PROVIDENCE
Medicare Advantage Plans
A division of Providence Health Assurance

To Whom It May Concern:

Re: CY 2019 Medicare Program Proposed Rules

On behalf of Providence Health Assurance (PHA) I would like to thank you for the opportunity to provide comments on the CY 2019 Medicare Program Proposed Rules.

Updates to the Definition of Marketing:

We strongly agree with the division of classifying materials between Marketing and Communications. We feel that offering health plans the opportunity to provide feedback and input in defining these two new categories would be beneficial.

We welcome additional clarity on marketing guidelines versus communication guidelines, and we are hopeful this will significantly improve our ability to create meaningful engagement with members. We ask for clarification regarding the health plan's ability to cite benefit coverage information in communications regarding health and wellness – a useful tool when promoting covered, preventive benefits, such as colonoscopy and mammography. We also encourage CMS to provide a comment period or other venue for health plans to provide input on guidelines for communications.

We are pleased to see CMS expanding the use of electronic communications to Medicare beneficiaries and requests CMS expands the opportunities by adopting new communications standards. A 2017 Providence Medicare Member Advisory survey of 1,857 respondents showed that 52% prefer to receive health and wellness communications via email (how we communicate with them), and 72% prefer to communicate via email to Providence Medicare Advantage Plans about their health and wellness (how they communicate with us). These results are a significant indicator that email is important to our members, and clear guidance on how electronic communications can be used in health and wellness is critical to our organization moving in this direction.

We encourage CMS to consider allowing other items, such as Part C and Part D EOBs to be sent electronically.

Implementation of the Comprehensive Addiction and Recovery Act of 2016 (CARA):

We disagree with the proposed guidelines for Drug Management Programs (DMP) as these guidelines in addition to the fact that all prescribers associated with a tax ID number (TIN) would be considered a single prescriber would result in too few identified beneficiaries to be meaningful (ie ~5 patients per year). We do, however, agree that all prescribers associated with a TIN be considered a single prescriber.

We disagree with the fact that sponsors "would not be able to vary the criteria" of these proposed guidelines to include more beneficiaries in the DMP. We believe this would significantly limit our ability

to make an impact in this patient population. At minimum, we would like to see the option to include potential at-risk patients for whom the prescriber has requested this service.

We strongly agree with continuing to utilize the existing appeal process for potential at-risk beneficiaries and not invoking the option of automatic escalation of appeals to external review. These appeals should go through the same process as other appeals allowing the Sponsor the opportunity to review additional information and potentially adjust their decision.

Part D Tiering Exceptions:

Given the recent rise in both brand and generic prescription drug prices, and our shared interest in providing an affordable premium we respectfully disagree with this stance. We feel that providing high cost medications at the lowest possible tier, instead of the tier with the next highest cost share, contributes to higher premiums for all instead of slightly higher cost shares for a few individuals.

Limitation to Part D Special Election Period (SEP) for Dual and other Low Income Subsidy (LIS)-Eligible Beneficiaries:

We agree with the proposed changes to SEP in that potential at-risk and at-risk beneficiaries are allowed a onetime annual SEP opportunity rather than the month-to-month movement to avoid disruption of continuity of care. The previous rule, in allowing these beneficiaries to move plans monthly once identified as potential at-risk and at-risk beneficiaries has required a significant amount of resources in order to provide continual and optimal case management.

We foresee complications if this proposal is finalized in determining whether members have already used their LIS SEP and would ask CMS not to penalize plans for rejections related to this election period.

In addition, we would ask for clarification from CMS as to whether a change in co-pay level only is considered a change in their LIS eligible status resulting in an available LIS SEP.

Changes to the Days' Supply Required by the Part D Transition Process:

We support the alignment of the long term care (LTC) day supply with that of outpatient setting. Operationally it would be simpler to administer a single limit as opposed to administering a separate LTC transition period.

Expedited Substitutions of Certain Generic and Other Midyear Formulary Changes:

We support allowing generic substitution mid-year, without the administrative burden to plan sponsor to administer this change. We feel however, that sending of errata or member notifications when a drug becomes generically available could defeat the cost-savings potential. It is common practice in other lines of business to automatically require generic for brand substitution at point of sale during generic entry.

Treatment of Follow-On Biological Products as Generics for LIS Cost Sharing and Non-LIS Catastrophic Cost Sharing:

We do not support the generic definition for biologic products as the industry has not accepted this concept of generic interchangeability of biosimilar products. We feel that the application of generic definition limited to non-LIS catastrophic and LIS cost sharing only is confusing and may cause unintended operational errors in administration.

