

Center for Regulatory Effectiveness

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August 14, 2014

Yale-New Haven Health Services Corporation/
Center for Outcomes Research and Evaluation
Lantana Consulting Group
cmsstarratings@yale.edu

Re: Overall Hospital Quality Star Ratings on Hospital Compare

Dear CMS Contractors,

The Center for Regulatory Effectiveness (CRE) is pleased to provide you with our comments in response to CMS's Call for Public Comments on the above-captioned project. CRE is a regulatory watchdog established by former senior career officials from the White House Office of Management and Budget. For more information about CRE, please see http://www.thecre.com/oira/?page_id=8.

CMS's Call states that the work you are performing on Hospital Compare is being performed under contract number HHSM-500-2013-13018I - T0001 Modification 000002. Thus, the work you are performing is part of CMS's \$800 million contract award for "Measure and Instrument Development and Support (MIDS) which involves assisting CMS in "developing, testing, refining, revising, maintaining, implementing, and publically reporting quality healthcare-specific measures."¹

Because you are performing the MIDS work under CMS contract, the data collected, evaluated and disseminated in the course of your work is subject to the Paperwork Reduction Act (PRA) and the Data Quality Act (DQA). OMB regulations explain that

A Federal agency is considered to 'conduct or sponsor' a collection of information if the agency collects the information, causes another agency to collect the information, contracts or enters into a cooperative agreement with a person to collect the information, or requires a person to provide information to another person, or in similar ways causes another agency, contractor, partner in a cooperative agreement, or person to obtain, solicit, or require the disclosure to third parties or the public of information by or for an agency.²

Attached please find a copy of a letter that we sent to CMS which explains the agency's legal obligation to develop the star rating in compliance with the PRA and DQA as well as with the requirements of the Medicare Act and the Administrative Procedure Act.

¹ fbo.gov/?s=opportunity&mode=form&tab=core&id=1538e24c6e17ce62bbb0fe4d1e67937d&cvview=0.

² 5 CFR §1320.3.

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Although universities and other research organizations may think that the DQA applies only to federal agencies, not themselves, this is a mistaken view. On this point, I note the letter to the American Council on Education from their outside counsel which concludes,

Plainly, if a university's goal is to have information published or used by federal agencies, it must ensure that such information passes muster under the DQA standards for federally disseminated information, as interpreted by OMB.³

As CMS contractors, both the Yale-New Haven Health Services Corporation and the Lantana Consulting Group are required to adhere to the requirements of the Data Quality Act and its implementing documents including OMB's government-wide Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies⁴ and OMB's Final Information Quality Bulletin for Peer Review⁵ as well as HHS's Department-wide information quality guidelines⁶ and CMS's agency-specific information quality guidelines.⁷

Only if the process used to develop the Star Ratings complies with the DQA will CMS be able to disseminate the ratings. On this point, I note the letter that HHS sent to the Director-General of the World Health Organization informing him the US government would not be able to use the Joint WHO/FAO Expert Consultation on Diet, Nutrition and the Prevention of Chronic Diseases because its development did not comply with the Data Quality Act. The letter explains that

under the U.S. Data Quality Act, USG agencies operate under guidelines for ensuring and maximizing the quality, objectivity, utility, and integrity of information disseminated to the public. These guidelines require agencies to adopt a basic standard of quality as a performance goal and take appropriate steps to develop a process for reviewing the quality of information before disseminating it, and to incorporate information quality criteria into agency information dissemination practices. . . .⁸

The HHS letter, sent in response to a Request for Correction under the DQA filed by CRE⁹ also informed the WHO that,

³ McKenna Long & Aldridge LLP, Letter to American Council on Education, September 10, 2003, http://www.nacua.org/documents/Data_Quality_Letter.pdf.

⁴ <https://www.whitehouse.gov/sites/default/files/omb/assets/omb/fedreg/reproducible2.pdf>.

⁵ <https://www.whitehouse.gov/sites/default/files/omb/assets/omb/memoranda/fy2005/m05-03.pdf>.

⁶ <http://aspe.hhs.gov/infoquality/Guidelines/index.shtml>.

⁷ <http://aspe.hhs.gov/infoquality/Guidelines/CMS-9-20.shtml>.

⁸ Department of Health and Human Services, Office of the Secretary to World Health Organization, Letter to J.W. Lee, MD, ("HHS Letter") January 5, 2004, p. 2, available at http://thecre.com/pdf/20041101_hhs.pdf.

⁹ Center for Regulatory Effectiveness, "Request for Correction of Information Contained in a World Health Organization Report," September 8, 2003, available at, http://www.thecre.com/pdf/20030908_correction.pdf.

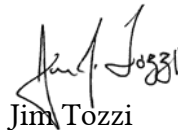
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The consultation process of the development of the WHO/FAO Report and the resulting Report itself would not meet these current U.S. data quality standards, as the process lacked a high degree of transparency, and the data and analytic results contained within the Report were not subject to formal, independent, external peer review, among other criteria.¹⁰

I recommend that the Center for Outcomes Research and Evaluation and the Lantana Consulting Group take the following steps to ensure that CMS is able to make use of your work products,

1. Ensure that the collection of data used in developing the ratings was collected in accordance with the PRA and has an OMB Control Number.
2. Ensure that all of the work you perform is reproducible by qualified third parties and publicly disclose for comment the data sets and documentation necessary for third-parties to conduct such verification.
3. Work with CMS to develop a peer review plan for the analytical components of the program, designating the program as “highly influential” (HISA), and in sponsoring an independent, expert, external peer review in accordance with the OMB/OIRA peer review requirements.

Respectfully,



Jim Tozzi
Member, Board of Advisors

Attachment, CRE Letter to CMS, July 8, 2015

cc:

Patrick H. Conway, MD, MSc, CMS, Acting Principal Deputy Administrator
Kimberly Belli Tatum, CMS Contracting Officer

¹⁰ HHS Letter, p. 2.