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March 5, 2018

Mr. Demetrois Kouzoukas
Principal Deputy Administrator
Centers for Medicare & Medicaid Services
Mail Stop C1-26-16
7500 Security Boulevard
Baltimore, MD 21244

Via Email and Regulations.gov Website

RE: Comments on Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 Call Letter

Dear Mr. Kouzoukas:

Thank you for the opportunity to provide comments on the 2019 Draft Advance Notice released on February 1, 2018.

Healthfirst is a not-for-profit, provider-sponsored plan serving New York City and Nassau, Suffolk, and Westchester counties. Our model promotes population health at the provider level by transferring most financial risk to our hospital system sponsors who, with their community-based partners, work with us to align incentives and ensure quality, member satisfaction, and efficiency. We are the largest Medicaid managed care plan in downstate New York and the #1 Medicaid plan for quality in the State.

We serve about 151,000 MAPD members. Approximately 60% are dually eligible for Medicare and Medicaid, and 80% receive the Low Income Subsidy (LIS). We have appreciated the opportunity over time to discuss the experience that regional plans like ours that predominantly serve low income members have had with the Stars rating system.

Our detailed comments and recommendations are outlined on the following pages.

If you have questions with regard to our comments and recommendations, please contact Michael Husmann, Director of Regulatory Affairs, at (212) 453-4457 or mhusmann@healthfirst.org .

Best Regards,

Pat Wang
President and CEO
Healthfirst Health Plan, Inc. – Contracts H3359 and H5441

Part 1: CMS-HCC Risk Adjustment Model for CY 2019

1. **Addition of new HCCs (P. 4)**
   CMS proposes adding five new condition categories (HCCs), modifying HCC55, and adding new factors to the six community and single long term institutional (LTI) segments to take into account a beneficiary's number of conditions that are in the payment model.

Healthfirst Comment:
Healthfirst supports periodical review and evaluation of the disease drivers to refine the CMS HCC model as a predictor of health care costs. Such reviews should always be conducted for each of the segments separately to ensure that the updates are specific enough to continue to improve the payment accuracy of the model.

2. **Taking Into Account the Number of Conditions of an Individual (P. 12)**
   CMS offers two HCC count models to account for the number of conditions of an individual – Payment Condition Count model and All Condition Count model.

Healthfirst Comment:
As CMS noted, "the model is already additive, and already effectively providing an adjustment as the number of conditions increases." As such, we believe introducing a new model to factor in condition count into the existing model is unnecessary.

Further, CMS notes that it estimated over twenty different models and in its initial evaluation found "none of the models that counted either payment conditions or all conditions consistently improved all evaluation statistics relatively to the base model." Additionally, the final two options presented both have the potential to introduce "noticeable variation" in risk score at the contract level. Given the possibility for such variance –for which plans have no control, we recommend that CMS reevaluate the models being considered and allow for plans the opportunity to adequately assess all options available beyond the two models presented.

3. **Encounter Data as a Diagnosis Source for 2019 (P. 23)**
   For PY 2019, CMS proposes to calculate risk scores by adding 25% of the risk score calculated using diagnoses from encounter data and FFS diagnoses with 75% of the risk score calculated with diagnoses from RAPS and FFS diagnoses.

Healthfirst Comment:
Healthfirst strongly supports the increased use of encounter data for PY 2019. We believe EDS will continue to provide CMS with greater insight into cost, utilization, risk, and quality metrics for all MAOs which will in turn illustrate the effectiveness of MAOs in generating quality outcomes for their enrollees.

Currently, MCOs each have distinctly varying logic on eligible diagnosis and EDS will ensure that uniform, CMS-identified filtration logic will be applied for risk adjustment purposes. Further, EDS creates transparency on whether encounters originate from claims or external risk adjustment activities allowing CMS to identify outliers at the contract level. Lastly, EDS data can ultimately be the single source of truth in setting both MAPD benchmarks and risk score calibration; currently, benchmarks are identified via CMS FFS data and risk score via RAPS – by aligning both under EDS, CMS has an opportunity to capture all data elements necessary to make informed decisions on appropriate future funding of the Medicare program. CMS should continue to push for increasingly greater reliance on encounter data as the source of diagnoses for the payment model.

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

4. **Section A. Contract Consolidations and QBP (P. 12)**
   CMS proposed when consolidations involve two or more contracts for health and/or drug services of the same plan type under the same legal entity combining into a single contract at the start of a contract year, the rating used to determine QBP status ("QBP rating") for that first year following the consolidation would be the enrollment weighted average of what would have been the QBP ratings of the surviving and consumed contracts using the contract enrollment in November of the year the Star Ratings were released.

Healthfirst Comment:
We continue to strongly support CMS's efforts to develop a new set of rules for the calculation of Star Ratings for consolidated contracts as the lack of an appropriate policy is inflationary to the Medicare program. It awards Star bonuses to contracts that are performing below 4 stars (i.e., it was reported that in 2017 alone, 1.4 M beneficiaries in consumed contracts will be moved from contracts below four stars to a contract in a bonus status, 4+ star contract). MedPAC estimates that overall, 20% of MAPD beneficiaries are in contracts whose Star Ratings have been distorted as a result of a contract consolidation.

CMS proposes to determine Star Ratings based on the enrollment-weighted average of the measure scores of the surviving and consumed contracts. We greatly appreciate CMS's recognition of the need to do something with regards to contract consolidations and urge it, at a minimum, to adhere to its original proposal and not, for example, push off the effective date.

Notwithstanding our appreciation for CMS's proposal, we would like to raise two concerns with this approach: (1) it does not eliminate inaccurate public quality ratings for consolidations that don't share exactly the same local market area and (2) it continues to incentivize gaming of the system as there are still enrollment-weighted average combinations that would result in unwarranted bonus payments (e.g., consolidation of two contracts with the same enrollment size, but with star ratings of 4.5 and 3.5 would likely earn a 4-star rating on the consolidated contract, resulting in a quality bonus payment for the entire membership).