Manufacturer Rebates and Pharmacy Pricing Concessions to POS:

It is a fair argument that the proposed rule interferes with negotiations between drug manufacturers and prescription drug plan (PDP) sponsors. One possible outcome of this proposed rule is that PDP sponsors are discouraged from aggressively negotiating rebates because the return on investment (ROI) would be lower and may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs. This rule could create/require a price structure wherein a certain amount of the rebate is passed directly to the member and ultimately to CMS. We also feel that this would be a large undertaking and could take years to put into operation. We expect this to require extensive changes to input/output processes for adjudicating claims. We have concern about administrative costs.

Restoration of MA Open Enrollment Period:

We are concerned about multiple plans submitting for the same election. If CMS decides to make this a final rule, we would ask that there be a specific process or timelines associated. We respectfully request that plans would not be penalized for this type of rejection if there is not a way to identify it through MARx.

We also have concerns about the open enrollment window taking away one of the advantages of being a 5 Star plan. We are concerned about the restriction on marketing during the open enrollment period. Even though the open enrollment period only allows members on a MA/MAPD plan to make a change to another MA/MAPD, the plans that sell both MA/MAPD plans and Medigap plans would be at an advantage. We are concerned that a company who sells both MA and Medigap plans will market heavily under their Medigap line of business using a generic marketing line of, “not happy with your plan, change now” to generate leads. This would generate inquiries from those on a MA plan, at which point the company can steer the conversation to their MA products.

If CMS is going to offer the open enrollment window, we feel they should allow marketing in order to keep the playing field equal.

Preclusion List Requirements for Prescribers in Part D and Providers and Suppliers in MA, Cost Plans and PACE:

This is an area of concern for claims processing when the Part D sponsor is required to provide a provisional fill. The costs that can be incurred during the 90 day period per member can be large especially in the current climate of rising drug costs. This is also of concern in regards of timeliness of updating the preclusive list to correctly identify and notify members in the provisional fill period. It would be beneficial to all for a retro review of updates to begin the process of the provisional fill with prescriptions that may have already been picked up prior to the member being updated on the preclusive list.

Reducing Unnecessary Paperwork Burden: Medical Loss Ratio:

We strongly support the explicit guidance for inclusion of Medication Therapy Management (MTM) Program in the medical loss ratio numerator as a quality improvement activities related expense to help our members.

Comments Specific to Star Ratings:

Support codifying Star Ratings Program policies via rulemaking process:

We strongly support the Medicare Advantage Stars program and appreciate CMS' continued support for the program. We find the program design to be generally concrete and logical, providing a meaningful framework for our quality program. Over the past seven years, PHA has consistently performed at a high level, which has been a point of pride for our organization and affirmed the high quality of service we provide to our members.

CMS proposes to use the Federal Register to introduce changes to the Star Ratings program. We are comfortable with CMS moving from guidance process to regulatory process and fully support the proposed two year lead time for changes. We agree with CMS' goal to have the rating system be a framework for continuous quality improvement and providing sufficient lead time to health plans allows for identification of opportunities, development and implementation of initiatives, evaluation and adjustments.

Recommend absolute percentile performance threshold for 5-star rating:

CMS has designed a highly competitive Stars program. Achieving 4, 4.5, and 5 Stars in the Medicare program is a significant accomplishment, requiring continuous improvement and commitment to quality.

However, we question whether Star ratings have been too restrictive in recognizing top performance. In five of the past seven years, PHA performed at or above the 95th percentile, but only achieved a 5-star rating in three of those years. PHA performed above the 90th percentile in six of the seven years.

Star Year	PHA Star Rating	Rank
2012	4.5	97th percentile
2013	4.5	96th percentile
2014	5	99th percentile
2015	5	93rd percentile
2016	4.5	86th percentile
2017	4.5	95th percentile
2018	5	97th percentile

We encourage CMS to consider a percentile rank threshold for 5-star performance, whereby all MAOs that achieved performance in that absolute percentile be recognized at the 5 Star level. The primary advantage of being a 5-star plan is the ability to enroll members year-round. This modest expansion of the 5 star rating would benefit Medicare members through a greater selection health plans and appropriately recognize top performance in the Stars program.

