COMMITTEE ON WAYS AND MEANS U.S. HOUSE OF REPRESENTATIVES WASHINGTON, DC 20515

October 13, 2020

Seema Verma Administrator Centers for Medicare and Medicaid Services (CMS) Department of Health and Human Services (HHS) Room 445-G, Hubert H. Humphrey Building 200 Independence Ave., S.W. Washington, DC 20201

RE: Use of Clinical Algorithms in CMS Programs

Dear Administrator Verma:

Racial inequities in health outcomes are unacceptable, and COVID-19 has made many of them more visible than ever. Examining and eliminating the impact of scientific racism on clinical medicine is an excellent starting point for addressing such inequities. In particular, I am deeply concerned about the research findings published in *The New England Journal of Medicine* (NEJM) on June 17, 2020. The article detailed findings that demonstrated racial bias in tools physicians and other providers use to make clinical decisions for conditions that span from childbirth to cancer care to kidney disease and impact both Medicare and Medicaid beneficiaries.¹ As the focal point for all quality, clinical, medical science issues, survey and certification, and policies for the Centers for Medicare & Medicaid Services (CMS) programs, the Center for Clinical Standards and Quality (CCSQ) should be both aware and particularly interested in this issue.²

In light of the Committee's ongoing work to understand and end racial health inequities, and our focus on reducing maternal mortality inequities, I have already sent letters to seven of the professional societies responsible for development and use of some of these clinical algorithms.³ I believe that collaboration across providers and payers will ensure that the provider community readies itself to make change in this space and write to request an update on how CMS uses these clinical algorithms in its programs.

¹ Vyas DA et al. Hidden in plain sight – reconsidering the use of race correction in clinical algorithms. 2020; DOI: 10.1056/NEJMms2004740.

² CMS. Center for Clinical Standards and Quality (last accessed October 8th), https://www.cms.gov/About-CMS/Agency-Information/CMSLeadership/Office_CCSQ

³ Ways and Means Committee, In a series of letters, Neal calls on Professional Medical Societies to push racial health equity agenda forward, (Sept 3, 2020), https://waysandmeans.house.gov/media-center/press-releases/series-letters-neal-calls-professional-medical-societies-push-racial

CMS leads the nation in developing quality-based incentives for health outcomes and delivery efficiency. Medicare is the largest payer for end stage renal disease, and Medicaid underwrites the majority of births among low-income women. For many of the clinical algorithms cited in the NEJM article, the "correction" factor for race or ethnicity assigns Black or Latinx patients risk scores that have the potential to worsen their health outcomes and deepen racial health inequities. CMS and CCSQ's approach to payment, quality guidelines, and clinical standards has an outsized impact on medical care across the United States. It is notable that Quality Improvement Organization (QIO) conferences have started integrating health equity into their agendas.⁴ Unfortunately, despite CCSQ being responsible for all quality-related activities – including survey and certification, technical assistance, beneficiary information, payment policies, and provider/plan incentives as well as the full and effective integration of these programs at CMS – health equity is not mentioned once in the description of CCSQ's scope.⁵ This is of deep concern, considering the urgent need for improvement on racial health inequities.

CMS should take this inquiry as an opportunity to immediately evaluate the unintended consequences of clinical decision tools, including algorithms developed by specific professional societies, along with their uses and relevance to CMS initiatives related to quality and safety for Medicare and Medicaid beneficiaries. For example, total Medicare expenditures for both chronic kidney disease (CKD) and end-stage renal disease (ESRD) were over \$114 billion in 2018, but much more could be done to prevent progression of this disease and addressing misuse of race in clinical algorithms could be part of the solution. ⁶ CMS should closely examine how these tools may impact racial equity within existing and planned value-based payment (VBP) programs as well as holistically ensuring accountability in all CMS programs for equitable outcomes.

In this vein, I ask that CMS provide a briefing for Committee staff by no later than October 30, 2020, regarding the current use of such clinical decision tools, including:

- 1. Does CMS currently rely on any of the clinical algorithms referenced in the table of the NEJM article? If yes, how are these clinical algorithms used?
- 2. Has CCSQ reviewed the issue of race and ethnicity within clinical decision tools, including algorithms? If yes, how has the Center assessed the impact of these tools on racial disparities in outcomes? If not, why has this not been examined? Please provide any analyses CMS has conducted.
- 3. What inquiries and guidance could CCSQ develop and disseminate quickly to better understand the use and impact of these algorithms while CMS works to implement a long-term strategy on use of these clinical decision tools?
 - a. Considering the Committee's past work on maternal health, the urgency of the maternal health disparities crisis and concerns about the vaginal birth after

⁴ https://qioprogram.org/qionews/articles/quality-conference-day-3-celebrating-health-equity-successes-and-committing-value

⁵ CMS. Center for Clinical Standards and Quality (last accessed October 8th), https://www.cms.gov/About-CMS/Agency-Information/CMSLeadership/Office_CCSQ

⁶ United States Renal Data System, (last accessed October 8th),

https://www.usrds.org/media/1734/v2_c09_esrd_costs_18_usrds.pdf

delivery (VBAC) clinical algorithm, what specific guidance could be issued in the short-term to address this clinical algorithm and its relationship to birthing options and outcomes for Medicaid beneficiaries?

- b. How will CCSQ quickly inform clinicians of the concerns about the impact of all the clinical algorithms in the NEJM article on racial health inequities?
- c. What guidance will CCSQ offer providers on how these concerns should be communicated to patients?
- d. What strategies can CMS develop to leverage QIOs as information sources on these clinical decision tools?
- 4. Does CMS plan to conduct any review of the clinical algorithms cited in the NEJM article or other clinical decision tools, and under what time frame? If this is not currently planned, I ask that you immediately complete a review of the consequences of the misuse of race in algorithms for services or items paid for by Medicare and Medicaid. This review should include identification of a stopgap measure that leverages your market influence to address the issues identified with the algorithms quickly while a more thorough review is conducted. Due to the nature of this request, please provide this information no later than November 30, 2020.
- 5. Are other agencies within HHS looking into this issue? If so, is CMS collaborating with its counterparts on these efforts? Please provide an update and the results of any such initiatives by November 30, 2020.

Thank you for your attention to this critical matter. If you have any questions about this request, please contact Orriel Richardson at Orriel.Richardson@mail.house.gov of the Committee on Ways and Means Majority Staff.

Sincerely,

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Richard E. Neal Chairman Committee on Ways and Means