As CMS finalizes the policy for contract consolidations effective January 2019, we ask that it also take these additional steps:

- CMS should report pre-consolidation contract performance on Medicare Plan Finder for contract consolidations effective 1/1/2018 so that Medicare beneficiaries are provided with accurate plan rating information during open enrollment for CY 2019.

- CMS should determine quality bonus payments based on pre-consolidation contract performance when the contracts were not consolidated for the entire measurement period. For example, for a consolidation effective January 2019, both the consumed and surviving contracts should continue to report separately and receive separate quality bonus payments through the 2020 Star Ratings period because the 2020 Star Ratings uses HEDIS performance from the 2018 measurement year. Pre-consolidation data to compute the Star Ratings actually earned by the pre-consolidated contracts is available and should be used until consolidated contract performance can be evaluated in its own right.

These recommendations are consistent with those suggested by MedPAC. MedPAC also recommended the establishment of local geographic areas for quality reporting. While we believe this is a promising

idea that deserves additional study and stakeholder feedback, its other recommendations to further refine policies to address the undesirable effects of contact consolidations should be adopted.

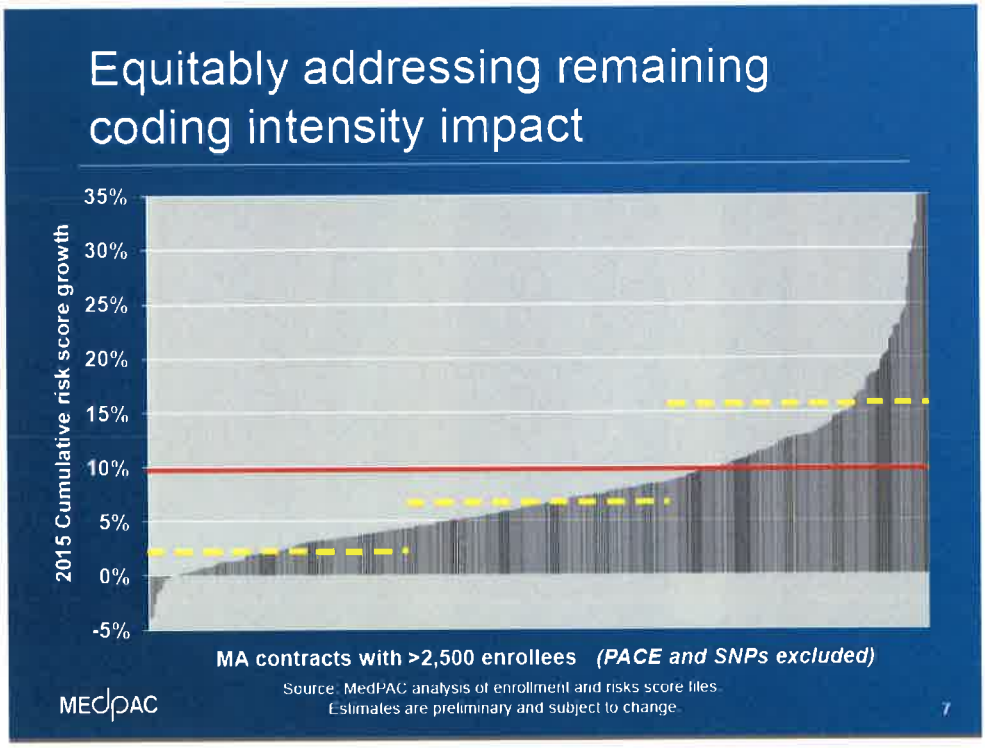
As noted, at a minimum, we urge CMS not to weaken its original proposal and to adhere to the effective date it proposed.

5. **Section K. Medicare Advantage Coding Pattern Adjustment (P. 35)**
   For 2019, CMS proposes to apply the statutory minimum MA coding pattern adjustment of 5.90 percent. Additionally, CMS is seeking comments on the coding pattern adjustment methodology for PY 2019.

Healthfirst Comment:

A 2014 CMS study titled "Measuring Coding Intensity in the Medicare Advantage Program" supports the idea that coding patterns across the MAO landscape are very heterogeneous. Failure to recognize these differences across plans by applying an adjustment based on average results is an inequitable outcome no matter what method is used to calculate the adjustment. In addition to failing to promote equity among plans, this approach rewards the most aggressive risk score maximization practices because the adjustment will by definition never be commensurate with increases above the average, a perverse incentive.

At its November, 2016 public meeting, MedPAC staff displayed the graph below. The graph arrayed the 2015 cumulative MA plan coding intensity of contracts with more than 2500 enrollees (excluding PACE and SNPs). It also portrayed the effect of a hypothetical 10% CIA applied as an across the board coding intensity adjustment versus a hypothetical application in three tiers according to the relative coding intensity. The current across-the-board adjustment significantly favors the contracts at the far right of the graph, i.e., those with the greatest coding intensity, while significantly disadvantaging those below the average by applying reductions in excess of their actual risk score growth.



We urge CMS to apply the CIA in a more equitable way. CMS should use a segmented approach to coding pattern adjustments that recognizes different levels of coding intensity among plans, with the aggregate value of the coding adjustment apportioned overall several tiers of plans that are grouped according to their actual coding intensity and scaled so that the lowest coding intensity factor is applied to the lowest coding intensity plans, and the highest factor to the highest intensity plans. The result will be a more equitable application of an adjustment aimed at closing the growing gap between FFS and MA risk scores. Anything else will continue to force some plans, with less coding intensity, to effectively subsidize those with greater coding intensity and to offset their reductions in risk scores with reduced benefits and increased costs shares for the members.

6. **Section L. Normalization Factor (P. 36)**
   CMS proposes to use 2013 through 2017 risk scores to calculate the normalization factor for the CMS-HCC model, PACE model, ESRD Dialysis model, and Functioning Graft model. CMS proposes to use 2012 through 2016 risk scores to calculate the normalization factor for the RxHCC model.