Significant concerns with improvement measures:

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 we agree with this objective, we disagree that that objective is achieved through the current policy. We find that improvement measures explicitly advantage low-performing MAOs; however, the picture is different for high performing health plans. 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 impossible to predict. These are undesirable attributes in a performance program that is otherwise fairly concrete.

In addition, 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 we feel this should not be assessed as a "significant decline" in the improvement scoring methodology – that assessment is neither fair nor accurate.

In addition, 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 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 encourage CMS to reduce the 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 feel that CMS should 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 to 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.

Oppose Plan level Star Ratings vs. Contract level:

CMS expressed interest in assigning Star Ratings at the plan level, rather than the contract level. We have strong concerns about this approach. We feel that it would multiply administrative costs for quality reporting. In order to achieve adequate sample size and accurate rates at the plan level, additional calculation, such as HEDIS, would need to be completed. This would impose significant operational and administrative burden on plans. While CMS acknowledges that some measures could still be calculated at the contract level, these are not the most administratively burdensome measures. This would also introduce a significant burden in coordinating marketing and communications materials for multiple plans in the event that the star ratings vary.

Additionally, a move to plan-level star ratings may have unintended consequences, including stifling innovation and discouraging plan service in difficult areas. Health plans may implement innovative models in one plan prior to expanding to multiple plans or the entire contract. This opportunity for innovation promotes population health and would be at risk under plan-level star ratings. MAOs may also be dis-incentivized to continue serving a difficult or poor-performing area, rather than invest in

quality improvement activities to improve performance and outcomes in the area. This may result in a reduction or lack of MA options in high-need areas.

If CMS requires more granular assessment and display of plan performance, we suggest more opportunity for health plans to have additional contract numbers, or a new market-level identifier for a contract. Alternatively, CMS may consider assigning Star Ratings at a market level (e.g. contiguous counties in a region). If CMS pursues this route, we would request that CMS propose options for how markets might be grouped and engage with health plans regarding the implementation, in consideration of the fact that this would be a significant program change.

Concerns about enrollment-weighted averages for contract consolidations:

We encourage CMS to consider the possibility of unintended consequences associated with the proposal to assign Star Ratings for contract consolidations based on enrollment-weighted average. While we acknowledge CMS' concern that the surviving contract may temporarily mask poor performance of the acquired contract, the proposed enrollment-weighted average may dis-incentivize high performing plans to partner with low-performing plans. As an alternative, CMS may consider a grace period that would neither reward nor disadvantage the surviving contract as a result of acquiring a poor performing contract. This may be another benefit of CMS considering market-level star ratings.

Concerns about adjustments based on geographic area:

Although we support geographic level Star ratings, we have concerns about modifiers based on geographic area. As much as the intent of fairness is commendable, we are concerned that the level of complexity and inability to replicate methodologies at an MAO or plan level would stifle quality improvement efforts. As stated earlier, policies that add complexity or unpredictability to the Stars program detract from its value of a concrete, understandable program structure. Efforts to modify performance results also introduce a potential for unintended consequences in scoring, as we have experienced with the improvement measure methodology. We feel that it is important to be cautious about adopting adjustments to stars cut points and ratings, as these elements will make it increasingly difficult to monitor true performance.

Strongly support revisions to methodology for calculating performance cut points:

We appreciate CMS' consideration of revisions to the process for establishing cut-points and the necessity that these cut-points accurately reflect plan quality. We have expressed concerns in the past regarding significant threshold increases, which may pose a risk of patient harm by plans and providers in pursuit of short-term, overly-aggressive quality goals that are not in the patient's best interest. We fully support CMS efforts to minimize year-over-year changes.

We also encourage CMS to revise the methodology used to assess star ratings for CAHPS measures. The requirement that performance be significantly better than the mean, as well as above the cut point for

that star rating, among other factors, does not capture true performance. Cut points are set based on national performance; thus, star ratings at the measure level should be assigned based on absolute performance.

Due to the subjective nature and difficulty in obtaining actionable information from member experience survey information, we strongly encourage CMS to retain a weight of 1.5 for all CAHPS measures.

Support removal of topped out measures:

We agree with CMS' concept of topped out measures and recommend that CMS move these measures to display for monitoring and reestablish within the Star Ratings program if demonstrated performance decline is observed. Given that there is no indication that there will be a limit to the number of measures introduced to the Star Ratings program, it is important that CMS remove topped out measures to ensure that QI efforts are focused appropriately.

