



December 17, 2008

Herb Kuhn  
Deputy Administrator  
Centers for Medicare & Medicaid Services  
Hubert H. Humphrey Building  
200 Independence Avenue, S.W., Room 445-G  
Washington, DC 20201

***RE: Medicare Program: Hospital Outpatient Prospective Payment System and CY 2009 Payment Rates; Changes to the Ambulatory Surgical Center Payment System and CY 2009 Payment Rates; etc. 2008-26212; Final Rule (Vol. 73, No. 223), November 18, 2008***

Dear Mr. Kuhn:

As you know, hospitals are committed to improving quality and to being transparent about their quality to the communities they serve. However, in the final outpatient rule released in November, the Centers for Medicare & Medicaid Services (CMS) included four new quality measures pertaining to outpatient imaging, claiming that they would help reduce the inappropriate use of testing. We have serious concerns about these measures (because, among other reasons, two are not based on medical evidence) and the process by which they were proposed, reviewed and adopted by CMS.

We urge CMS to suspend the use of these four measures in much the same manner that it suspended use of the measure pertaining to flu vaccination rates several years ago, and the surgical care measure of antibiotic use when new studies raised questions about which antibiotic(s) would be most helpful for particular patients.

In short, three concerns prompt us to request that CMS suspend implementation at this time:

- **CMS' Selection of Flawed Measures.** Two of the measures at issue – contrast media for abdominal scans and mammography follow-up – are seriously flawed and are not based on medical evidence.
- **CMS' Failure to Adopt Measures that Reflect Consensus Among the Affected Parties.** The process for proposing and adopting these measures failed to comply with the requirements of the law authorizing CMS to link reporting of outpatient quality data to payment.
- **CMS' Failure to Allow for Adequate Public Review and Comment.** The process CMS used for public review of the measures did not meet the requirements of the *Administrative Procedure Act* (APA). Nor did it meet the requirements of the Medicare statute.

Our detailed concerns are outlined below.

### **CMS' SELECTION OF FLAWED MEASURES TO ADOPT**

**In adopting the measures use of contrast abdomen CT and Mammography follow up rates, CMS arbitrarily and capriciously exercised its Congressionally prescribed authority to link outpatient reporting to payment.** While two of the proposed measures passed NQF review and were deemed scientifically acceptable, two did not. They were the aforementioned Use of Contrast: Abdomen CT and Mammography Follow-up Rates. These measures were rejected for similar reasons.

- *Use of Contrast: Abdomen CT.* The measure assesses the percentage of patients given contrast media as part of a CT scan of the abdomen. There is a lack of evidence in the published literature to determine the appropriate use of contrast for these patients. Without evidence that tells when it is appropriate to use contrast media, the choice is left to an individual clinician's best judgment. Since patient needs and clinical judgments vary, it is impossible to know what the appropriate number of studies should be. Neither the public nor health professionals will be able to use the data to judge the quality of care provided.
- *Mammography Follow-up Rates.* This measure assesses the number of women who are called back for an additional mammogram when uncertainty remains after the first one. By reporting these recall rates, CMS implies that a higher-than-average follow-up rate is undesirable. CMS seems to assume that higher-than-average recall rates will occur as a result of the inability of the physician reading the initial mammogram to discern potentially cancerous tissue from normal tissue or benign cysts. However, there are many reasons why higher-than-average recall rates can occur. As noted by the NQF Steering Committee, some clinicians may be more cautious with the patient populations they serve because of higher rates of cancer among certain populations of women. Others may serve a patient population whose genetic makeup leads to denser breast tissue. For example, providers with a larger cohort of younger patients will have higher-than-average recall rates due to the known screening issues in this population, e.g., denser breasts and a lack of prior studies for comparison. The measure does not take these differences into account.

Since there is a lack of clinical evidence, or even expert consensus, there is no agreement on what the appropriate performance rate should be. A hospital with a follow-up rate of 35 percent may be providing service equally high in quality to a hospital with a follow up rate of 5 percent if one adjusts for underlying differences in the patient populations. The NQF Steering Committee voiced a very real concern that this measure would send a signal to physicians not to recall patients as often. Their reluctance to recall patients may increase the number of breast cancers that are not diagnosed until they are at a more advanced stage of development.

