



SEP 22 2015

Mr. Jim Tozzi
Center for Regulatory Effectiveness
1601 Connecticut Avenue, N.W.
Washington, DC 20009

Dear Mr. Tozzi:

Thank you for your July 8, 2015, letter on behalf of the Center for Regulatory Effectiveness (CRE) to the Centers for Medicare & Medicaid Services (CMS) concerning the implementation of the Medicare Advantage (MA) and Part D star rating system and regulatory requirements related to transparency and the reproducibility of the star rating computation methodologies. Although you refer in passing to other ratings systems developed and used by CMS, the focus of your letter is the MA and Part D star ratings system, so we have focused our analysis and response accordingly.

The CMS star ratings methodologies have been developed and are regularly updated in compliance with applicable law, as discussed below. As we make changes to the methodology and measures from year to year, we will take your comments into consideration.

1. Provision of Notice and Opportunity for Public Comment

You argue that CMS must follow *Federal Register* notice and comment rulemaking required by the Administrative Procedure Act (APA, 5 U.S.C. § 553) and by § 1871 (42 U.S.C. § 1395hh) in promulgating rules that use CMS's star rating program in determining bonuses, rebates, and eligibility. You also maintain that § 1853(b) (42 U.S.C. § 1395w-23(b)) does not authorize a different process for promulgating rules relating to CMS's star rating program because § 1853(b) applies *only* to the announcement of capitation rates and factors used in making adjustments to such rates. We disagree with your assessment. As we set forth below, the specific process set forth in § 1853(b) of the Act, and not the general § 1871 or APA process, is the appropriate mechanism through which to announce and seek comment for proposed changes to the MA payment methodology, which includes the star ratings programs.

Section 1853(b)(2) provides, "the Secretary shall provide for notice to Medicare Choice organizations of proposed changes to be made in the methodology from the methodology and assumptions used in the previous announcement and shall provide such organizations an opportunity to comment on such proposed changes." The statute applies to announcements of capitation rates, factors used in making adjustments to such rates, and changes to the methodology used to arrive at such rates. Because the star ratings system is now integrated into

the payment methodology – a mechanism used to determine how much a plan is paid, and not the mechanism by which (or a rule about when) a plan is paid – the quality rating is part of the process for setting benchmarks and capitation rates under § 1853, and the process for announcing changes to the star rating systems falls within the scope of § 1853(b).

Section 1853(b) sets forth a process for announcing changes in MA payment methodologies that is in lieu of the *Federal Register* process required by the APA and § 1871. Section 1853(b) requires that announcements with respect to capitation rates and adjustments to such rates be made in a manner intended to provide notice to interested parties. With respect to changes in methodology explicitly addressed in § 1853(b)(2), notice of proposed changes must be provided to Medicare Choice organizations, now known as Medicare Advantage organizations, and such organizations must be provided an opportunity to comment on the proposed changes. CMS has consistently applied § 1853(b) of the Act to adopt MA payment methodologies in a manner intended to provide notice to interested parties, including MA organizations, and we use § 1871 of the Act and APA rulemaking to adopt rules to govern other aspects of the payment process (e.g., appeals, bidding processes) for MA plans. CMS's consistent issuance on its website of Advance Notices (i.e., the annual proposals) and Rate Announcements (i.e., the final announcements) pertaining to changes in its capitation rates, factors used in making adjustments to such rates, and changes to the methodology used to arrive at such rates are in full compliance with § 1853(b). Each year since the quality rating system became part of the payment methodology, CMS has announced and adopted changes to star rating measures and the calculation methodology by way of the Advance Notice and Rate Announcement process. Although not expressly required by § 1853(b), there is a star ratings Request for Comment process before the Advance Notice and Draft Call Letter are released; this Request for Comment provides MA organizations and other stakeholders an opportunity to request changes to and raise concerns about the star ratings methodology and measures. The MA and Part D star ratings Technical Notes issued with the ratings each year describe in detail how the methodology is applied. Further, CMS affords MA organizations multiple opportunities each year to review their data and ask questions before their star ratings are finalized. Our existing process is fully compliant with § 1853(b) and provides ample opportunity for public comment and input for the ratings system.

