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Submitted electronically via PartCandDStarRatings@cms.hhs.gov

Marilyn Tavenner, Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
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Washington, D.C. 20201

Re: Request for Information: Data on Differences in Medicare Advantage and Part D Star Rating Quality Measurements for Dual-Eligible versus Non-Dual-Eligible Enrollees

Dear Administrator Tavenner:

The Visiting Nurse Service of New York (VNSNY) appreciates this opportunity to comment on the above-referenced Request for Information (RFI)¹ soliciting input on the relationship between dual-eligible status and lower Medicare Advantage (MA) and Part D quality outcomes.

As one of the oldest and largest not-for-profit home health care safety-net providers in the country, VNSNY is committed to the vulnerable populations we serve – the vast majority of whom present unique care management challenges that warrant targeted solutions. Roughly half of the nearly 150,000 New Yorkers we serve annually are Medicare and/or Medicaid beneficiaries. Our patient population is extremely diverse, roughly half of whom are of minority backgrounds and one-fourth of whom do not speak any English.

In addition, VNSNY CHOICE Health Plans, an affiliate of VNSNY, serves roughly 30,000 members through both MA and New York State Medicaid Managed Care products. The vast majority (70%) of our MA enrollees are in one of our Special Needs Plans (SNPs) for dual-eligible beneficiaries.

Regarding the RFI at hand, we commend CMS' recent decision² to suspend the termination of the contracts of MA organizations and Prescription Drug Plan (PDP) sponsors that have three or more consecutive years of low star ratings (low performing indicator (LPI) in and prior to the 2015 plan year. We believe that the lack of appropriate risk adjustment inherent in the Star Ratings methodology unduly disadvantages MA SNPs which serve dual-eligible enrollees.

We appreciate that, rather than effectuate a policy with detrimental implications to high-risk dual-eligible enrollees, CMS has instead sought to inform its understanding through this invitation to submit additional data and research. It is our hope that, through this broader process, CMS will continue to engage with plans, providers, and the patient community to ensure that in implementing a policy intended to foster continuous improvement, it does not inadvertently do so at the expense of our most vulnerable.

Furthermore, as important national discussions led by the National Quality Forum (NQF) and others continue in earnest on a transitional period to assess the impact of risk-adjusting quality measures for socio-economic status (SES) factors, we respectfully request that CMS implement a “do no harm” approach as more actionable data is developed. A variety of solutions should be considered, such as comparing like plans – such as D-SNPs – to each other, rather than treating all plans the same for purposes of Star Rating assessment. Plans could receive an adjustment to their Star Rating based on the portion of their enrollees that are dual eligible, due to the strong body of research demonstrating that plans serving a high number of duals trail other MA plans in Star Rating performance once all other factors are controlled for.

Toward both the intermediate goal of not disadvantaging plans serving high-needs beneficiaries and the long-term goal of adjusting quality measures for SES factors, enumerated below is a consolidated – but certainly far from exhaustive – compilation of pertinent research reflecting the strong relationship between SES factors and quality outcomes. This research has significant implications when assessed in the context of the dual-eligible population who are more likely to be of poor health status, low health literacy, low income levels, and for whom the current Star Ratings performance metrics fail to reflect these unique characteristics.

In conclusion, for purposes of improving the Star Rating program to best measure the quality of coverage and care plans delivered to their enrollees, we strongly urge CMS to consider all valid, peer-reviewed literature and evidence. The standard asserted by CMS in the RFI – i.e., the repeated emphasis on *causality* – is a standard found virtually nowhere else in the history of CMS decision-making. Without an opportunity to implement a randomized, controlled trial, which is implausible given the awareness by duals and their plans of their dually-eligible status, demonstration of causality is impossible in this instance.

When a policy so demonstrably disadvantages certain plans and their enrollees, putting such a high hurdle at the starting gate of attempts to have a meaningful dialogue about the issue is unhelpful at best, and counterproductive at worst. As the proprietor of the Star Rating and broader MA programs, we believe it is incumbent upon CMS to remedy the unintended but real consequences of maintaining the existing approach to measuring the performance of D-SNP plans. VNSNY would welcome the opportunity to work with CMS and other partners to continue to pursue evidence that can bolster the foundation for a long-term solution to this important challenge.

I. Social Determinants of Health among Dual-Eligible and Managed Care Patients

Even a brief look into the literature about dual-eligible patients and socioeconomic characteristics associated with health outcomes gives us many examples of the challenges faced when caring for this population.