Healthfirst Comment:

In 2017, CMS changed the methodology used to determine the normalization factor from the quadratic method used from 2015 to 2017 to the linear method used prior to 2015. Under this approach, the proposed 2019 normalization factor for the CMS-HCC model is 1.041 and 1.038 for the current and 2019 "Payment Condition Count" models respectively. This represents an approximate 2.3% increase to the normalization factor from 2018, which reduces risk scores.

This large increase in the 2016 and 2017 average FFS risk score is inconsistent with prior year's observations where the FFS trends for 2011 through 2015 averaged 0.3%. We believe using more recent data of 2016 and 2017 FFS risk scores in the calculation creates unnecessary instability to MA payments. The 2011-2017 FFS risk scores and the annual trends are included below:

Year	Risk Score (1)	Risk Score Trend
2011	0.988	
2012	0.996	1.008
2013	0.995	0.999
2014	0.998	1.003
2015	1.000	1.002
2016	1.022	1.022
2017	1.034	1.012

(1) Source: Page 38 of the 2019 Advance Notice.

We request that CMS use a broader time period, e.g. 2011 to 2017, or 2012 to 2017 FFS risk scores, to calculate the normalization factor.

In addition, CMS proposed to use 2012 through 2016 risk scores to calculate the normalization factor for the RxHCC model. We believe CMS has the flexibility to change the years that are deemed reasonable for this calibration. If 2012 through 2016 risk scores were used for the RxHCC model calculation, it may be appropriate to be consistent and use the same years for the CMS-HCC model as well.

Attachment VI - Draft CY 2019 Call Letter – Section I – Parts C and D

7. **New Measures for 2019 Star Ratings (P. 107)**
   CMS proposes two new measures Statin Use in Persons with Diabetes (SUPD) (Part D) *and* Statin Therapy for Patients with Cardiovascular Disease (Part C) *for 2019 Star Ratings.*

Healthfirst Comment:
Healthfirst supports the recommendation to move the *The Statin Use in Patients with Diabetes (SUPD)* measure to a triple weighted outcomes measure. The support of using statin medications in patients diagnosed with either Type 1 or Type 2 Diabetes is clearly stated in the ACC/AHA guidelines on the treatment of blood cholesterol to reduce atherosclerotic cardiovascular risk in adults. The guideline recommends that patients with diabetes, 40-75 years of age without clinical atherosclerotic cardiovascular disease should have a statin initiated to prevent a cardiovascular event such as a myocardial infarction or a stroke from occurring. This is an important consideration in managing the health outcomes of patients with diabetes and preventing the development and/or progression of cardiovascular disease. Additionally, the American Diabetes association standards of care for diabetes states that statin therapy should be initiated in patients with diabetes regardless of baseline lipid levels. Lastly, poorly controlled diabetes is a common secondary cause of elevated LDL Cholesterol and Triglycerides requiring statin therapy.

Although the SUPD measure is not similar to the other triple weighted outcomes measures that address medication adherence, this measure is equally important as it addresses an important addition of statin therapy to patients with diabetes. Guidelines strongly support the use of statins in patients with diabetes due to the strong outcomes from clinical trials highlighting the benefit of statin therapy both as primary and secondary prevention of cardiovascular disease and mortality.

8. **Changes to Measures for 2019 – Medication Adherence (ADH) for Hypertension (RAS Antagonists), Medication Adherence for Diabetes Medications (Part D) (P.109)**
   CMS proposes to expand its data source for identifying all Part D enrollees with ESRD for exclusion from the measures to include ICD-10 codes found in both Part A & B claims

Healthfirst Comment:
We support the expansion to include ICD -10 codes found in Part A & B claims to members with ESRD. Using only the EDB ESRD indicator may not capture all instances where a member has ESRD and the expansion would help improve the accuracy of identifying these members.

9. **Changes to Measures for 2019 – Medication Adherence (ADH) for Hypertension (RAS Antagonists), Medication Adherence for Diabetes Medications, and Medication Adherence for Cholesterol (Statins) (Part D) (P. 109)**
   CMS proposes to concatenate consecutive stays to create a single admission and discharge date for the PDC adjustment.

Healthfirst Comment:
We support the concatenation of consecutive stays to create a single admission and discharge date for PDC adjustment. This would simplify the removal of denominator days.

10. Proposed Scaled Reductions for Appeals IRE Data Completeness Issues (P. 114)

CMS proposes statistical criteria to reduce a contract's Star Rating for data that are not complete or lack integrity using Timeliness Monitoring Project (TMP) data or audit. The reduction would be applied to the measure-level Star Rating for the applicable appeals measures. (Pg. 114)

Healthfirst Comment:

We support CMS's proposed new rule for scaled reductions for the Appeal measures. However, we ask that CMS consider the same approach across their entire policy on data integrity. CMS's current Data Integrity policy does not distinguish between the deliberate submission of inaccurate data and the unintentional occurrence of minor errors and mistakes. A new approach is needed to correct rates within set standard timeframes when there is no finding of intended bias by the reporting entity. We propose the following approach to appropriately penalize plans for data validation audit failures:

- CMS should create a process to vet data submission rejection appeals based on a set of established criteria. This evaluation criteria should take into consideration the following important factors:
    - Beneficiary impact – Will beneficiaries be unduly harmed if data correction is not allowed?
    - Data Transparency – Will data correction materially improve transparency of quality information to beneficiaries?
    - Nature of Issue – What is the root cause of the issue? Were there extenuating circumstances (e.g., natural disaster)? Where does primary culpability lie?
    - Health Plan Activity – Did the plan exercise best practices in the regular submission process and in resolving the issue? Is the plan able to submit complete and accurate data?
    - History of Data Integrity issues – Does the plan have any findings of intended bias in the last 3 years?
    - Timing – Is it operationally feasible to incorporate corrected data in time for reporting purposes?
- We recommend that CMS use a third party such as NCQA, (funded by plans wishing to appeal) to review and evaluate the plan's data submission based on the criteria suggested above. The third party should be charged with making a fair and appropriate determination on the course of action.
- If the third party finds that the incorrect data submission was not intentional – the following set of actions can be administered by CMS:
    - Provide the plan a narrow window for resubmission of the corrected data (e.g. 2 weeks) or
    - Have the measure be non-reportable in the applicable Star Ratings Cycle and/or
    - Penalize plans in the form of a Notice of Non-Compliance instead of reducing a contract's measure rating to 1 Star
- If there is more than one data validation failure found that was intentional, CMS should penalize plans with a Civil Monetary Penalty

