January 16, 2018

http://www.regulations.gov
Centers for Medicare & Medicaid Services
Department of Health and Human Services
CMS-4182-P,
P.O. Box 8013,
Baltimore, MD 21244-8013.

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

-on Behalf of-
InnovaCare, Inc. / MMM Healthcare, LLC
(Contracts H4003, H4004, H7522)

Dear Ladies and Gentlemen:

The undersigned, the Chief Compliance Officer of MMM Healthcare, LLC, is hereby submitting the comments below to CMS with respect to the proposed rule CMS- 4182- P "*Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program"*("Proposed Rule").

Medicare Advantage and Part D Prescription Drug Program Quality Rating System

We applaud recent efforts to generate significant transformation to the healthcare system in order to improve quality of care, and that this entails a monumental task that requires the development of complex and holistic strategies. The MA Quality Rating System has proven to be an important tool to support these efforts. We commend CMS for taking the steps to codify the existing Star Ratings System for the MA and Part D programs, while pursuing the objective of clarifying rules and providing plans with more predictability to encourage long-term initiatives. We have analyzed the Proposed Rule in this regard and would like to share with you our comments, concerns and recommendations. We have delineated a set of topics under which discussion will be expanded.

SURVEY MEASURES

At present over 30% of the Star Rating weight goes into CAHPS and HOS. While we recognize the importance of the voice of the consumer, it is also important to keep in mind that certain elements, listed below, may adversely impact the results of these measures for reasons not within the control of the plan sponsors.

- **Cultural differences**
  - Certain populations resist responding to surveys, particularly complex ones with more than 60 questions.
  - Certain topics are sensitive and may not receive responses such as questions about urine incontinence.
  - Surveys are written and designed in English and only official translations may be used, often resulting in terms, wording and usage not familiar to the reader.
  - The selected measures focus greatly on the experience the member has with the providers and intends to measure against standards that are not necessarily aligned to service culture observed. For example:
    - Getting Appointments and Care Quickly- All plans in Puerto Rico fail to obtain above average results for the measure of Getting Appointments and Care Quickly. Upon analyzing the composite of questions for our plans, there is one question, regarding how often the patient was seen "within 15 minutes of your appointment time," which has outlier results adversely impacting the overall result for the measure. In Puerto Rico, however, the local medical services culture is still mainly focused on the basis of an appointment date during which patients are served in the order they arrive, without setting a specific time. Asa result respondents of the survey are likely confused because they are not necessarily used to an appointment time. While the plans are continually trying to change this practice, it is already part of the local service culture and change comes slowly. Additionally, the provider exodus being experienced in Puerto Rico is generating the need for providers who stay in the Island to serve more patients on a daily basis, contributing to longer waiting times on appointment dates.
    - Getting Needed Drugs- The one question impeding a sustained above-average performance is "In the last 6 months, how often was it easy to use your prescription drug plan to fill a prescription by mail?" This question exhibits a mean score below 35% while the two other related composite questions have a mean score of over 90%. While plans certainly cover prescription by mail and it is a safe process, it is not the

preferred means for patients. In fact, over 95% of respondents answer that they do not use the service. In such a a scenario the outcome of this question becomes a penalty to the plan.

- Annual flu vaccine- All plans in Puerto Rico show a below average response on this survey question. Despite educational efforts by the plans, clinics and organized interventions—all with support from government and other entities-- there is a general reluctance by consumers to vaccinate against the flu, and others get vaccinated less frequently than annually. Since the plan cannot force members to get vaccinated, the unavoidable low score on this question has an unfair adverse impact on the low variability score required for the Reward Factor calculation.

- **Respondents' Social Determinants and Demographics**
  - CMS has recognized the impact of social determinants on the outcome of several measures, mostly related to clinical care measures. CAHPS and HOS measures are case mix adjusted taking into account several aspects that might be interpreted as a consideration for social determinants. One of those aspects with significant impact is dual eligibility. Nevertheless, the reality is that in a scenario where education levels may be lower than seen in other markets, and where so many social aspects including language, cultural background, and geography play such a significant role, survey measures require consideration beyond aspects considered in the case-mix adjustment.
  - In addition, the general Medicare population makes it more likely that recollection will be a burden, especially from events that have occurred months earlier, or even on a specific date, such as the reference start date to be vaccinated against the flu. Additionally, in the case of HOS outcome measures on improving or maintaining physical and mental health over the course of two years, while the plans activities move around improving the patient healthcare status, it is natural that as time passes, patients are more prone to experience certain health deterioration. Not to mention that with a higher disenrollment rate experienced due to the dual eligibility nature of members, the sample size of these outcome measures diminishes, making them less representative of the plan design.
  - The identity of sample respondents are kept confidential. We recognize why that is but as a result the plan losses an opportunity to analyze what occurred

and what improvement activities can be put in place to improve outcomes. A related issue that we noticed in the RY2018 Plan Preview was that the universe files shared with the vendor do not flag all dual eligible because the IDR information may be incomplete, and thus the dual eligible composition is available only at the aggregate level. This also could lead to uninformed and thus faulty adjustments.