A. Overall Social Determinants of Health and Health Outcomes

As is well documented in the literature, but unfortunately not necessarily implicit in Medicare's reimbursement policies, health care in the U.S. is burdened with enormous disparities associated with a variety of factors, including insurance status, income, and race.³ Highly vulnerable populations, classified as those with complex medical problems exacerbated by social needs,⁴ are one of the fastest growing segments within the U.S.⁵ To address the complex needs of these patient populations, health care practitioners must understand social determinants of health and utilize a comprehensive health definition, including biological, social, and psychological dimensions.⁶

It bears underscoring that vulnerable populations are more likely to be in poor health and to experience worse health care outcomes. In particular, they are at higher risk of having multiple chronic health problems, mental illness, substance abuse, and disability as well as personal and social factors that adversely affect their health and act as barriers to accessing and benefiting from care.⁷ Poor employment levels and income undermine the ability of these vulnerable populations to maintain health insurance coverage, gain access to high quality health care, and achieve health and well-being.

In general, socially disadvantaged groups include racial minorities, the poor, and those with low social support, who may feel financially or socially isolated. Socially disadvantaged groups have much to gain from accountable care, particularly in terms of quality, because they experience overall worse health, have higher prevalence of many conditions (i.e., chronic conditions and substance abuse), and receive much lower quality of care overall.⁸ For example, research shows:

- ***Vitals.*** Social determinants have an impact on glycemic control, LDL, and blood pressure.⁹
- ***Quality of Life.*** Socially disadvantaged individuals are more likely to report having a lower quality of life and self-rated health.^{8,9}
- ***Readmissions.*** Evidence suggests that 30-day readmission rates are correlated with patients' socioeconomic status and race¹⁰; social factors¹¹ such as housing stability and social supports; and community resources,¹² such as access to timely primary care resources and other supports and services. Predictive models that include social determinants are better at forecasting readmission than models based solely on administrative data.¹³
- ***Allostatic Load.*** Being male, older, having lower income, less education, being Mexican-American and being both black and female were all independently associated with a worse allostatic load (a summary measure of biological risk, incorporating nine biomarkers). After adjusting for these characteristics, living in a lower neighborhood SES (NSES) was associated with a worse allostatic load. The relationship between NSES and allostatic load did not vary significantly by gender or race/ethnicity.¹⁴

B. Health Insurance Status

The majority of dual-eligible beneficiaries – whom many of the plans potentially impacted by CMS' LPI termination policy primarily serve – are both socioeconomically disadvantaged and in poor health. Approximately 86 percent of individuals eligible for Medicare and Medicaid have incomes below 150 percent of the federal poverty level (FPL) and 60 percent bear the burden of living with multiple chronic conditions.^{4,15} The research denoting the implications of health insurance status on health outcomes is staggering. Of note:

- ***Service Utilization.*** Individuals who lack health insurance are less likely to have a regular source of care, are more likely to not seek treatment because of costs, are more likely to use fewer and less appropriate health services, are less likely to receive timely preventive and screening services, and are less likely to receive appropriate care for management of their health conditions.¹⁶
- ***Health Inequities.*** Uninsured and underinsured adults have dramatically worse health care experiences than their insured counterparts, including having higher rates of cost-related access problems, being less likely to be up-to-date with preventive care, and less likely to rate their quality of care as excellent or very good.⁷
- ***Preventive Screenings.*** The percentage of people who receive screening for breast, cervical, and colorectal cancer is far below national targets, and the shortfall is especially high among uninsured adults.¹⁷

C. Income

Regarding SES more broadly and its documented impact on health care quality and outcomes, it is a longstanding fact that, all too often, low-income individuals and families experience substantial disparities in health care and health outcomes when compared with their more well-off counterparts.⁴ Specifically:

- ***Health Coverage.*** Low income adults are most at risk of lacking health coverage through an employer and are more likely to be uninsured, especially for long periods of time.¹⁸
- ***Medication Adherence.*** Medication non-adherence is increasingly recognized to be associated with socioeconomic hardship.^{19,20,21,22,23,24} In chronic conditions such as HIV/AIDS, factors such as poverty, and in particular food insufficiency and hunger²⁵ and unstable housing,²⁶ have been associated with medication non-adherence. In relation to cardiovascular disease, low SES has been found to be associated with low adherence in a number of different contexts.^{27,28,29,30} Observational research has identified several patient, medication, disease and environmental factors that may explain variations in adherence across populations.^{27,31}
 - ***Strategies for Improvement.*** Promising evidence has emerged to help validate strategies to improve medication adherence among disadvantaged populations. These strategies are generally complex: simultaneously targeting patients and physicians; addressing social, financial, and treatment-related

adherence barriers; and called for broader guidelines, regulatory and communication-based policies.³²