We note that all rules that tie the Part C and Part D star rating system to bonuses, rebates, and MAO eligibility determinations were promulgated in adherence to *Federal Register* notice and comment rulemaking under the APA and § 1871. See 42 C.F.R. §§ 422.258(d)(7) and 422.266 (76 F.R. 21,432, 21,485-91, 21564-67 (April 15, 2011)) and §§ 422.505, 422.510, 423.504, and 423.506 (77 F.R. 22,072, 22,108-115, 22,168, 22170-71 (April 12, 2012)).

Interpreting § 1871 and the APA notice and comment rulemaking requirements to apply here would be inconsistent with the statutory scheme. If changes affecting MA payment amounts were subject to § 1871 *Federal Register* notice and comment rulemaking, then MA organizations and other interested parties would have the opportunity to provide input through that process, and the specific process set forth in § 1853(b) would be, at best, superfluous. Moreover, given the timing built into the bid process under § 1853 and § 1854 of the Act, the 60-day comment

period required under § 1871 would not permit issuance of the final notice in time for MA organizations to prepare their bids. We, therefore, believe that the § 1853(b) process is to be substituted for, and not provided in addition to, the *Federal Register* notice and comment rulemaking process required by § 1871 and the APA.

2. Paperwork Reduction Act

Your letter also challenges CMS's compliance with the Paperwork Reduction Act (PRA). CMS has consistently collected the information used to calculate star ratings in accordance with the PRA. There are multiple sources of data for the various star rating measures, including Healthcare Effectiveness Data and Information Set (HEDIS), Consumer Assessment of Healthcare Providers & Systems (CAHPS), and Health Outcomes Survey (HOS) data as well as medication therapy management (MTM) data and call center performance data. CMS identifies for the public in both the annual Call Letter and the MA and Part D Technical Notes the data sources for the measures. CMS provides public notice and receives the Office of Management and Budget's (OMB) approval of the burden imposed on the public by these sets of data in accordance with the PRA. The burden costs associated with each collection are stated in the supporting documentation packages attached to each Information Collection Request (ICR) posted on the OMB/OIRA website.

Much of the data used to calculate star ratings is also collected for other purposes, including the routine monitoring of contracting organizations' compliance with program requirements as well as the review and development of new Part C and Part D program policies and guidance. The number of uses to which CMS puts collected data has no impact on the burden placed on the public by the conduct of the collection itself. The cost to a contracting organization to provide, for example, MTM data, does not increase with each use of that data by CMS. Thus, there is no specific or cumulative PRA burden associated with CMS's development and calculation of star ratings that must be disclosed to the public. Nevertheless, because CMS specifically identifies the data sources for each star rating measure, individuals can always obtain a general sense of the burden imposed on the public by the calculation and assignment of star ratings by reviewing the ICRs approved by OMB posted on the OMB/OIRA website for each identified data source.

3. Reproducibility of Individual Star Ratings

You also assert that CMS has failed to comply with OMB guidelines related to information dissemination. CMS is aware of and follows the OMB's *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated by Federal Agencies* (February 22, 2002). This guidance directed agencies "to develop information resources management procedures for reviewing and substantiating (by documentation or other means selected by the agency) the quality (including the objectivity, utility, and integrity) of information before it is disseminated." HHS complied with OMB's directive when it issued *HHS Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated to the Public*, <http://aspe.hhs.gov/report/hhs-guidelines-ensuring-and-maximizing-quality-objectivity-utility-and-integrity-information-disseminated-public>,

as well as *Guidelines for Ensuring the Quality of Information Disseminated to the Public*, the more specific guidelines for CMS (found in part II, section E). Both of these documents indicate that they were issued in conformance with OMB's 2002 directive.