11. 2019 Star Ratings Program and the Categorical Adjustment Index (P. 122)

Beginning in 201, the PQA will include draft recommendations on risk adjustment of the three medication adherence measures: Medication Adherence for Diabetes Medications, Medication Adherence for Hypertension, and Medication Adherence for Cholesterol. Additionally, all three adherence measures would be risk adjusted for sociodemographic status (SDS) characteristics to adequately reflect differences in patient populations

Healthfirst Comment:
We strongly support the risk adjustment for SDS characteristics including age, gender, dual eligibility/LIS status, and disability status. As a plan with a high proportion of dual and LIS members, there are significant challenges to reaching our members as many have frequent changes to their contact information. Additionally, these members face significant financial hardships which also has an impact on their ability to remain adherent on their medication(s). While we remain vigilant in attempting to remove these barriers for our members, risk adjustment for SDS characteristics will further account for and appropriately adjust for external factors that remain outside of a plan's control.

12. **2019 Star Ratings Program and the Categorical Adjustment Index (P. 123)**
NCQA has received approval from the Committee on Performance Measurement (CPM) to implement stratified reporting of four of the measures used in the Star Ratings Program: Breast Cancer Screening, Colorectal Cancer Screening, Comprehensive Diabetes Care – Eye Exam Performed, and Plan All-Cause Readmissions.

Healthfirst Comment:
We strongly support NCQA's implementation of stratified reporting at the measure level for beneficiary-level sociodemographic status (SDS) characteristics to allow plans to identify disparities and understand how their population mix is affecting their measure rates. We urge NCQA and CMS on the following:

- Expand stratified reporting to all Medicare Star HEDIS measures and for the following beneficiary-level SDS characteristics: age, gender, dual eligibility/LIS status, and disability status
- Use stratification information for risk-adjustment at the measure level for beneficiary-level SDS characteristics as proposed by PQA for triple-weighted Medication star measures

13. **2019 Star Ratings Program and the Categorical Adjustment Index (P. 125)**
The measures selected for adjustment for the 2019 Star Ratings include six Part C measures and two Part D measures. For MA (MA-only, MA-PD) and 1876 contracts, the Part C measures selected for adjustment for the 2019 Star Ratings include: Annual Flu Vaccine, Breast Cancer Screening, Diabetes Care – Blood Sugar Controlled, Medication Reconciliation Post-Discharge, Osteoporosis Management in Women who had a Fracture, Plan All-Cause Readmissions. For MA-PDs and PDPs, the two Part D measures selected for adjustment for the 2019 Star Ratings include: Part D Medication Adherence for Hypertension and MTM Program Completion Rate for CMR.

Healthfirst Comment:
CMS's use of the Categorical Adjustment Index (CAI) for the Star Ratings was an important first step towards the aim of ensuring that the Star Ratings system fairly evaluates all plans, including those serving high proportions of members with social risk factors. With two years of experience with the CAI and with the release of the ASPE report ("Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs, December 2016), we ask that CMS consider progressing its approach for the 2020 Star Ratings so that it more accurately and adequately accounts for social risk of members. Specific comments and suggestions are as follows:

- **Develop an Equity Bonus**. ASPE notes that the CAI is a reasonable short-term strategy, but in the longer-term, a strategy like a targeted star adjustment should be considered. One way that ASPE suggests this could be done is by providing an "explicit star adjustment for achieving high performance for dual/LIS beneficiaries." (ASPE Report, P. 209) The approach of constructing an "equity bonus" to reward contracts for achieving high performance for those beneficiaries with social risk factors is particularly compelling: "First, a weighted average of the ratios of each contract's performance for dual/LIS beneficiaries on each of the 19 clinical measures versus the

average performance for dual/LIS beneficiaries across all contracts in the respective clinical measure was created. A bonus of 0.5*(proportion dual/LIS) was applied for all contracts for which this weighted ratio was greater than 1. For example, if a contract had an 80% pass rate for a particular measure for its dual/LIS beneficiaries, when the average was 75% pass rate, that contract would receive a ratio for that measure of 80/75 or 1.07. This 1.07 ratio would be averaged in a weighted fashion (using the weights assigned under the Star Rating scheme) with similarly created ratios for the other 18 measures to create a final ratio. If that ratio is greater than 1, a 0.5*proportion LIS/dual bonus would be applied, such that if a contract had 100% dually-enrolled beneficiaries it would receive the full 0.5 star bonus. If it had 75% dually-enrolled beneficiaries it would receive 0.5*0.75, or 0.44, stars." (ASPE Report, P. 211)

- **Implement ASPE's recommendation to scale the quality bonus payment so that it is not all-or nothing**. While the Equity Bonus approach described above is not budget neutral, the ASPE report notes that scaling the Quality Bonus would allow money to be reallocated to contracts. It would also alleviate the immense financial pressure created by the current all-or-nothing methodology.
    - "Money to reward contracts that perform particularly well for beneficiaries with social risk factors could be reallocated from current Quality Bonus Payments by moving to a scaled Quality Bonus Payment system rather than an all-or-nothing 5% bonus at the 4-star threshold, which may have additional value in terms of the behavioral economics of incenting contracts to continually improve."
- **If CMS continues to use the CAI adjustment for 2020 Stars instead of moving to a longer-term adjustment, we request that CMS updates the criteria for measure inclusion in the CAI.**
    - The current criteria are that (1) the median within-contract difference for LIS/Dual to non-LIS/non-Dual must be at least 5% or (2) LIS/DE members performed worse than non-LIS/DE members in all contracts.
    - The criterion that all contracts need to show that LIS/Dual-eligible members perform worse than non-LIS/DE members is excessively stringent. We suggest that this criterion be updated to 90% of contracts showing that LIS/DE members perform worse than non-LIS/DE. This would bring in Controlling Blood Pressure, Medication Adherence Diabetes, and Medication Adherence Cholesterol to the CAI for 2019 Stars.
    - Instead of using a within-contract difference of 5% for all measures, use a number that is meaningful for each measure being considered. For example, a 1% difference in medication adherence is statistically significant for our plan, but the standard for inclusion in the CAI is much higher at 5%.