- One potential explanation is that ‘one-size-fits-all’ measures are ill-equipped to address the heterogeneity in adherence behavior that exists between social groups. Strategies may therefore be more effective if they:
 - are designed for, and targeted to, specific groups such as those of socioeconomic disadvantage; and
 - take into account multiple pathways through which social disadvantage may influence patients’ medication-taking behavior.³³
- Strategies simultaneously directed at patients and physicians/practices, targeting physician’s prescribing behavior as well as interventions to reduce patient social (i.e. transportation, housing, employment), financial (i.e. medication costs) and treatment-related barriers to enable patients to adhere to prescribed therapy have been found to be most effective, resulting in significant improvements in the risk of adherence. The most successful strategy was targeted to and specifically tested among a socioeconomically disadvantaged population.³³ Despite testing strategies within socioeconomically disadvantaged groups, relatively few interventions or supporting policies addressed directly the dimensions for socioeconomic disadvantage potentially causing non-adherence such as affordability and other costs associated with accessing treatment.³³
- **Regular Provider of Care.** Adults with low incomes are at greater risk of not having a regular provider, as compared with higher-income adults. Nearly all adults (93 percent) with incomes at or above 200 percent of the federal poverty level have a regular doctor or usual source of care, compared with 83 percent of adults with income below 200 percent of poverty.⁷
- **Health Inequities.** Results from the Commonwealth Fund 2010 Biennial Health Insurance Survey confirm that low income adults have dramatically worse health care experiences than their higher-income counterparts. Overall, low income adults report higher rates of cost-related access problems, are less likely to be up-to-date with preventive care, and less often rate their quality of care as excellent or very good.⁷
- **Cost-related Access Problems.** Low and modest-income patients forgo or delay needed care when faced with cost-sharing that is high relative to their limited incomes.^{34,35,36} Fifty-four percent of adults with income below 200 percent of poverty reported having at least one cost-related access problem, compared with 34 percent of adults with income at or above 200 percent of poverty.⁷
- **Preventive screenings.** Nonelderly adults with low incomes are less likely to receive recommended preventive services and screening tests, including blood pressure and cholesterol checks, Pap tests, colon cancer screens, and mammography.⁷

- ***Rating Quality of Care.*** To assess the quality of patients' clinical experiences, the 2010 Biennial Health Insurance Survey asked respondents to rate the quality of care they received. Less than half (47 percent) of all nonelderly adults rated the quality of their care as excellent or very good. However, the ratings for uninsured and low-income adults were far worse than for those with insurance or higher incomes. Thirty-five percent of adults with incomes below 200 percent of poverty rated the quality of their care as excellent or very good, compared with 54 percent of adults with income at or above 200 percent of poverty. Similarly, about one-quarter (27 percent) of nonelderly adults without health insurance coverage rated the quality of their care as excellent or very good, compared with 54 percent of insured nonelderly adults.
- ***Hospitalizations.*** Patients having a lower income were more likely to be hospitalized than peers having the highest income, and this effect of SES remained virtually unchanged after controlling for every other variable studied. In a fully adjusted model, patients in the lowest income quintile had approximately 3 times the odds of hospitalization relative to counterparts in the highest income quintile (odds ratio = 2.93; 95% confidence limits: 2.19, 3.93).³⁷

D. Education

Lower educational attainment has been linked to higher rates of unemployment as well as lower compensation.¹⁵ Just as education impacts employment, employment opportunities in turn impact income and subsequently health. Specifically:

- ***Education Attainment Level.*** Socially vulnerable populations are more likely to have lower levels of education and less interaction with schools.⁴
- ***Education & Mortality.*** Educational differences in mortality for the total population and for specific causes of death are most prominently explained by family income and health behaviors. However, there are age-related differences in the effects of the mediating factors - the education–mortality relationship is much stronger for younger than for older adults, and the effects of specific clusters of mediators vary by age. Higher education enables individuals to effectively coalesce and leverage their diverse and substantial resources to reduce their mortality and increase their longevity.³⁸
- ***Language Barriers.*** Language barriers can make it more difficult for providers to share treatment plans for chronic conditions with non-English-speaking patients.⁴

II. Other Social Determinants of Health and Health Outcomes

A. Neighborhood Conditions

Unhealthy housing and neighborhood conditions are among the most proximate and well-defined threats to the health of disadvantaged communities.³⁹ Just as the housing environment can have a significant health impact, so too can the surrounding community.

