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Sent via email and first class mail

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Dear Mr. Slavitt and Dr. Conway:

The Part C and D Medicare five-star ratings system is a laudable concept in that it seeks to inform consumer choice in the market rather than attempting to regulate the market through command-and-control regulations.

Nevertheless a number of entities have contacted CRE to express concerns regarding the manner in which the program is designed and implemented, including its burdens, its lack of compliance with the provisions of applicable law regarding notice-and-comment rulemaking and gaps in the transparency of the rating methodology.

The basic rating methodology has been in use since 2008, and it appears that an impartial and independent overall assessment of its utility and quality is advisable to ensure consumer and provider confidence in the system. Such an assessment appears particularly important in view of the recent extension of the system as a basis for making bonus payments and rebates and determining eligibility.

It appears that the concerns expressed below also apply other Medicare ratings programs including those for quality comparisons of hospitals and nursing homes.

## I. NOTICE-AND-COMMENT RULEMAKING REQUIREMENTS

To date, CMS has not been proceeding through Federal Register notice-and-comment rulemaking in promulgating the star ratings programs or use of the program in determining bonuses, rebates, and eligibility. Instead, it has issued annual proposals, calls for comments, and final rules through announcements posted on its websites. One important consequence of this lack of Federal Register rulemaking is that individual comments are not posted on www.regulations.gov so that interested persons cannot assess for themselves the validity of the comments and the agency response. Instead, the agency only posts summaries of comments and respond to its own summaries.

It is our assessment that the CMS procedure of not using Federal Register rulemaking is a violation of the Medicare and APA rulemaking provisions. The Medicare rulemaking provisions, 42 U.S.C. § 1395hh, require Federal Register notice-and-comment rulemaking for every "rule, requirement, or other statement of policy … that establishes or changes a substantive legal standard governing the … payment for services, or the eligibility of … entities, or organizations to furnish or receive services …." Because the star rating program is now used to determine bonuses, rebates, and eligibility, this provision has applied. CMS' use of the star rating system in this manner also amounts to promulgation of "substantive" rules and brings it within the Administrative Procedure Act's Federal Register notice-and-comment requirements, 5 U.S.C § 553.

In the past, CMS has relied on 42 U.S.C. § 1395w-23(b) to avoid Federal Register rulemaking.[1] However, that provision applies only to announcement of capitation rates and adjustments to such rates, and the provision does not specify the manner of such announcements. The star rating system is now a fusion of both a consumer information program and a payment system – that is, star ratings are used both to inform consumer choice and to determine bonuses and rebates. The star rating system is also used to eliminate low-performing providers from eligibility. As such a hybrid program, the star rating system must undergo Federal Register rulemaking procedures. The non-specific "announcement" language of § 1395w-23(b) does not negate the very specific language of § 1395hh.

CRE, in its capacity as serving as a regulatory watchdog, has worked with every federal agency and many of their sub-organizations over a number of decades.

CMS, with the possible exception of the star rating program, has an established history of violating the Administrative Procedure Act. These violations range from the failure to conduct a notice and comment rulemaking on a program that lead to the termination of thousands of small businesses to an instance where a court has opined that CMS lacked statutory authority to regulate only to have CMS issue the regulation which was voided by the court as a guidance document.

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[1] "The Secretary shall annually determine, and shall announce (in a manner intended to prove notice to interested parties) … (A) the Medicaree +Choice capitation rate for each medicare+Choice payment area for the year, and (B) the risk and other factors to be used in adjusting such rates … for payments for months in that year."

CRE is not in the business of issuing star ratings, but if it were, CMS, with the possible exception of its star rating program, would be given one star.

## II. COMPLIANCE WITH PAPERWORK REDUCTION ACT ("PRA") REGULATIONS FOR INFORMATION COLLECTION REQUESTS

The PRA and its regulations require most information collections to be published for notice and comment and approved by OMB's Office of Information and Regulatory Affairs. Approved collections ("ICRs") are listed in OIRA's PRA inventory by agency. See http://www.reginfo.gov/public/do/PRAMain.

The CMS star ratings methodologies begin with the gathering of data on numerous "measures," such as availability and use of certain medical procedures or screenings, health outcomes, follow-up, and patient satisfaction with service. These data are acquired by CMS from various sources, both within and outside HHS.

