costs that will match prescription drug event (PDE) records.

MAC changes must be updated on a weekly basis but because the updated prices are not reflected in MPF until the next set of files are posted; any drugs with a MAC increase will return a price accuracy index > 1.

Additionally, brand drugs, and some generics, are not reimbursed a MAC amount. Reimbursement is typically based on a percentage of the AWP or WAC. Because AWP and WAC prices can change on a daily basis, anytime there is an increase in AWP or WAC between the date the MPF files are submitted to the date they are posted claims will return a price accuracy index > 1.

PHA supports exclusion of service area reductions from disenrollment measure.
PHA supports CMS proposed rules for exclusion of service area reductions from the disenrollment measure.

References:
[1]Greenland, P. & Peterson, E. (2017). The New 2017 ACC/AHA Guidelines "Up the Pressure" on Diagnosis and Treatment of Hypertension. *JAMA, 318, 21*, 2083-2084. doi:10.1001/jama.2017.18605

[2]Whelton, P.K. & Carey, R. M. (2017). The 2017 Clinical Practice Guideline for High Blood Pressure. J*AMA, 318, 21*, 2073-2074. doi: doi:10.1001/jama.2017.18209

PHA supports new Beneficiary Access and Performance Problems (BAPP) considerations decoupling audit findings and Star Ratings:

PHA supports the separation of audit findings and enforcements from the Star Ratings program for the reasons listed by CMS. We would request more detail on the proposed measure and an additional opportunity to comment prior to inclusion on the display page or in the Star Ratings program.

PHA supports scaled reductions for data integrity on appeals measures:

PHA supports the use of scaled reductions and application only to relevant measures. We are concerned that the short window of data may not be an accurate depiction of annual results. PHA has conducted the Timeliness Monitoring Project (TMP) in early spring each year so far, which may be a higher volume of appeals because new members to the plan have recently started using benefits at the beginning of the year, which can result in a higher number of appeals in response to this. PHA would also like to confirm that only appeals data from the TMP are included in this assessment; TMP also includes prior authorizations (PAs), claims, and direct member reimbursements (DMRs), which should not be included. We continue to encourage CMS to use data validation for these purposes, rather than implementing new programs, or discontinue data validation if it is not an integral part of ensuring data integrity. Finally, the use of audit data in addition to TMP data still presents the issue of inequity in assessing health plans because not all health plans are audited. This does not resolve the issue at hand of potential inequity in application of the data integrity policy where related to audit findings.

PHA has concerns about Proposed Scaled Reductions for Appeals IRE Data Completeness Issues:

PHA is concerned about withdrawn cases being counted as an appeal. We feel that withdrawn cases should not be included in this calculation because these may occur for a number of reasons, including if a member has asked the plan to stop the review or based on the Independent Review Entity (IRE) interpretation of the request of the member. There are also times when an appeal was forwarded to IRE, but then the member/provider provides new information, allowing the plan to approve the appeal based on the new information. This should withdraw the appeal and not be included due to the new decision being outside of the allowed timeframe and would not be an upheld case going to the IRE, likely resulting in an overturn. The health plan should approve the appeal, as this is the right thing to do for the member. Including withdrawn appeals in the measure calculation removes the Stars incentive for plans to do the right thing for the member in this situation because they are penalized either way. PHA also strongly disagrees with utilizing "projected" data. As a sponsor with a low number of cases forwarded to the IRE, a projection is likely to overinflate our true error rate, and subject our contract to a more severe penalty than reality would warrant. An alternative could be to allow plans who disagree with the projection to submit additional universe data for an updated and accurate Star Rating reduction.

PHA opposes reporting High Risk Medication (HRM) measure on display:

PHA disagrees with placement of HRM measure on the display page prior to changing the metric from Pharmacy Quality Alliance (PQA) as the current metric, we feel is unreliable. Please provide plan updated HRM data through Acumen after the new list has been adopted to provide sufficient time for plans to adopt/plan for metric. For the other metrics, we would like to receive data from Acumen on these metrics when possible.