Significant concerns with adding physician experience survey:

We understand the importance of the provider network in the quality of care received by MA members. We proudly attribute our strong Stars performance to the strength and quality of our provider network. However, we oppose new survey measures based on provider experience. A new survey would introduce significant financial and administrative burden on the health plan and the results may be of questionable value.

In addition, a physician survey introduces burden to primary care providers who are already strained. Based on current provider survey efforts, it is very difficult to obtain responses and we find that often a member of the office staff completes the survey on behalf of the clinic rather than the physician.

We appreciate that physician experience is a priority topic for CMS; however, we feel that that interest should not start and end with MAOs. As a first step, CMS could conduct a general provider survey regarding experience with MAOs and Original Medicare to understand the larger healthcare landscape and pressures facing providers.

If CMS decides to pursue a physician experience survey, health plans and provider groups should have the opportunity to provide input on the development of the tool. CMS should also develop criteria to ensure that only physician practices with a sufficient number of members assigned to their practice are included in the survey. Due to the current requirements around network adequacy, there may be clinics with a small number of assigned members.

Support scaled reductions and caution against imposing multiple penalties:

We support the scaled reductions associated with findings in data monitoring for appeals and grievances. We propose that only appeals-related information from the timeliness audit be applied to reductions in the appeals star measures. The timeliness audit includes pharmacy and healthcare services claims, such as prior authorizations and direct member reimbursements, which occur prior to the appeal process. For reductions on the appeals measures, it should be well-defined that it is a result of appeals-related data issues.

We caution against CMS inflicting multiple penalties for the same timeliness issue, rather than at each level of untimely processing (i.e., level 2 only.) We understand and support CMS in upholding data integrity and encourage CMS to do so at an appropriate level. We encourage CMS to consider using data validation to monitor data integrity on appeals and grievances.

Interested in BAPP revision proposal:

Based on prior communication from CMS, we were expecting proposed changes to the Beneficiary Access and Performance Problems measure and for that measure to move to the display page for 2019 Stars. We are disappointed that no new information was shared as part of this proposed rule and would request that CMS deliver more information on changes to this measure.

Support the removal of QIP and request timely decision:

We support CMS' rationale and decision to discontinue the management of the Quality Improvement Program. We agree that this work is duplicative of our other quality initiatives and largely creates more administrative work rather than adding value to the improvement efforts. We request that a decision on this proposal be made so as to limit the resources invested in developing a new 2018 QIP.

Concerns regarding appeals reopenings:

We urge CMS to consider providing additional guidance for plans and the IRE for reopening IRE level appeals. The current guidance is vague and supports the IRE review, leaving limited ability for the plans to contest decisions that may have been made incorrectly. In the event that the IRE overturns the plan's decision, and upon further investigation the plan determines that the IRE made an incorrect decision based on benefits, health policy, clinical decision or otherwise, we would like CMS to take steps to ensure Maximus take seriously health plan requests for reopening. There are situations where IRE staff made an inappropriate decision regarding an overturn, as experienced in an appeal, where an overturn decision was extended to an unrelated case for the same member. We were denied a reopening in this situation where it was absolutely merited to re-review the cases. Re-opening a case is an important process for confirming that the appropriate decision was made.

Concerns regarding methodology for D02: Appeals Auto-Forward and untimely effectuation rules:

We would like to advocate for alignment between C23 and D02 in that dismissed and withdrawn cases are not counted in the Star metric. Additionally, it would better represent overall plan performance to include all reviews performed at the first and second level in the calculation. For example, PHA performed 5,107 reviews in 2016, a factor that is not incorporated into the current methodology. With just 16 late cases in 2016, our true late case percentage is 0.3%, which we feel is a more accurate assessment of review timeliness.

We would also advocate on behalf of the member regarding CMS imposed regulations. Currently, any case found to be late is required to be forwarded to the IRE, regardless of the known outcome of the case. Cases that can be approved, but are untimely, are forwarded to the IRE and cause delays in patient care as the member, provider, and plan await the IRE's decision. There have been cases in which medically appropriate therapy was delayed while the IRE made its determination. There have also been numerous occasions in which the IRE has taken longer than 60 days to provide a response back to the plan. CMS should allow plans to effectuate an authorization, if appropriate, prior to forwarding to the IRE. This would aid in providing medically appropriate therapy to enrollees in a timely manner.