14. New 2019 Display Measure – Plan Makes Timely Decisions about Appeals (Part C) (P. 140)
CMS is proposing for display a new appeals measure which includes cases dismissed by the IRE because the plan has subsequently approved coverage/payment (using 2017 data).

Healthfirst Comment:
We support CMS's decision to place the revised Plan Makes Timely Decision about Appeals (Part C) measure on Display for the 2019 and 2020 Star Ratings.

15. Changes to Existing Display Measures – Hospitalizations for Potentially Preventable Complications (Part C) (P. 141)
CMS proposes to retain this measure as a 2019 display page measure. CMS will propose through rulemaking moving it to Star Ratings with a weight of 1 for the 2022 Star Ratings. In subsequent years, CMS intends to weight it 3 as an outcomes measure.

Healthfirst Comment:
We support CMS's decision to place the revised Hospitalizations for Potentially Preventable Complications (Part C) measure on Display for the 2019 and 2020 Star Ratings.

16. **Changes to Existing Display Measures – High Risk Medication (Part D) (P. 141)**
CMS proposes to adopt a specification change made by the PQA to measure specifications for the numerator (beneficiaries with at least two fills of the same HRM drug on different dates of service) for the 2019 display measure.

Healthfirst Comment:
We support the change to the numerator specification to include two fills on different dates of service. This allows plans to have another layer of intervention and to act retrospectively to modify a member's therapy.

17. **Changes to Existing Display Measures – Antipsychotic Use in Persons with Dementia (APD) (Part D) (P. 141)**
CMS proposes to display the rates for the two population breakouts on the 2019 display page (in addition to the overall APD rate currently displayed). CMS will assess adding the APD measure to the Star Ratings in the future, which would be proposed through rulemaking.

Healthfirst Comment:
We agree with the recommendation to maintain APD as a display measure set to help curb the inappropriate use of antipsychotics in members with dementia. We support the display of the two population breakouts to the 2019 display page.

18. **Changes to Existing Display Measures – Use of Opioids from Multiple Providers and/or at High Dosage in Persons without Cancer (Part D) (P. 142)**
The PQA's Measure Update Panel and Quality Metrics Expert Panel approved non-substantial changes to the measures. Additional changes made by the PQA to these measures include: the opioid treatment period for Measures 1 and 3 must be 90 days or more; ICD-9 and ICD-10 codes will be changed to align with the American Medical Association (AMA) Physician Consortium for Performance Improvement (PCPI) cancer value set; and all buprenorphine products indicated for medication-assisted treatment (MAT) will be excluded. CMS proposes to add only the OHDMP measure to the 2019 Part D display page (using 2017 data). All three measures will continue to be reported to Part D plan sponsors through the Patient Safety reports.

Healthfirst Comment:
We do not support the inclusion of this measure in the Star Rating program. Although endorsed by PQA, we do not believe that each one of these three measures accurately identifies inappropriate opioid utilization. Currently, there are no FDA approved maximum dosages for opioids and there are situations where members are using dosages above the 120mg Morphine Milligram Equivalent (MME) for a medically necessary diagnosis other than cancer pain. We believe that only using 120mg MME to identify over-utilizers is not targeted enough to detect a high percentage of fraud and abuse cases. We also believe that assessing for multiple providers and pharmacies may not take into account prescribers in the same practice and different branches of a chain pharmacy. Additionally, if we are able to detect fraud or abuse from a member using multiple prescribers and pharmacies, we are not permitted by the Part D program to lock-in a member to a particular pharmacy or prescriber.

We agree that the measure that combines high dosage opioids and multiple providers is better positioned to detect inappropriate behavior; however, we are unclear as to how this differs from the Overutilization Monitoring System (OMS). Through OMS, we are best able to review patient behavior and implement measures to prevent opioid overutilization in real-time using point of sale edits and quantity limits. We do support changes to the measures which include a 90 day treatment period, ICD 10 codes, and exclusion of buprenorphine products.

19. **Potential Changes to Existing Measures – Medication Adherence (ADH) for Cholesterol (Statins) (Part D) (P. 146)**
    The PQA updated this measure for 2018 to exclude beneficiaries with ESRD. CMS proposes to apply this exclusion to the 2020 Star Ratings (based on 2018 data.

Healthfirst Comment:
We agree with the recommendation to exclude beneficiaries with ESRD from the Medication Adherence for Cholesterol measure. Both RASA and Diabetes measures have this exclusion.

20. **Potential Changes to Existing Measures – Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Reviews (CMR) Measure (Part D) (P. 147)**
    The PQA updated this measure for 2018 to include a new denominator exception.

Healthfirst Comment:
We support this recommendation.