A review of the OIRA inventory appears to show few information collections associated with the star ratings methodology. It appears that some of the information used in the star ratings methodology comes from third parties (such as the HEDIS data); however, if the party's data collections were supported with financial assistance from the agency, they would be subject to the PRA regulations. CMS should publish information on whether all of its star ratings data collections, and which ones, were approved by OIRA, along with the OMB control numbers and reference numbers.

Even more surprising than the scarcity of information collection approvals for the star ratings program indicated in the OIRA PRA inventory is the burden cost shown for those information collections. The burden costs shown are mainly zero, which does not appear credible. We request an explanation of this.

We also note that burden costs could be disguised by submission of information collection requests in a piecemeal fashion and by using differing titles and explanations for the ICRs. We recommend and request that all ICRs supporting a star ratings program be submitted and published for comment in a consolidated manner, clearly identifying them as collection requests for the star ratings program, and that the cumulative estimated burden cost for all such information collections be reported.

We note that CRE and others have observed and experienced deficiencies in CMS' compliance with the PRA on a number of occasions in the past. See, *e.g.*, http://www.thecre.com/oira/?p=1141 and http://www.thecre.com/oira/?p=888.

## III. REPRODUCIBILITY OF INDIVIDUAL STAR RATINGS

The OMB/OIRA Data Quality Act ("DQA") regulations require that when an agency disseminates influential scientific, financial, or statistical information, it must provide sufficiently high transparency regarding the data and methods used to produce the information

that a qualified third party could substantially reproduce and verify that information. 67 Fed. Reg. 8452 (Feb. 22, 2002).[2] The U.S. Court of Appeals for the D.C. Circuit has held that those rules are "binding" and have "the force of law."[3]

Although the methodology for calculation of star ratings at the measure-specific, domain, and overall levels is set out in considerable detail in the CMS "Technical Notes," it appears that overall star ratings depend on the star ratings for individual measures, which in turn depend on the star-specific cut points for the individual measures. Those cut points, in turn, appear to depend on the validity of the data collection inputs for individual plans or entities. The validity of those data inputs will depend on the validity of the data collection process under the Paperwork Reduction Act, as discussed above. This raises the question of whether the data collection process, and the data input into the cut-point determination methodology, are sufficiently accurate and reproducible.

The original OMB/OIRA government-wide IQA guidelines addressed this reproducibility requirement in part by directing agencies to employ a pre-dissemination review process to ensure that this requirement would be met. The guidelines state: "As a matter of good and effective agency information resources management, agencies shall develop a process for reviewing the quality (including the objectivity, utility, and integrity) of information before it is disseminated." 67 Fed. Reg. at 8459. The preamble explanation of this directive states: "Agencies are directed 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." 67 Fed. Reg. at 8453.

Various agencies have complied with this pre-dissemination review directive by issuing specific guidance on the matter, including forms on which to document the review – *e.g.*, DOT (http://www.transportation.gov/sites/dot.gov/files/docs/DOT%20Information%20Dissemination%20Quality%20Guidelines.pdf, at 19-20), EPA (http://www.epa.gov/region2/science/qmp/pdfs/pdr-guidelines.pdf and http://www.epa.gov/region03/esc/qa/pdf/IQG_review_checklist.pdf), and NOAA (http://www.nefsc.noaa.gov/publications/crd/crd0301/pdfs/dqacertguide.pdf). It does not appear that CMS has similarly complied with this OMB/OIRA directive.

The star ratings program has already come under judicial challenge for violation of DQA quality requirements, and CMS has acknowledged deficiencies. See http://www.thecre.com/oira/?p=3699.

In view of the importance of the star ratings system, its complexity, and particularly since it is now used not only to inform consumer choice but also to determine eligibility, bonus payments, and rebates, we believe that it is time for an independent expert review and test of the

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[2] And see the HHS conforming IQA rules at http://aspe.hhs.gov/infoquality/Guidelines/part1.shtml#c, sec. C, 4, f., and the CMS IQA conforming rules at, sec. D, 4, f; http://aspe.hhs.gov/infoquality/Guidelines/CMS-9-20.shtml, sec. V, d.

[3] *Prime Time Int'l, Inc. v. Vilsack*, 599 F.3d 678, 685 (D.C. Cir. 2010) (citing the Supreme Court's decision in *United States v. Mead Corp*.).

validity of the methodology and the reproducibility of ratings. We believe this should be done by utilizing the peer review process under the DQA peer review rules. This is discussed below.