We recommend the following:

- Allow plans to adjust survey content to accommodate to the cultural or market differences that are evident and justifiable. The adjustments in language or methodology would be shared with CMS with sufficient notice, and upon approval, provided to the authorized vendors for the survey disposition or execution. To streamline the process, CMS may choose to create a committee to evaluate all requests for a population segment or area through a single process, to develop appropriate adjusted tools for those segments/areas.
- Reclassify HOS questions on Improving or Maintaining Physical and Mental Health to carry a member experience weight of 1.5, as opposed to an outcome weight of 3, and generally not having survey questions with a weight above 1.
- Divulge all adjustment flags to authorized survey vendors in order to facilitate an additional point of adjustment validation without necessarily sharing the identity of respondents with the plans.
- Examine results of surveys across categories set for the categorical adjustment index to explore the possible need of additional adjustments for these measures.

ADDITION, REMOVAL OR MODIFICATION OF STAR RATING MEASURES

The Proposed Rule includes the consideration to add measures that evaluate quality from the perspective of adopting new technology (for example, the percent of beneficiaries enrolled through online brokers or the use of telemedicine). While technology has been dictating the path for innovation in many services, including access to care, and it certainly represents a great development opportunity, caution should be exercised. Considerations such as regional technological access and infrastructure, as well as adoption levels should form part of this assessment. A balance between the use of technology and the continuation of personal touch should always prevail, particularly while dealing with this demographic.

In addition to the above referenced recommendations regarding the management of survey measures, there are other operational measures that should be re-evaluated. For example, the

"Members Choosing to Leave the Plan" measure is greatly impacted by the demographics and social determinants that make up the membership profile. Members who are SNP eligible are free to switch plans throughout the contract year. Additionally, disenrollment surveys demonstrate that the main reason for disenrollment is financial. This is especially prevalent in SNPs which exhibit a greater utilization rate or have lower member incomes, and thus are more prone to have members who shop back and forth for benefits, even if monetary differences seem to be insignificant. Additionally, eligibility interruptions have an impact on the way members' care is managed and their care coordination. CMS should consider the proportion of SNPs, particularly dual-SNPs within a contract in order to apply an expected disenrollment coefficient to diminish the penalizing impact of having higher proportion of SNP members within the covered membership. Further analysis should be completed to determine if refined rules should be applied to SNP enrollment to promote better care management and coordination.

The Proposed Rule also mentions the intention to include survey measures of physicians' experiences with plans and anticipates the development of a survey tool for collecting standardized information on their experiences with health and drug plans. While we agree that it is important to measure the physicians' experience with plans, further consideration to the development of industry standard survey tools that measure the patients' experience at the individual physician or provider level should be exercised and used by CMS to evaluate providers' performance, whether as individual FFS Medicare contractors or providers of MA care. Plans should act upon individual provider's results.

In general terms, the Proposed Rule would establish provisions for the addition, removal or modification of Star Rating measures to be consistent with current methodological practices. However, the following elements should be taken into consideration:

- Regardless of the measure change type, all changes should be announced prior to the commencement of the measurement period in order to provide plans the opportunity to properly implement changes at the systems, network, or operations levels that might be necessary to guarantee proper measure management.
- In the case of technical specifications that provoke a legacy measure (with original specs) versus an updated measure with new specs, please consider that there might be instances where keeping a legacy and a new measure might not be realistic.
- In the case of changes where the denominator of the measure is narrowed, this could well be a substantive change worth incorporating immediately without use interruption for the Star Ratings program. Some measure denominators may result in population so small that relatively insignificant changes in numerator compliance can create a big adverse change in the measure result. Caution should also be observed on measures where a lower rate is better.

- Please provide further guidance to ensure that, in the event a measure specification change is made to add tests to the numerator, in those instances where the lower the fraction the better the score, the measure would move to display status.