PHA has concerns regarding multiple data sources for Opioid Overuse metric:

PHA proposes using a single source for the opiate metric and not both as this is administratively burdensome and causes confusion for reporting. We support display of PQA's opioid measures for

Part D, however the multiple providers and pharmacies (4 of each) seems of low value and is more geared toward Fraud, Waste and Abuse.

PHA supports clinically and encourages long lead time to operationalize:
PHA supports the clinical appropriateness of these assessments for high risk members beyond Special Needs Plans (SNP). Transitional Care Management (TCM) framework may be expanded to support these additional assessments, but it would require IT efforts by our system and provider partners, as well as new workflows for functional/cognitive/falls risk/goals of care and advance care planning. This implementation would require extensive change and support to operationalize these assessments and achieve real improvement; therefore, PHA recommends long lead time to prior to inclusion in Star Ratings program.

PHA has concerns regarding accurate reporting of adult immunizations:
PHA acknowledges and supports the clinical importance of adult immunizations but would express concerns around the ability to accurately capture all immunizations for comprehensive reporting.

PHA supports Polypharmacy measure reporting:
PHA is in support in reporting these new measures in the Patient Safety reports to start analysis of value of these measures and potential for impact to improve population safety.

PHA supports consideration of non-warfarin oral anticoagulants measure:
PHA agrees with addition of non-warfarin oral anticoagulants adherence measure. PHA disagrees with addition of non-infused disease modifying agents in MS measure, as with this disease, patients are frequently modifying their therapy. In addition, we ask for clarification as to how would this calculate progressive vs relapsing forms of MS and if the population being treated is accurate?

PHA has concerns regarding Civil Monetary Penalty (CMP) Icon:
PHA is concerned that by displaying an icon or other type of notice on the Plan Finder for sponsoring organizations that receive a CMP that it would open the door for more icons for other CMPs and more crowding in the presentation design. In addition, CMP's are often assessed on events that happened in the past and have since been corrected. This could also create confusion for members looking at a mix of potentially good (5 star icon) along with a negative (CMP icon) for the same plan. We support the identification of this for beneficiaries, but would recommend this is done in a different means.

PHA supports Audit of the Sponsoring Organization's Compliance Program Effectiveness:
PHA agrees with CMS' proposal to allow sponsoring organizations that have undergone a program audit to treat the program audit as meeting the annual compliance program audit requirement for one year from the date of the CMS program audit. We feel that this proposed change would lessen the burden on the plans.

PHA recommends palliative care exclusion for advanced illness:
At the present time, PHA recommends ICD-10 code Z51.5 as marker for patients receiving palliative care and therefore appropriate for exclusion from HEDIS measures for that year. CMS and health systems will need to develop definitions by which palliative care diagnosis code is appropriately applied and monitored.

PHA recommends inclusion of ambulatory and home blood pressure readings:
In alignment with current clinical practice guidelines, PHA recommends that ambulatory and home blood pressure readings that are documented in the treating provider's medical record be considered acceptable for the purposes of assessing the efficacy and appropriateness of a clinician's treatment plan, as measured by the Controlling Blood Pressure measure.

The 2017 American College of Cardiology/American Heart Association (ACC/AHA) guidelines support a practice shift toward the use of home blood pressure (BP) readings as a viable clinical and diagnostic tool. A physician-composed editorial piece in a recent issue of Journal of the American Medical Association (JAMA) stated: "the [ACC/AHA] guideline recommends a newer approach to out-of-office BP measurements using ambulatory or home BP monitoring to both confirm the diagnosis of hypertension and to titrate BP-lowering medication"[1] . Additionally, the incorporation of out-of-office BP measurements aids in the detection of "white-coat and masked hypertension"[2]. In essence, the guideline prompts clinicians to begin using patient reported information regarding BP, as a valuable diagnostic tool.

Of mention, the updated guideline also encourages alignment with practices shifts already well-established outside of the United States (US); "there is clearly strong evidence to suggest that knowing the BP of an individual outside the clinic setting is more predictive of outcomes than their clinic BP and brings the US guidelines more in line with those used already in Europe"[2].