### **CMS' FAILURE TO ADOPT MEASURES THAT REFLECT CONSENSUS AMONG THE AFFECTED PARTIES**

**CMS ignored specific legislated requirements to adopt measures reflecting consensus among affected stakeholders and endorsement by a consensus building organization.** In the *Tax Relief and Health Care Act of 2006*, Congress authorized the Department of Health and Human Services to link outpatient payments to the reporting of quality data using measures

selected by the Secretary, but the Secretary was not given unfettered authority to choose measures. Instead, the legislation stipulated:

- (i) The Secretary shall develop measures that the Secretary determines to be appropriate for the measurement of the quality of care (including medication errors) furnished by hospitals in outpatient settings and that reflect consensus among affected parties and, to the extent feasible and practicable, shall include measures set forth by one or more national consensus building entities.

We believe the phrase “that reflect consensus among affected parties” was meant to refer to approval by the Hospital Quality Alliance (HQA), an organization that includes representatives from all affected stakeholder groups and that was created to guide the public reporting of credible, useful information on hospital quality. The HQA did not adopt any of these measures. Moreover, the measures reflect no consensus among affected parties whatsoever – in direct contradiction of the statutory requirement.

Further, the phrase “shall include measures set forth by one or more national consensus building entities” was meant to refer to the work of the NQF, but only two of the measures were endorsed by the NQF. Admittedly, the legislation does allow the Secretary some flexibility in applying the requirement that the measures have been set forth by one or more national consensus building entities if it is not feasible or practical, but there is no indication in the final rule that it was infeasible or impractical to obtain the consensus of NQF members on these measures as national standards. Rather, CMS seems to have arbitrarily chosen these measures without paying attention to the legislative requirements.

#### **CMS’ FAILURE TO ALLOW FOR ADEQUATE PUBLIC REVIEW AND COMMENT**

**CMS did not fulfill its administrative responsibility to provide adequate notice and opportunity for meaningful public comment on these measures.** When CMS proposed the four measures of medical imaging efficiency, the measures were still in the early stages of the National Quality Forum (NQF) review process, and detailed information on the measures was not yet publicly available. Furthermore, CMS did not provide any detailed information about the measures in the proposed rule. The only information presented in the proposed rule on which the public could comment were the titles of the measures, which alone do not provide sufficient information to enable intelligent analysis and comment. These measures were developed by CMS without consultation and, when the rule was published, only CMS knew the measure specifications. These are the details that identify which patients are included in the measures, which are excluded, and what information is used to calculate a performance rate. Interested parties needed to know what patient population was eligible and what scientific evidence supported CMS’ belief that the measurement addressed a critical aspect of quality.

Under the APA, CMS is required to provide the public adequate notice of what the agency proposes to do in order to allow the public to comment on those proposals. In the context of a proposal to establish outpatient imaging quality measures, the agency must provide all relevant information for any measures it intends to use, including the structure of the measure, the applicable patient population and any other facts used by the agency to inform its decision to

propose the measure; this information is essential to assure fully informed and meaningful comments.

Four weeks into the public comment period on this rule, the NQF published the information needed to understand and appropriately review these measures; however, **the NQF process is not a substitute for CMS' obligation to publish information in its proposed rules.** While the NQF's publication put information in the public domain, not every interested party who typically relies on the *Federal Register* as the authoritative source for the information needed to review and comment on proposed federal rules would have known to look at the NQF's Web site for additional information. Nothing in the *Federal Register* notice or on CMS' Web site pointed to this source of information. Further, the NQF process is not a substitute for CMS' obligation to provide an opportunity for a meaningful notice and comment. The NQF provided only 28 days for its 400 organization members and 21 days for most of the public who are not members to comment; thus is far shorter period than mandated by the APA and section 1871(b) of the Social Security Act as being available to the public to comment on Medicare rules.

In conclusion, we believe that these four imaging measures should not be used for public reporting on hospital outpatient care at this time. We look forward to working with you to address these concerns, and to discussing how the HQA can continue to provide useful input to CMS to avoid problems such as this in the future because our members are committed to ensuring better care for their patients. Should you have any questions about our comments, please feel free to contact Nancy Foster, AHA vice president for quality and patient safety, at (202) 626-2337 or [nfoster@aha.org](mailto:nfoster@aha.org).

Sincerely,

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