American Hospital Association

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January 16, 2009

Sent Via FAX: 202-395-6974

OMB Office of Information and Regulatory Affairs
Attention: Bridget Dooling, CMS Desk Officer
New Executive Office Building
Room 10235
Washington, DC 20503

RE: Disclosure of Financial Relationships Report ("DFRR"): Form Number: CMS-10236 (OMB#: 0938—New), Vol. 73, No. 245 Fed. Reg., December 19, 2008

Dear Bridget Dooling:

On behalf of our more than 5,000 member hospitals, health systems and other health care organizations, and our 38,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposal to establish a mandatory Disclosure of Financial Relationships Report (DFRR) for hospital relationships with physicians.

We urge the Office of Management and Budget (OMB) to deny CMS authorization to proceed with this information collection as proposed. CMS repeatedly has failed to meet its burden under the *Paperwork Reduction Act* (PRA) to demonstrate that the proposed collection "is the least burdensome necessary." CMS' explanation of the purpose and need continues to be insufficient to justify the time, effort and dedication of resources that would be required of community hospitals. In addition, the current regulations do not support imposition of the broad-based, all-encompassing demands of the DFRR.

CMS' PROPOSAL DOES NOT SATISFY THE PRA REQUIREMENTS

CMS is seeking clearance for the second time for an "information collection request" that will require hundreds of community hospitals to report information, supply documents and make certain legal certifications regarding their relationships with physicians. With the exception of the number of hospitals affected – 400 instead of 500 – and the estimate of burden – an increase from 31 to 100 hours (still, in our estimation, understated) – the proposal is substantially identical to the one submitted to OMB in September 2007 and withdrawn in April 2008 in the face of serious objections by the AHA and others.

CMS, again, has not demonstrated a problem or concern that would merit this intrusive, costly and very burdensome demand on community hospitals. At most, it offers a general statement that it will use the information to determine the compliance of each hospital with the physician self-referral law, and to assist in developing a disclosure process for all hospitals. Yet CMS' submission makes clear that its purpose cannot be met through the DFRR. **We again object to the proposed information collection request on behalf of the hundreds of community hospitals that would be subject to this unreasonable mandate.**

The DFRR cannot achieve the stated purpose.
By emphasizing the limitations of the DFRR review in its submission, CMS effectively acknowledges that the review process cannot be a reliable measure of compliance. CMS explicitly advises hospitals that they cannot rely on the results of the review as a determination that their contracts comply with the self-referral law. Furthermore, CMS warns hospitals that any finding of no violations is effectively irrelevant for purposes of future review of the same information, whether by CMS or another government entity. **By its own admission, CMS has established that this burdensome tool will not produce reliable information for determining hospital compliance or for any future policy development.**

Equally important, CMS' use of the DFRR would be fundamentally unfair. While each hospital is required to expend maximum resources in responding, there is no possibility that they can walk away from the review with clearance from the agency that their contracts are compliant. Hundreds of community hospitals effectively would be required to disclose all information regarding compensation arrangements with physicians without any benefit.

CMS regulations create a complex web of ever-changing guidance. The challenge of determining what is required is daunting, and the consequences of a violation can be draconian. Yet CMS imposes only the extraordinary burden of the DFRR on hospitals. **If the DFRR is for the purpose of determining compliance, hospitals should be able to rely on CMS' findings that there are no violations and have the benefit of a binding determination that cannot be second-guessed by CMS or others.**

The burden imposed on community hospitals is significantly understated.
The burden estimate and CMS' description of what a response will require are still at odds with what will actually be required of hospitals. Record keeping is predominantly manual, not electronic; documents are decentralized, not centralized; and there is no required "self-referral law" filing system.

Some anecdotal estimates of the burden estimates for hospitals:

- The number of contracts affected could include: 400; 500-600; or 800-1,000.
- At least 200 hours will be needed just to identify and assemble all of the relevant contracts.
- Three to four weeks would be required to fully respond, assuming no vacations or holidays for involved staff.
- Two to three months would be required to respond with one full-time equivalent employee's time.

- Smaller hospitals would have fewer contracts, with fewer staff to complete the work, and a greater need for outside attorneys or auditor support.
- Hospitals with a fiscal year that does not coincide with the calendar year would be required to provide documents for two fiscal years, doubling their workload.

While CMS has increased (insufficiently) its estimate of burden in this proposal, it has made no adjustment in the magnitude of what it requires of hospitals. Information is still required for 12 different categories of compensation arrangements. For those categories most commonly engaged in (e.g., personal services or recruitment arrangements), CMS asks for copies of every contract in effect during a calendar year. Depending on the size of the hospital, documents will be required for hundreds or thousands of contracts. (Requiring only one copy if an agreement is used uniformly would have limited effect and not materially reduce the burden.)

In addition to locating, assembling and copying the documents, the information would need to be reviewed to enable the CEO to make the required certifications. Legal counsel would routinely be involved in these reviews. While CMS has recognized that completion of the process is more than ministerial, its latest estimate of burden still falls significantly short of the mark. Its increase in the cost estimate is also significantly understated. For example, CMS assigns a rate of $57 per hour in estimating the costs for attorney's fees. This is extremely unrealistic for an attorney with the degree of specialty that is required to master the self-referral regulations.

CURRENT REPORTING RULE DOES NOT SUPPORT THE DFRR

Under the current reporting rule, routine mandatory reporting is not required. While mandatory reporting was included in the proposed rule, CMS made a conscious decision to abandon that approach because of the undue burden. While CMS reserved the right to make individual requests, the DFRR is not an individualized request but a general demand. To proceed under the current rule, CMS would need to establish a specific need for information from an individual hospital. Instead, the DFRR makes a broad-based demand unrelated to the specific circumstances of each hospital. **A change in regulation is required to pursue that type of request.**

CMS also continues to reference its response to the congressional directive in the *Deficit Reduction Act of 2005* (DRA) that it "develop a strategic and implementing plan" to address issues of concern to Congress regarding "physician investment in specialty hospitals." The AHA supports and encourages CMS to complete the work it started and any additional work that may be needed to address the physician investment issue of concern to Congress. However, that is unrelated to this information collection request and CMS should not blur the two: The DRA did not mandate and does not justify the information collection request regarding community hospitals' compensation arrangements.

The AHA urges OMB to deny CMS authorization to proceed with the DFRR as proposed.

For additional background and ease of reference, the AHA's previous comment letters to CMS and OMB on the DFRR are attached. If you have any questions, please feel free to contact me or Maureen Mudron, deputy general counsel, at (202)626-2301 or mmudron@aha.org.

Sincerely,

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Rick Pollack
Executive Vice President

Attachments

AHA Comment Letter to CMS, July 16, 2007
AHA Comment Letter to OMB, October 10, 2007
AHA Comment Letter to CMS, DFRR section, June 9, 2008