CUT POINTS

Cut points are in a way the core for the determination of Stars Ratings. We recognize the amount of effort that CMS invests in order to calculate and determine cut points and also agree that establishing a methodology with changing thresholds encourages continuous improvement. Plans that wish to reach 5 Stars goals must set their performance targets at the highest levels, despite the determination of cut points. Notwithstanding this, because rating results depend on how the plan's execution compares against that of all plans in the nation, having knowledge of of all plans' results is useful.

The Part C and D Performance Data page from CMS publishes the information on specific measure scores per contract of all contracts which will be active in each Rating Year, but the information on contracts that had performance in a Measurement Year but will not be active during the Rating Year is not published. The performance of these contracts is used as part of the clustering or relative distribution analysis done to determine cut points. While year over year Cut Points have had certain stability, some peaks are observed for some measures. Terminated contracts can have outlier characteristics impacting cut points behavior.

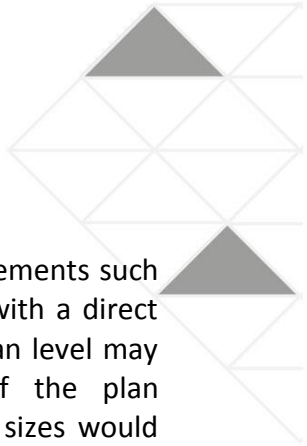
In light of the spirit to keep processes transparent, it is recommended that all individual scores used to determine cut points are made public.

On the other hand, there are measures for which the star level thresholds are very closely grouped. This is generally observed on survey measures. Further analysis on the impact of case-mix adjustment and the applicability of reliability analysis on the cut points determination should be exercised.

We would also like to recommend that as part of the analysis done, cut points or a reasonable facsimile to cut points are determined or simulated for display measures.

RATING LEVELS

The Proposed Rule introduces the concept of assigning Star Ratings at different levels such as plan (PBP) level, Parent Company level, or consolidated markets level.
Having the capability to evaluate performance at the plan level might seem to be a good option to offer consumers a sense of how well the benefits under the plan are managed. However, it



also makes it more complex to calculate. Additionally, analysis has shown that elements such as plan design (i.e. copays) play a role in the members' behavior towards care, with a direct impact on plan performance outcomes. Scaling ratings down to the individual plan level may create performance differences that are not necessarily representative of the plan performance. Additionally, measure reliability issues due to inadequate sample sizes would influence results and create bias, adding complexities to the rating system and it could make it more difficult for individual consumers to evaluate options as they might be confused by different results for different plans under the same sponsor brand and service area.

Regarding reporting of measure data at a higher level, such as parent organization versus contract, whereas all contracts share the same results in some cases, particularly for the call center measures when calls are served by the same call center, we recommend that a project is performed as to demonstrate and evaluate possible alternatives. The same exercise should be done with the consideration of contract market area reporting when a contract covers a large geographic area. While simplification may result from this approach, it should be carefully evaluated as it may not take into account differences experienced across geographical segments within a large area, inhibiting other considerations such as social determinants of health.

Foreign Language and TTY availability constitute measures that capture member access. This measure relies on the availability of a translator or TTY to monitor random calls during a specific time frame, but languages chosen for monitoring translators are standard and not necessarily proportional to the actual languages spoken by the served populations. In the case of Puerto Rico, for example, Spanish is spoken by over 99% of local residents, with the remaining 1% speaking other languages not necessarily used for the monitoring or in the correct proportion used this purpose. Future consideration should be given to adjusting monitoring languages to the ones actually spoken by a plan's or area's beneficiaries, or removing the measures. From the perspective of process simplification and operational burden both for CMS and the plans, we recommend consideration of using a single, combined rate for both Part C and D, similar to what is done for Members Choosing to Leave the Plan and Complaints measure.

CONTRACT CONSOLIDATIONS

We disagree with the proposal to assign Star Ratings based on the enrollment–weighted mean of the measure scores of the surviving and consumed contract(s) so that the ratings reflect the performance of all contracts involved in a consolidation. The Star Ratings for a contract are based upon its performance over a period of time and are intended to reflect how well a contract manages their enrollees. CMS should use its discretion and power to monitor consolidation practices, which still represent less than 4% of the total contracts, and further

evaluate contracts' performance in the event of noticeable wrongful consolidation practices. This evaluation should include whether or not upon consolidation into new contracts, performance of future measurement periods for the surviving contract occurs, versus that of the consumed contract.
The proposed mechanics for the determination of first year ratings and second year ratings as well as for the purposes of QBP determinations add complexities and burden to the calculation system.