Neighborhoods can influence health through physical characteristics as well as through the structure and composition of the built environment. Physical characteristics of a neighborhood that impact health include air and water quality as well as proximity to facilities that produce or store hazardous materials. The Centers for Disease Control and Prevention (CDC) defines unhealthy housing as the presence of characteristics that might negatively affect the health of its occupants.⁴⁰

- ***Race, Ethnicity, and Lack of Resources.*** Analyzing data from the 2009 American Housing Survey, the CDC found that over 28 percent of blacks lived in unhealthy housing units, totaling nearly 4 million housing units.²⁵ An additional three million housing units occupied by Hispanics were considered unhealthy as well.¹⁸ Both blacks and Hispanics were found to be more likely than their white counterparts to live in unhealthy housing.¹⁸ Additionally, the CDC acknowledged that unhealthy housing disproportionately affects the populations that have the fewest resources.¹⁸
- ***Housing.*** Many socially disadvantaged people are either homeless or reside in rural or impoverished neighborhoods.⁴
- ***Concentrated Geographic Areas.*** Socially disadvantaged people are frequently concentrated within geographic areas, and thus the challenges to their participation in an Accountable Care Organization (ACO) largely occur at the level of communities and health care organizations.⁴ A major driver of overall poor quality is the concentration of care for socially disadvantaged groups in a subset of geographic areas that have worse transportation and lower performing hospitals and providers.^{41,42}
- ***Medication Adherence and Access.*** Adherence and access to medications was lower among low-income rural living individuals.^{43,44}

B. Health Literacy

Socially disadvantaged populations are more likely to have lower health literacy compared to their more advantageous counterparts.⁴ Further, limited literacy populations have been shown to experience poorer health outcomes. For example:

- ***Readmissions, Emergency Department Visits, and Mortality.*** Low health literacy was associated with higher mortality rates,^{4,45,20,46,47} and greater use of emergency care and rehospitalizations.^{26,29,48,49}
- ***Preventative Screening.*** Individuals with low health literacy were less likely to receive preventative services such as, mammography screening and influenza vaccine.²⁶
- ***Medication Adherence.*** A factor contributing to poor medication adherence is health literacy – the ability to understand and use health information to make important decisions affecting one’s health.^{16,50,51,52,53,54,55,56} Previous studies have shown that limited-literacy patients have difficulty correctly identifying medicines^{40,57,58} and understanding how to take medicine.^{26,41,52,59,60,61,62} They are reluctant to ask questions of providers, possibly because they are ashamed to admit they do not

understand.^{33,63,64} Unless they have a trusted confidant, limited-literacy patients might be reluctant to ask others for the kind of help needed to take their medicines correctly.

- ***Physician-Patient Communication.*** Patients with inadequate health literacy are more likely to have low self-efficacy,⁴⁶ and less interaction in physician-patient encounters,⁶⁵ which in combination with physicians' use of complex medical language,⁶⁶ results in lower quality and clarity of physician-patient communication.⁴⁰ The quality of communication with patients and providers is measured using items from the Interpersonal Processes of Care in Diverse Populations instrument (IPC),^{40,67} which assesses clarity of explanations, responsiveness to patient concerns, and involvement of patients in decision-making. Further, in outpatient research that utilized the IPC, Schillinger et al.⁶⁸ found that patients with inadequate functional health literacy reported significantly worse communication on the domains of general clarity, explanations of processes of care, and explanations of condition and prognosis.
- ***Self-Management Skills.*** Patients with low health literacy have limited knowledge of disease self-management skills.⁶⁹

C. Race/Ethnicity

As national data demonstrates, there are residual racial differences in health at every level of SES for multiple indicators of health status, including self-rated health, heart disease mortality, hypertension and obesity.⁷⁰

- ***Preventable Disease, Readmissions, and Mortality.*** White disparities in health/illness are reflected in higher prevalence rates of preventable diseases and mortality rates reflecting premature death among minority races.^{4,71,72} Older age and non-White race were associated with worse outcomes including hospital readmission and mortality.¹¹
- ***Access and Utilization of Health Resources.*** Racial minorities experience distinctive stressors generated by their relatively lower socioeconomic status and higher likelihood of residing in poor neighborhoods; their health care access and utilization also often is hindered by strained resources.^{73,74}

D. Social Supports

As the research reflects, vulnerable populations are more likely to lack social support systems (e.g., family members at home), which contribute to a disproportionate risk of readmission after hospital discharge.^{4,27,75,76}

III. Concluding Remarks

In closing, we appreciate the transparent RFI process by which CMS has engaged with stakeholders and experts to inform its understanding of the degree to which SES causes variation in Star Ratings performance. It is our hope that, as CMS reviews the research and analyses

reflected above and in additional submissions, it will in turn implement necessary refinements to the Star Ratings program that are more aligned with the unique characteristics of the beneficiaries served by these health plans, especially dual-eligible Special Needs Plans (SNPs).

Again, we strongly urge CMS to take immediate action to ensure that plans serving high-risk beneficiaries are not unduly disadvantaged under the current misaligned ratings methodology. Furthermore, a longer-term solution – one that includes an evidence-based approach to adjusting measures due to SES factors – is critical to ensuring that beneficiaries' access to quality health care is not disrupted. Should you have any questions or wish to discuss our comments further, please feel free to contact Hany.Abdelaal@vnsny.org or Linda.valentino@vnsny.org.

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