21. **Potential New Measures for 2020 and Beyond – Transitions of Care (Part C) (P. 148)**
    CMS appreciates feedback received about a new HEDIS Transitions of Care measure with four indicators

Healthfirst Comment:
CMS proposes to add a Transitions of Care composite measure as an intermediate outcome measure. We have the following concerns with this measure:

- This is a process measure, not an intermediate outcome measure. This measure does not look at outcomes or assess quality of care post-discharge; it is solely a process measure focused on documentation. As such, if the measure is included in the Star Ratings, it should be weighted as a process measure (1x).
- Documentation of the four care transition processes included in this measure varies considerably among provider practices since this documentation can be captured in numerous ways (e.g. EMR, fax, email, etc.), thus posing challenges to collecting the data in a consistent manner.
- Health plans would have to use chart review to submit data for this measure since care transition documentation cannot be captured through claims data alone. This would substantially increase plans' chart review burden each year.
- The Medication Reconciliation Post-Discharge indicator for this measure would be redundant since this is an existing Medicare Part C Star measure. Therefore, the inclusion of medication-reconciliation as part of the Transitions of Care measure would be duplicative. We strongly urge CMS to remove the proposed fourth indicator from the Transitions of Care composite measure (leaving it to just 3 components) and keep the existing Medication Reconciliation Post-Discharge measure as a separate Star measure.

22. Potential New Measures for 2020 and Beyond – Polypharmacy Measures (Part D) (P. 152)

Polypharmacy: Use of Multiple Anticholinergic (ACH) Medications in Older Adults (Poly-ACH). CMS plans to add the measure to the display page for 2021 (2019 data) and 2022 (2020 data). CMS will consider this measure for the 2023 Star Ratings (2021 data), which would be proposed through rulemaking.

Healthfirst Comment:

We do not support the inclusion of this measure in the Star Rating program. The HRM measure – which is very similar in nature to the Polypharmacy measure – already takes anticholinergics into account and achieves the same goal of switching a high risk elderly member on these agents to a more clinically appropriate alternative.

23. Potential New Measures for 2020 and Beyond – Polypharmacy Measures (Part D) (P. 153)

Polypharmacy: Use of Multiple Central Nervous System (CNS)-Active Medications in Older Adults (Poly-CNS). CMS will consider proposing this measure through rulemaking for the 2023 Star Ratings (2021 data). CMS also plans to re-evaluate the utility of reporting the HRM Patient Safety reports and display measure since many of the same drugs are included in both the Poly-ACH and Poly-CNS measures.

Healthfirst Comment:

We do not support the inclusion of this measure in the Star Rating program. Similar to the comment above, the HRM measure takes CNS active agents into account and achieves the same goal of switching a high risk elderly member on these agents to a more clinically appropriate alternative.

24. Potential New Measures for 2020 and Beyond – Polypharmacy Measures (Part D) (P. 154)

Concurrent Use of Opioids and Benzodiazepine. CMS proposes to begin reporting the Concurrent Use of Opioids and Benzodiazepines measure in the Patient Safety reports for the 2018 measurement year. CMS plans to add the measure to the display page for 2021 (2019 data) and 2022 (2020 data). CMS will consider this measure for the 2023 Star Ratings (2021 data) pending rulemaking.

Healthfirst Comment:

We do not support the inclusion of this measure in the Star Rating program. Currently, we track and monitor members who are identified as potential opioid over-utilizers and are also receiving benzodiazepine through OMS reports. Through OMS, we are best able to review patient behavior and implement measures to prevent opioid over-utilization in real time using point of sale edits and quantity limits.

25. Potential New Measures for 2020 and Beyond – Additional PQA Medication Adherence Measures (Part D) (P. 154)

Adherence to Non-Warfarin Oral Anticoagulants (ADH- NWOA); Adherence to Non-Infused Disease Modifying Agents Used to Treat Multiple Sclerosis (ADH-MS). Given the high cost of these medications and the importance of adherence for achieving positive outcomes, CMS may consider including these measures within the quarterly outlier reports to Part D contracts through the Patient Safety Analysis Website in the future, along with the beneficiary-level data so contracts can focus adherence improvement efforts for these members.

Healthfirst Comment:
We agree with the continued exclusion of the Adherence to Non-Warfarin Oral Anticoagulants as well as the Adherence to Non-Infused Disease Modifying Agents Used to Treat Multiple Sclerosis from the Star Ratings program at this time. Many multiple sclerosis treatments are specialty medications which are most closely monitored and involved in adherence programs.

26. Meaningful Difference (Substantially Duplicative Plan Offerings) (P. 171)
CMS proposed to eliminate the meaningful difference requirement beginning in CY 2019 as part of the Medicare Program

Healthfirst Comment:
We strongly support the proposal to eliminate the MA meaningful difference requirement. The current meaningful difference calculation is mainly driven by the out-of-pocket-costs (OOPC) value differential and does not take into consideration factors that are significant to the beneficiaries – such as plan premiums –while limiting the number of plans available in the market to address the needs of the population. Eliminating the meaningful difference requirement would allow plans to make appropriate modifications to specific plans as needed without the need to forcibly change other plans to create preset differences in plan values.

27. Health Related Supplemental Benefits (P. 182)
CMS intends to expand the scope of the primarily health related supplemental benefit standard

Healthfirst Comment:
We support the expanded scope of the health related supplemental benefits; we believe, as CMS intends, the expanded scope has the potential provide services to "diminish the impact of injuries or health conditions and reduce avoidable emergency and health care utilization" where it was previously not allowed. However, we are concerned about the broadly defined scope of services and the potential for challenges to ensuring the included services truly fall within the scope of health related supplemental benefits. We request that CMS provide additional guidelines, such as approved list of expanded services and/or benefit maximums (e.g. dollars limits, visit limits, etc.) – to be modified each year as appropriate – to ensure uniformity as well as appropriateness across all plans.

28. Rewards and Incentives for Completion of a Health Risk Assessment (HRA) (P. 186)
MA plans may include the completion of an HRA as a permitted health-related activity in an RI Program.

Healthfirst Comment:
We support CMS's proposal allow for rewards and incentives for the completion of a Health Risk Assessment. The HRA is a significant part of the members' care management process and the incentives will provide a greater opportunity for plans to engage members in this process.

29. Expanding the Part D OTC Program (P. 186)
CMS is soliciting feedback from stakeholders on Part D OTC enhancements that could be considered for future policy.