Concerns regarding methodology for D03: Appeals Upheld:

The current Star measure calculation penalizes plans which have consistent, fair first and second level review programs. In 2016, PHA made an adverse decision on 1,633 Part D cases, of which only 18 (1.1%) cases were escalated to the IRE by the provider or member. This demonstrates how effectively we provide fair first and second level reviews, and how our benefits provide efficacious covered alternatives. We maintain high provider engagement to help clinicians provide evidence-based alternatives that they feel meets member needs, resulting in low appeals. These effective member-centered interventions and collaboration with providers result in a very low denominator under the current measure methodology, which makes our plan and others applying this philosophy subject to random variation that does not reflect true plan performance. Furthermore, only five of the 18 cases sent to the IRE were overturned, yielding a true case rate of 0.31% (5 overturned cases in 1,633 adverse decisions.)

Additionally, there are several instances where cases were overturned by the IRE due to allowing non-Part D supported indications and showing disregard for our CMS-approved clinical policies. These five overturned cases award PHA a 3 star on this measure because it does not account for the other 1,628 cases where an adverse decision was made that the member or provider received as fair and appropriate.

A proposed solution could be the following formula: [Number of cases overturned by the IRE] / [Total Denied Coverage Determinations] *100. This would account for plans that have excellent first and second level review programs, and provide effective, medically accepted covered alternatives for their enrollees through member-centered interventions and collaboration with providers.

Oppose exclusion of UTC Medication Therapy Management and propose MTM move to display for 2019 Stars:

We strongly oppose the MTM CMR completion rate being an active measure for 2019 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 still doing this as they did not receive the clarification. 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 2019.

In addition, we believe the purpose of the MTM measure is to improve medication use, reduce the risk of adverse events, and improve medication adherence for our Medicare patients. If we are unable to contact patients by any other means, we feel we should be able to complete these CMRs with the patient's provider. Significant issues have been identified based on the comparison of the provider's medication list, chart notes, and pharmacy claims such as medication adherence, duplication of therapy, and inappropriate medication use. Without the opportunity to include these medication reviews in our STARs measure, we will not have the resources to review the patients we are unable to contact which would provide lower quality care for these Medicare patients.

Concerns for quality measurement of frail elderly:

We would like to acknowledge the effectiveness of the current Star Ratings program for monitoring quality across the Medicare population and recognize that there are some populations that may not be appropriately accounted for within the membership. The Star Ratings clinical metrics may not be sound for frail patients with advanced illness, where the patient's goals need to be the primary focus, not preventive health goals. We would encourage CMS to consider using palliative care ICD diagnosis or palliative care billing codes as exclusions for appropriate measures.

Recommend inclusion of ambulatory and home blood pressure readings:

In alignment with current clinical practice guidelines, we recommend 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 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 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" (Greenland & Peterson, 2017). Additionally, the incorporation of

out-of-office BP measurements aids in the detection of "white-coat and masked hypertension" (Whelton & Carey, 2017). 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" (Greenland & Peterson, 2017).

Concerns regarding methodology for Statin Use in Persons with Diabetes (SUPD):

We support 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. However, we feel that CMS did not 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. This measure includes more robust clinical considerations for patient eligibility and thus appropriateness of statin use.

Specifically, many patients are intolerant to statin therapy, and we 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, we propose 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 additional 3.6% of patients in the numerator; therefore, capturing patients that are receiving quality care as this measure intends.

Concerns regarding methodology for D11: 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. 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. 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.

Additionally, 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.

Concerns regarding methodology for D13: 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.

Second, 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.

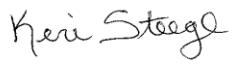
Finally, we have shown sustained year over year improvement with this measure (2016 - 82%, 2017 - 83%, and 2018 - 84%). PHA improved by 1% over last year but proceeded to drop from 5-star to 4-star.

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.

Sincerely,



Keri Steege
Medicare Compliance Officer
Providence Health Assurance – H9047

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
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
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
American College of Cardiology Task Force on Expert Consensus Decision Pathways. 2017 Focused Update of the 2016 ACC Expert Consensus Decision Pathway on the Role of Non-Statin Therapies for LDL-Cholesterol Lowering in the Management of Atherosclerotic Cardiovascular Disease Risk. *J Am Coll Cardiol*. 2017;70(14):1785-1822.
American Diabetes Association. Standards of Medical Care in Diabetes – 2017. Diabetes Care. 2017;40 (Supp 1):S1-S135.
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.