## IV. DQA PEER REVIEW OF THE RATINGS METHODOLOGY

In 2005, OMB/OIRA promulgated DQA government-wide peer review requirements[4] to supplement the more general requirements it had promulgated in 2002.[5] The rules require peer review of "influential scientific information" and "highly influential scientific assessments" and agency posting in advance of its peer review plans for such information and assessments, with opportunity for public participation. The requirements for "highly influential scientific assessments" are considerably stricter than those for "influential scientific information."

The peer review requirements apply to the star ratings program, at least that program applicable to Parts C and D, because the program involves analysis of medical science data, such as the need for certain medical tests or treatments and outcomes. The star ratings program should be considered a "highly influential scientific assessment" (a "HISA") because it requires synthesis of multiple factual inputs derived from the medical sciences, and is novel and has very large financial impacts through its impacts on bonuses and rebates and influence on consumer choice of individual providers.

A HISA peer review requires review by an independent, external peer review group, and opportunities for public participation in the review, and a final peer review report.

The CMS information quality guidelines state, with regard to influential scientific information, that "CMS routinely seeks input from qualified peer reviewers, inside and outside the Federal government prior to dissemination of this type of information." Sec. VII.[6] Yet there is no indication that CMS has conducted or sponsored any peer review or posted peer review plans for a star rating program.

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[4] The OMB/OIRA peer review "Bulletin" has a judicial review disclaimer at its end; however, the D.C. Circuit has previously held, in *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1022-23 (D.C. Cir. 2000) that a similar disclaimer was mere agency "boilerplate" and could not immunize the agency from judicial review when the "guidelines" at issue contained clearly mandatory provisions and were legislative rules. The peer review "Bulletin" is likewise a legislative rule because it contains many clearly mandatory provisions and was promulgated pursuant to the rulemaking provisions of the Paperwork Reduction Act, 44 U.S.C. 3516. Moreover, its statement that the Bulletin is intended for the internal management of the government is transparently (and ironically) inaccurate – it is intended to ensure and maximize the quality of government information disseminated to, and used by, the public. Finally, the peer review guidance is a supplement to the 2002 government-wide IQA guidelines that have been ruled to be legislative rules by the D.C. Circuit in *Prime Time*, *supra*.

[5] 70 Fed. Reg. 2664 (Jan. 14, 2005).

[6] http://webcache.googleusercontent.com/search?q=cache:6tMNRQiyEn0J:aspe.hhs.gov/infoquality/Guidelines/CMS-9-20.shtml+&cd=11&hl=en&ct=clnk&gl=us.

Even in the absence of these peer review requirements, we believe that the importance of the ratings justifies, as a matter of good public policy, independent, expert, external peer review of the methodology with regard to its validity, utility to the public and the medical community, and reproducibility.

**SUMMARY**

To summarize the discussion above, CRE recommends that in order to ensure the quality and utility of the star ratings system, and to avoid litigation and controversy over its validity, CMS should undertake the following actions:

1. CMS should follow Federal Register notice-and-comment rulemaking proceedings for the star ratings programs.

2. CMS should notice in the Federal Register, and submit information collection requests (ICRs) to OMB/OIRA in a consolidated form, particularly with regard to burden cost estimates, so that the public can comment on the program's data gathering as a whole. Titles to ICRs relating to the star rating programs should clearly indicate their connection to that program.

3. CMS should conduct a formal, documented pre-dissemination review of the reproducibility of the star ratings before it proposes star ratings rules for notice and comment.

4. In view of the importance and visibility of the star ratings programs, CMS should issue a peer review plan for the analytical components of the program, designating the program as "highly influential" (HISA), and sponsoring an independent, expert, external peer review in accordance with the OMB/OIRA peer review requirements.

CRE believes the star ratings program is sufficiently important that CMS should take every practicable measure to ensure its quality and validity in the eyes of the public and service providers.

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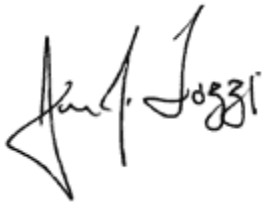
CRE requests that it be notified by CMS of its responses to the above points and any actions it will take to pursuant to the above CRE recommendations to ensure and maximize the quality of the star ratings programs. The aforementioned notifications will be taken into consideration prior to CRE filing a DQA petition against a specific Star Rating or requesting the Office of Management and Budget to exercise its enforcement authorities under the Paperwork Reduction Act.

Respectfully,



Jim Tozzi