DEVELOPING RULING FOR MANAGEMENT IN LIGHT OF CATASTROPHIES

Shortly after the impact of hurricanes Irma and María, CMS made a request to contracts impacted by these catastrophic natural events to provide an analysis on the repercussions that the current state of emergency would have on their Ratings.
Most recently, CMS expressed its intention to propose that the CAHPS, HOS, and HEDIS measures reporting becomes optional for the following Ratings year for contracts solely operating in Puerto Rico, given ongoing issues with contacting or providing care to enrollees in MA plans with service area(s) in Puerto Rico. Contracts would receive last year's Star Ratings for these measures, if they choose not to report them, or the higher of this year's and last year's Star, if they choose to report them. All other contracts would be required to report these measures, unless the contract requests, and CMS approves, an exception.

We recognize that the Proposed Rule was already under development for quite some time before several states and territories were impacted by significant natural disasters. However, these disasters raised the need to define policy around the management of Star Ratings in light of such events. We recommend that this become a subject to be included within the finalized Proposed Rule. In addition, we recommend that this same treatment is given to all Star Rating measures. and, as we responded to CMS's request for comments on this issue, Overall and Summary Ratings should be no less than the result for the most recently evaluated Rating, RY2018 in this case.

There are additional considerations relating to the impact of natural or other disasters which we would to bring to your attention:

- In the case of Overall or Summary Stars Rating, leaving measures the same as prior year may have the net impact of reducing the score on Improvement with detrimental results. Thus, adopting the highest rating between the one obtained for RY2018 and RY2019 might work for the best.
- These types of events might not only have an impact on the Rating to be calculated immediately after the disaster, but also for additional rating years. The following are just some examples to illustrate this situation:

- The Health Outcome Survey establishes a baseline for future comparison thus for some HOS measure the impact can continue being experienced for RY2020, RY2021, and RY2022.
- HEDIS measures with measurement or collection periods that go beyond a single calendar year may be impacted as well. For example, Osteoporosis Management for Women with fracture will be impacted for RY2020 as well:
  - RY2019: Identifies denominator events from 7/1/2016 to 6/30/2017, and numerator events until 12/31/2017.
  - RY2020: Identifies denominator events from 7/1/2017 to 6/30/2018, and numerator events until 12/31/2018.
  - Consideration should be given to possible instances where a same territory or state suffers the impact of significant disasters during two consecutive measurement years.

PART D TIERING EXCEPTIONS

We request that CMS be more specific on the regulations and provide examples of the various formulary structures and how tiering exceptions would work.

MEDICARE ADVANTAGE AND PDP QUALITY RATING SYSTEM

We believe that the Measure of Appeals Upheld: Fairness of Drug Plan's Appeal Decisions does not accurately reflect how often an Independent Reviewer found that the drug plan's decision to deny an appeal was fair. For example, the IRE may have had additional information from the physician which the plan did not receive and although it used the correct criteria it did not receive the necessary information.

ANY WILLING PHARACY STANDARDS TERMS AND CONDITIONS AND BETTER DEFINE PHARMACY TYPES

In response to the request for comments on certain specific proposals:

- We recommend that the time frames for providing standard terms and conditions should be within five (5) business days (instead of two (2)).

- We find that the definitions of retail pharmacy and mail order pharmacy provided in the Proposed Rule strike the correct balance to prevent confusion and can be viewed as maintaining plan flexibility for dispatch deliveries versus walk-ins.
- We agree that certain conditions such as cancer, MS, rheumatoid arthritis, etc. should be managed through specialized pharmacies to increase the likelihood of clinical interventions to handle complex conditions like these, and we suggest that to be so qualified a pharmacy should have a credentialing certification recognized by an accrediting organization.

EXPEDITED SUBSTITUTIONS OF CERTAIN GENERICS AND OTHER MIDYEAR FORMULARY CHANGES

The Proposed Rule would allow generic substitutions at any time of the year rather than waiting for them to take effect two months after the start of the plan year. Will CMS add to their Formulary Reference File (FRF) all generics that have an equivalent brand in the FRF timely?

LENGTHENING ADJUDICATION TIMEFRAMES FOR PART D PAYMENT REDETERMINATIONS AND IRE RECONSIDERATIONS

We have a concern that cases that expired at our level and go directly to IRE will have a greater delay in obtaining meds due to longer TATs at IRE level.

* * *

We very much appreciate the opportunity to comment on these proposals and to present the recommendations we believe will help the beneficiaries enrolled in the MA program in Puerto Rico. We trust that these comments will be taken into consideration and incorporated in the Final Call Letter and Guidance.

Very truly yours,

Myra Plumey
Chief Compliance Office
MMM HEALTHCARE, LLC