Healthfirst Comment:
Similar to the expansion of the Health Related Supplemental Benefits, in general, we support CMS considerations that would allow for more flexibility for plans to meet the health care needs of its members more efficiently and effectively. However, we believe clear guidelines and limitations are necessary to ensure the uniform and appropriate interpretation of these considerations across all plans. In New York City, where we serve our members and OTC program are currently popular, there is a wide range of benefits available across the market with limited guidance – benefit amounts vary significantly, marketing of these benefits are inconsistent, and monitoring the usage of OTC benefit to offset more costly alternatives is nonexistent.

We appreciate that CMS is looking for additional ways to meet the needs of members in ways that are currently not available today. However, we request that CMS clearly specify the parameters, guidelines, and limitations to the Part D OTC program to ensure appropriateness as it looks to expand the program. Specifically, we recommend that CMS review the usual and appropriate range of utilization of OTC products to offset the use of a Part D drug and provide a benefit range that is deemed appropriate for OTC usage.

30. Improving Drug Utilization Review Controls in Medicare Part D – Retrospective DUR: OMS Metrics (P. 202)
CMS proposes changing the Opioid Daily Dose measurement period from 12 months to 6 months to align with the revised OMS criteria measurement period. Also proposes to report a second Opioid Daily Dose rate with a 90 MME threshold.

Healthfirst Comment:
We support CMS's proposal to change the Opioid Daily Dose measurement period from 12 months to 6 months to better align with the revised OMS criteria measurement.

31. Improving Drug Utilization Review Controls in Medicare Part D – Concurrent DUR: Cumulative Morphine Milligram Equivalent Daily Dose (MME) Safety Edits for High, Chronic Prescription Opioid Users (P. 207)
CMS proposes to require plans to have a POS formulary-level hard reject edit for a cumulative MME (cMME) of 90 or more and no additional qualifiers such as multiple opioid prescribers and/or filling opioid prescriptions at multiple pharmacies. In order to reduce disruption to beneficiaries exceeding the cMME level, CMS also proposes to allow a one-time 7 day supply fill of the opioid that triggered the edit.

Healthfirst Comment:
We support all of the efforts by CMS to reduce the inappropriate use of opioids; however, we have several concerns as it relates to the current proposals. These are the following:

- There is a concern that if all exception requests as a result of this reject are expected to be expedited there would be a significant risk of denying the coverage determination for lack of information, even with the minimal supporting statement requirements. Plans are expected to extend the turnaround time at least 24 hours for exception requests, allowing at least 48 hours to obtain a prescriber's supporting statement for an expedited exception. This may not be sufficient time to get a response from prescribers on weekends and holidays.
- Because 21 CFR 1306.13 and the Comprehensive Addiction and Recovery Act (CARA) of 2016 allow for a Schedule II controlled substance to be partially filled in certain situations, we would like CMS to confirm that plans will not be penalized for allowing partial fills of schedule II controlled substances in audits. To facilitate noting appropriate partial fills in the PDE, CMS will

need to expedite the approval for use of the NCPDP "Prescribed Quantity" field. Without this field, appropriate partial fills will appear as refills on the PDE and will fail an opioid audit.

- CMS has solicited feedback on how to best communicate this new edit to beneficiaries, especially at POS. This presents quite a challenge. CMS could require plans to issue a special transition fill letter. However, this letter would take several days to reach the beneficiary and significantly reduce the time allotted to get a coverage determination before the 7 days' supply ran out. This would also require significant new development that may not be able to be completed by 1/1/2019.
- CMS has not addressed its expectation of plans when the beneficiary pays cash and submits a reimbursement request. The beneficiary would have already received the full quantity. Does CMS expect these claims to be treated as a presumptive quantity limit exception request and only reimburse for more than the 7 day transition supply if the prescriber attests that the higher dose was medically necessary?
- Would the current POS edit exclusions for beneficiaries with cancer and those in hospice still apply? We would not recommend any additional exclusions, as this would nullify the intent of this proposal being a beneficiary safety issue.

Included below are our recommendations:

- We suggest CMS allow the 7 days' supply for any hard reject opioid claim, regardless of the number of prescriptions presented at the same time.
- We ask CMS to clarify whether the 90 MME hard reject at POS is intended to replace other formulary level opioid quantity limits.
- We ask CMS to confirm that the MME edit itself is exempted from transition fill per Chapter 6, 30.4.8 of the Prescription Drug Benefit Manual.
- We ask CMS to confirm that if an opioid triggers a prior authorization, quantity limit, or non-formulary drug reject, that these rejects take precedence over the 90 MME hard reject (i.e., the 7 days' supply does not apply).
- We ask CMS to confirm that if the opioid claim triggers a prior authorization, quantity limit or non-formulary edit during a transition fill eligible period the up to 30-days' supply transition fill rules would apply rather than a 7-days' supply fill.
- We recommend that CMS not require all coverage determination requests for a rejected POS edit be treated as expedited (unless requested by the beneficiary or the prescriber) due to concerns that requests may be denied due to lack of information within the expedited exception turnaround time.
- We ask CMS to clarify its expectations for reimbursement requests that exceed the 90 MME. If the prescriber does not authorized the higher MME, confirm that the plan should only reimburse the beneficiary for the 7 day supply that would have been allotted at POS.
- We recommend that CMS expedite the approval for use of the NCPDP "Prescribed Quantity" field so that plans can demonstrate to CMS auditors that partial fills of schedule II drugs were appropriate.

32. Improving Drug Utilization Review Controls in Medicare Part D – Concurrent DUR: Days Supply Limits for Opioid Naïve Patients (P. 212)

CMS intends to establish a days supply limitation policy for opioid naïve patients in this year's final 2019 Call Letter.

Healthfirst Comment:

We support the establishment of a days supply limitation policy for initial fills opioid naïve patients and agree with the 7-day limit. We do request that CMS clarify whether this 7 day limit applies only to short-

acting opioids, or if it should apply to both short-acting and long-acting opioids. We also request that CMS verify that the minimum look-back period to determine initial use is 108 days.