PHA supports CY 2019 Formulary Reference File (FRF):
PHA is in support of a summer formulary update window. PHA also suggests lengthening the timeframe of the window to accommodate Plans who would like to submit early to meet Materials deadlines and for Plans who would like the option to submit updates if they occur. PHA also suggests that CMS maintains a list of the drugs that were removed from the FRF. We feel this would deter health plans from requesting the drug be added back to the FRF in the future.

PHA supports Over-The-Counter (OTC) Program:
PHA supports the Part D OTC enhancements. We would also like to ask, could OTCs be incorporated into the formulary for member ease to know which OTCs would fall into this should they choose the OTC option.

PHA opposes exclusion of UTC Medication Therapy Management (MTM) and propose MTM move to display for 2019 Stars:
We strongly oppose the MTM Comprehensive Medication Reviews (CMR) completion rate being an active measure for 2017 and believe it should be moved to a display measure. Through the majority of 2017, the CMS audit team advised health plans and MTM vendors that they could complete CMRs with the provider's office when they were unable to contact a patient by other methods. In October this guidance was reversed by the CMS MTM team stating that we were not able to do this. We were notified that the CMS audit team had been educated on this and should provide correct guidance going forward. We were able to remove these CMRs from our data however other plans are likely still doing this as they may not have received the clarification. PHA reached out to CMS specifically for clarification however, we have confirmed with another MTM vendor who did not reach out specifically for clarification and they have continued this practice. They are continuing to operate under the original guidance until told otherwise. Therefore the CMR completion rate for these plans would not accurately reflect the true CMR completion rate and should not be included in the overall STARs rating for 2017.

PHA opposes legal guardianship requirement for TRC:
PHA opposes the strict requirement that medical records include documentation of legal guardianship. It is not common to find legal guardianship documented in records unless there is a specific reason such as dementia or incompetence, etc. and the family has actually taken the legal actions necessary for obtaining legal guardianship. For all the other times, including less severe circumstances where someone else oversees the members care, e.g., a family member or caregiver,

we feel that it would be more reasonable to require documentation of permission to discuss care versus legal guardianship status.

PHA opposes Proposal to add concurrent opioid- Gabapentin/Pregabalin flag to Overutilization Management System (OMS):

PHA disagrees with utility of adding Gabapentin/Pregabalin flag to OMS primarily because many prescribers are utilizing Gabapentin to decrease opioid usage. While studies have shown minimal improvement with Gabapentin in chronic back pain, it is also being used for indications including fibromyalgia, neuropathy, and restless legs syndrome which are quite common in our Medicare population. Reaching out to patients and providers about this combination may undermine the effort to decrease the use of opioids in addition to resulting in the frustration of both patients and prescribers with the Plans.

PHA has concerns with capacity to implement hard edits at 90 Morphine Milligram Equivalents (MME) as well as the 7 days allowance:

PHA doesn't believe this could be automated to allow a 7 day supply for the first claim but block the second claim. DUR/PPS codes should work to override claims for the pharmacy. This seems like a challenging concept to be able to operationalize and would be confusing for our pharmacies and members. Also most opioids are CII and most state laws require that if a member gets a partial fill of a CII prescription the remaining portion would be voided. The member would then need to obtain a new prescription which could delay care or could be a challenge for someone that is dealing with acute pain. A general benefit design that allows a 7 or 14 day supply for first fill regardless of dose and PA requirement for subsequent fill would be more reasonable. Member and provider should also receive notification after the first fill so they know a PA will be required before the next fill.

PHA supports Inhalation Durable Medical Equipment (DME) Supply Drugs:

PHA agrees with this methodology to determine correct coverage for inhalation DME.

PHA supports Immunosuppressants Used to Prevent Transplant Rejection:

PHA agrees with the proposed methodology to ensure best available evidence is being used to determine part B coverage of immunosuppressants.

Sincerely,

Providence Health Assurance