CMS must address the issues pertaining to the medication adherence metrics for PDPs with a high percentage of LIS enrollees.

The Company is a sponsor of stand-alone Part D prescription drug plans and respectfully submits the following comments to the Request for Comment Request for Information – Data on Differences in Medicare Advantage (MA) and Part D Star Rating Quality Measurements for Dual-Eligible versus Non-Dual-Eligible Enrollees issued by the Centers for Medicare and Medicaid Services ("CMS") on September 8, 2014.

The Company appreciates CMS's acknowledgement of this issue and the opportunity to comment. CMS perhaps stated it best when it noted the following:

> Chronic disease and disability are common in the LIS population. More than 80 percent of Part D enrollees who had spending high enough to reach catastrophic coverage were LIS enrollees. Additionally, the reassignment process can present additional challenges for LIS enrollees such as new formularies, requirements for prior authorizations, step therapy or quality limits, processes for exceptions, appeals and grievances, and contacting their plan. **This makes it more challenging for LIS enrollees to maintain access to their drugs.**

(*See*, *Proposed Regulations Pertaining to the Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program*s, 79 Federal Register 1918, 1952, January 10, 2014.)

The Company on a number of occasions has submitted to CMS that certain of the Star Ratings metrics, and specifically the medication adherence metrics, are an issue for plans with large populations of low income subsidy ("LIS") enrollees. In recent years, numerous studies done by several organizations have shown that LIS enrollees are historically less adherent than non-LIS enrollees. The absence of an adjustment in the Star Ratings metrics to account for these inherent differences in the LIS beneficiary population creates an unfair comparison of performance for those plans that have a high population of LIS enrollees. Further, the current way the Star Ratings Program methodology for the medication adherence metrics operates threatens the existence of Part D plans that provide an important benefit to a population of beneficiaries in need of that benefit.

Company Data

The Company has conducted extensive analyses of the calculations used to determine the plan rating in each of the patient safety metrics. Through coordination with its pharmacy benefit manager, reporting has been developed a methodology which identifies members who are non-adherent. Once a member has been identified as non-adherent or at risk of becoming non-adherent, that member becomes a part of the Company's Medication Adherence Program. In the most recent plan year, when reviewing each of the three patient safety measures, the Company's LIS beneficiary population on average scores seven to nine percentage points lower in adherence than the Company's non-LIS beneficiary population. This trend is also evidenced in prior years' data and in nationwide data for all Part D plans combined.

Although plans may employ the same medication adherence strategies to all of the plan's beneficiaries, the LIS enrollee population presents difficulties in effectively providing the follow-up and persistence to ensure adherence to medication regimens. With regard to our program, the Company has implemented multiple initiatives aimed specifically at increasing medication adherence for all members.

These programs have been developed around the CMS patient safety metrics that are a part of the yearly plan rating.

Addressing the various reasons for each individual's non-adherence and attempting to change routine behavior is a demanding task and despite the use of resources to make beneficiaries adherent, the Company's efforts have led to very little change in the adherence scores for the LIS beneficiary population.

Research and Commentary on Difficulties with LIS Population

The overarching difficulty with the adherence metrics is that despite the plan's best efforts, the behavioral tendencies of this population of beneficiaries is beyond the plan's control. Numerous studies have been done, and specifically, research has shown medication adherence is highly dependent on a combination of factors such as education, socioeconomic status, and health status. In a January 2014 Health Affairs article entitled "Socioeconomic Characteristics Of Enrollees Appear To Influence Performance Scores For Medicare Part D Contractors," the authors concluded that, with regard to achieving a satisfactory score based on the Star Ratings program, "some companies have a substantial advantage over others because of their enrollees' socioeconomic characteristics, with more than a third of the variation in adherence scores tied to these characteristics." The study authors concluded that "CMS should seriously consider the case-mix adjustment of medication adherence scores for the Part D program."

Researchers at Inovalon have reviewed the differences between dual eligibles (all LIS – all dual eligibles are LIS but not all LIS are dual eligible; an LIS member may not be on Medicaid) and non-duals. The study found that a significant association between dual eligible status and lower Star Ratings. The study authors concluded that the Star Rating system unfairly penalizes plans serving a high proportion of dual eligible beneficiaries. (*See, Inovalon study on Impact of Dual Eligibles on CMS Five-Star Quality Measures and Member Outcomes in Medicare Advantage Health Plans,* October 2014.)

In March 2014, the National Quality Forum issued a report wherein a panel focused on the lack of CMS policy around accounting for socioeconomic differences in the plan's beneficiary population. The issues that concerned the Panel included: (i) providers avoiding serving disadvantaged populations to ward off being labeled a poor performer, which then worsens access to care for vulnerable patients; (ii) funds – based on performance-based incentives – shifting from those that serve the disadvantaged to those that serve the affluent. Safety net providers then have fewer resources to care for vulnerable populations and the array of additional services that they need; and (iii) consumers and payers avoiding providers who serve disadvantaged populations because they are labeled poor performers, which may not accurately reflect underlying quality of care. (*See, National Quality Foum Draft Report on Risk Adjustment for Socioeconomic Status or other Sociodemographic Factors,* March 2014.)

Furthermore, members of Congress have taken note of the various studies on the issues with socioeconomic differences in beneficiary population. Specifically in March 2014, ranking members of the House of Representatives Energy & Commerce and Ways & Means Committees sent a letter to Administrator Tavenner noting the issues with the Star Ratings program and urging CMS to review data on LIS beneficiaries and the difficulties this beneficiary population presents when it comes to achieving an adequate star rating.

Proposed Case-Mix Adjustment

The Company has previously advocated for a case-mix adjustment and has been involved in a working group within the Pharmacy Quality Alliance on such a solution.

The first part of this adjustment would require CMS to compare adherence scores within each plan population – LIS to LIS and non-LIS to non-LIS. CMS would determine adherence ratings for each plan's LIS beneficiaries based on the adherence rates of all plans' LIS beneficiaries. It follows that CMS would then determine adherence star ratings for each plan's non-LIS beneficiaries based on the adherence rates of all plans' non-LIS beneficiaries. There would be separate cut points in adherence scores for LIS and non-LIS. The reported adherence star rating for each plan would then be the weighted average of the plan's LIS and non-LIS star ratings.

Conclusion

The Company realizes there are public perception concerns with regard to making adjustments for a certain population of plan enrollees (i.e., the notion that a different standard for LIS enrollees may reflect a lack of concern for the safety and well-being of those beneficiaries). However, taking into account a plan's LIS enrollee population for purposes of assigning a Star Ratings for the medication adherence metrics would not result in a negative public perception or create a message that adherence is less important for those beneficiaries. Adherence remains a very important issue for all plan beneficiaries; however, the plan cannot continue to operate effectively if socioeconomic differences are not taken into account.

The absence of an adjustment that acknowledges these inherent differences between the LIS and non-LIS plan populations has the effect of unfairly penalizing Part D plans with high percentages of LIS enrollees. CMS can avoid penalizing Part D plans for the medication adherence rate differences between LIS beneficiaries and non-LIS beneficiaries by case-mix adjusting the medication adherence scores.

As CMS strives to meet its priority of "making quality health care more affordable for individuals, families, employers, and governments," it cannot be the intent of the Star Ratings Program to penalize PDPs that serve a high percentage of LIS enrollees when such plans are providing an affordable option to such individuals.