One challenge with applying a limit to initial fills is around new members where we do not have prior claims history. Should we assume that any short-acting opioid prescribed during a transition fill eligible period is for an opioid naïve patient and apply the 7 day limit? If the prescription is for a long-acting opioid and the beneficiary is a new member, should we assume continuing therapy and allow a transition fill or not apply the 7 day limit? Will we need to submit the 7 day limit in the formulary submission? We do not recommend that the 7 day initial supply limit replace any other opioid quantity limits the plan intends to submit as part of its formulary. In addition, we recommend that beneficiaries in LTC facilities be exempt from the initial fill for acute pain requirement. Beneficiaries that transition from Part A coverage for their LTC stay to Part D coverage will appear as new beneficiaries to the Part D plan. In addition, should beneficiaries with an active cancer diagnosis be excluded from this edit?

Additionally, we do not recommend adding an MME limit in addition to the 7 days' supply at this time. This would add confusion for the member, prescriber and pharmacist, and would be difficult to describe in member-friendly language. It will also be difficult for the dispensing pharmacist to explain the exact reason for the claim denial at POS. We would need to be able to explain the 90 MME limit at POS vs a different limit for initial opioid prescriptions vs any other opioid quantity limit submitted as part of the formulary. There currently is not a way to differentiate different quantity limits based on acute vs chronic therapy for the same drug through the NCPDP telecommunication standards. In addition, adding an MME limit to the 7 day initial opioid prescription limit would increase the complexity of developing the appropriate edit (especially if the MME limit varies depending on acute vs chronic use of the drug), and may not be achievable by 1/1/2019.

In the Cumulative Morphine Milligram Equivalent Daily Dose (MME) Safety Edits for High, Chronic Prescription Opioid Users section, CMS clearly indicates that if the opioid that exceeds the 90 MME is in an unbreakable package of > 7 days' supply nothing should be dispensed. If an initial opioid prescription exceeds 90 MME and is in an unbreakable package of > 7 days' supply, CMS has not indicated their expectation. Would the cumulative MME edit take precedence and no opioid would be dispensed? We recommend that CMS allow the pharmacy to dispense the smallest unbreakable package size for both the 90 MME hard reject and the initial opioid 7 day limit if the smallest unbreakable package size exceeds a 7 day supply.

Similar to the 90 MME hard edit, CMS has not addressed their expectation of when the beneficiary pays cash and submits a reimbursement request for an initial opioid that exceeds the 7 days' supply. The beneficiary would have already received the full quantity. Does CMS expect the plan to only reimburse for a 7 days' supply, or should these claims be treated as a presumptive quantity limit exception request and only reimburse for more than the 7 day supply if the prescriber's supporting statement confirms that the longer duration was medically necessary?

Included below are our recommendations:

- The 7 day initial prescription limit should apply only to short-acting opioids.
- As ask CMS to confirm that a minimum of 108 days is appropriate to determine new vs continuing therapy.
- If the 7 day limit is only to be applied to short-acting opioids, we recommend that these claims not be transition fill eligible. However, if CMS expects the 7 day limit to apply to all initial opioid prescriptions, we recommend that the long-acting opioids be transition fill eligible in order to not interfere with ongoing therapy.
- LTC pharmacies be allowed to override the initial 7 day limit for beneficiaries previously on opioids that have transitioned from Part A to Part D coverage.

- Beneficiaries being treated for cancer-related pain should be exempt from this edit.
- CMS not consider an MME limit in addition to the 7 day limit on initial fills at this time.
- For opioids in unbreakable packages, CMS allow the pharmacy to dispense the smallest unbreakable package if that amount exceeds a 7 day supply for both the initial fill limit and the 90 MME hard stop edit.
- We ask CMS to confirm that for beneficiaries who pay cash to obtain more than the 7 day supply limit, the plan should only reimburse for the 7 day supply.

33. Improving Drug Utilization Review Controls in Medicare Part D – Concurrent DUR: Opioid Duplicative Therapy Safety Edits (P. 213)

CMS expects all Part D plan sponsors to implement a soft POS edit for duplicative LA opioid therapy beginning in 2019, with or without a multiple prescriber criterion.

Healthfirst Comment:

We support the requirement for a duplicative therapy soft reject edit for multiple long-acting opioids. CMS brings up the issue of multiple opioid edits (both soft and hard rejects) and setting up a hierarchy to message and manage them. We agree that there will be opioid claims that trigger multiple rejects for cMME limits, days' supply limits, duplicate therapy, concurrent therapy, other quantity limits, prior authorization and non-formulary rejects; and this will create confusion for pharmacists, beneficiaries and prescribers. In addition, there are many other agencies with differing requirements for the management of opioid prescriptions, including the DEA, FDA REMS content, Boards of Pharmacy and States. Because of all of these competing requirements, it is important that all Medicare plans utilize the same edit hierarchy. We recommend that CMS work with PCMA and NCPDP to develop a standard hierarchy list that can be utilized across all Part D plans.

We recommend that CMS require a soft reject edit for duplicative long-acting opioids only. We recommend that CMS work with PCMA and NCPDP to create a standard edit hierarchy for claims that have multiple opioid edit rejects that can be used by all Part D plans.

34. Improving Drug Utilization Review Controls in Medicare Part D – Access to Medication-Assisted Treatment (P. 216)

CMS expects all Part D plan sponsors to implement a soft POS edit for duplicative LA opioid therapy beginning in 2019, with or without a multiple prescriber criterion.

Healthfirst Comment:

We agree that plans should not be discouraging the utilization of medication-assisted treatment (MAT) for opioid use disorder. We also agree that in most cases any prior authorization on MAT should allow approval through the end of the plan year. However, when buprenorphine alone (not in combination with naloxone) is use for MAT induction therapy, we feel that it is appropriate to shorten the approval for this indication to 3 months in order to encourage transition to a buprenorphine/naloxone product for maintenance.

We recommend that CMS allow for a shorter duration of approval for buprenorphine (without naloxone) when used for MAT induction therapy in order to encourage the transition to a buprenorphine/naloxone product, or other appropriate MAT, for ongoing therapy.