Section IV of the CMS Guidelines provides Agency Administrative Complaint Procedures. The Guidance specifically outlines the procedures an individual should take to seek a correction of information disseminated by the agency, and it specifies that CMS will review the information provided, will determine whether a correction is warranted, and if so, what action to take. An individual who is dissatisfied with CMS's initial determination may pursue an administrative appeal.

Further, CMS annually publishes sufficient information that the ratings assigned to MA and Part D plans can be replicated. The public, including beneficiaries, may review the data on each measure to come to their own conclusions about the quality of each plan. The MA and Part D Technical Notes provide full transparency on how the star ratings are generated and provide details on the specific data used and the statistical procedures employed in the calculation of the star ratings. When the data are posted for consumer use, all of the underlying numeric measure data are provided to the public to enable them to make their own inferences about performance. Based on data posted on <http://go.cms.gov/partcanddstarratings> and the MA and Part D Technical Notes found at this same link, the calculations for the star ratings can be reproduced. The measures included in the star ratings are collected as part of CMS's administration of the Part C and Part D program, and, in many cases, are collected directly from health and drug plans. The majority of measure specifications come from consensus-based organizations; thus, the measure specifications have been thoroughly tested and reviewed by multiple experts and panels.

A central focus for CMS has been on the accuracy and completeness of the data that are included as part of the star ratings program. As noted in the Technical Notes, CMS's policy is to reduce a contract's measure rating to 1 star if it becomes clear that biased or erroneous data have been submitted. This exclusion would apply to cases where CMS finds mishandling of data, inappropriate processing, or implementation of incorrect practices by the organization/sponsor have resulted in biased or erroneous data. Examples would include, but are not limited to: a contract's failure to adhere to HEDIS, HOS, or CAHPS reporting requirements; a contract's failure to adhere to Plan Finder or Prescription Drug Event data requirements; a contract's errors in processing coverage determinations/exceptions or organization determinations; compliance actions due to errors in operational areas that would directly impact the data reported or processed for specific measures; or a contract's failure to pass Part C and Part D reporting requirements data validation related to organization/sponsor-reported data for specific measures.

If an MA or Part D plan sponsor believes that there is an error in any of the data that make up the star ratings, there are multiple opportunities for the plan sponsor to inform CMS and have the data corrected, if necessary. Prior to the star ratings being posted on www.medicare.gov, all plan sponsors have two plan preview periods to review their data and to let CMS know if there are any data issues. MA plan sponsors also have an additional opportunity to appeal their calculated

star rating through an administrative review process as part of the MA Quality Bonus Payment program.

4. DQA Peer Review of the Ratings Methodology

Finally, you assert that CMS is required to subject the quality star ratings system methodology to peer review as influential scientific information and highly influential scientific assessments under current OMB guidance. We disagree. CMS is also familiar with OMB's "*Final Information Quality Bulletin for Peer Review*," which can be found here: <https://www.whitehouse.gov/sites/default/files/omb/assets/omb/memoranda/fy2005/m05-03.pdf>.

CMS's star rating system is exempt from the provisions of this Bulletin per Section IX. (7). Agencies need not have peer review conducted on information that is disseminated *in connection with* routine rules that materially alter entitlements, grants, user fees, loan programs, or the rights and obligations of recipients thereof. Information pertaining to the star rating methodology is disseminated in connection with rules that materially alter entitlements and the rights and obligations of Medicare Part C and D providers. Indeed, as noted above, CMS published a final rule tying its star rating system to bonus payments and rebates in 2011 and published a final rule tying its star rating system <http://go.cms.gov/partcanddstarratings> to authority to exclude plan sponsors who perform poorly. 76 F.R. 21,432; and 77 F.R. 22,072.

Thank you again for providing CMS with CRE's observations and questions concerning the administration of the Medicare Part C and Part D star rating program. CMS appreciates your continued interest in the program.

Sincerely,

A handwritten signature in black ink, appearing to read "Sean Cavanaugh", with a long horizontal flourish extending to the right.

Sean Cavanaugh