



**American Hospital
Association**

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October 10, 2007

Sent Via FAX: 202-395-6974

OMB Human Resources and
Housing Branch
Attention: Carolyn Lovett
OMB 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. 72, No. 178 Fed. Reg., September 14, 2007***

Dear Ms. Lovett:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our 37,000 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 (DFRR) reporting system for hospital relationships with physicians.

We urge the Office of Management and Budget to deny CMS authorization to proceed with this information collection as proposed. CMS offers no justification for this broad-based, intrusive and extremely burdensome demand on community hospitals. In addition, the DFRR is outside the scope of the current regulation on reporting requirements. If CMS wishes to broaden the scope of those reporting requirements, it must do so by amending the regulation.

DRA DOES NOT JUSTIFY THE PROPOSED DFRR

CMS’ stated rationale for the DFRR largely relies on the *Deficit Reduction Act of 2005* (DRA), which directed CMS to “develop a strategic and implementing plan” to address issues of concern to Congress regarding “physician investment in specialty hospitals.”

The DFRR, however, is a mandatory reporting instrument, initially directed at 500 hospitals, requiring disclosure of information and the submission of related documents on physician



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investments in hospitals and compensation arrangements between hospitals and physicians unrelated to whether those physicians have an investment interest. Of the original 500 hospitals, only about 150 are specialty hospitals in which physicians have an investment interest. The vast majority of the hospitals are community hospitals whose relationships with physicians are structured through contracts to perform particular functions. The DRA did *not* direct CMS to study compensation arrangements between community hospitals and physicians.

If CMS believes a mandatory survey instrument is needed to address physician investment issues, the AHA would support a revised proposal specific to the investment interests of physicians in “specialty hospitals,” the issue of concern to Congress in the DRA. The fact that CMS stated in the plan it submitted to Congress its intent to develop a disclosure process for all hospitals does not satisfy the requirements of the *Paperwork Reduction Act* (PRA), nor exempt CMS from complying with its existing rule on hospital reporting.

CMS’ SUBMISSION DOES NOT MEET THE PRA REQUIREMENTS

CMS 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 examine the compliance of each hospital with the physician self-referral law, and to assist in developing a disclosure process for all hospitals.

The DFRR is highly inappropriate as a pilot test for a disclosure process. The grossly underestimated burden (hours and costs) provided by CMS indicates a lack of adequate testing of the survey instrument with potential respondents. The inclusion of 500 hospitals in what is essentially a pilot test only magnifies the problem. Instead of beginning with the minimum number of hospitals needed to achieve its goals, and to do so in the most cost-effective manner, the DFRR begins with the maximum burden and no articulation of objectives against which the manner and method can be evaluated. There also has been no exploration of a less costly and burdensome approach. A field test of the instrument with a small number of hospitals of varying size and complexity should be required to both develop a more realistic assessment of survey burden and to assess whether the data collected would achieve goals that should be clearly set forth. This is especially important for the new segments related to compensation that were not part of the earlier survey used to develop CMS’ DRA-required report to Congress.

CMS has grossly understated the burden for responding to the compensation questions.

Responding to the DFRR will be a predominately manual, not electronic, effort. CMS requests information on nine different categories of compensation arrangements. For those categories most commonly engaged in (e.g., recruitment arrangement), it 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. And the number of contracts only begins to describe how many pieces of paper will need to be copied. CMS estimates that the average burden for hospitals will be six hours. In most instances, that will not cover the time devoted just to copying the documents that need to be submitted.

Copying the documents will be the last step and the least of what it will take for a hospital to comply. They must identify all the relevant contracts, where they are located, and assemble them in a central location. Only then can the kind of review and analysis be completed that will be necessary to answer the specific questions asked and enable a CEO to make the certification that is required. Anecdotally, the burden estimates for hospitals include:

- At least 200 hours just to identify and assemble all the relevant contracts.
- Three to four weeks to fully respond, assuming no vacations or holidays for involved staff.
- Two to three months to respond with one FTE's time.
- The number of contracts affected: 400; 500-600; 800-1,000.
- Smaller hospitals will have fewer contracts, with fewer staff to complete the work, and have a greater need for outside attorneys or auditor support.
- Hospitals with a fiscal year that is not a calendar year are required to include arrangements from two fiscal years, doubling their workload.

Some questions require information on arrangements for which a simple review of the agreement will not be sufficient. For example, knowing which specific exception an arrangement relied on when more than one may be applicable will not necessarily be noted in the contract. Only an attorney's review will allow a hospital to determine that information.

CMS seems to believe that electronic record systems have been created specific to the terms of the DFRR. This is simply not the case. The threat of a \$10,000-per-day penalty for late responses suggests that hospitals had a pre-existing duty to anticipate this type of demand. That also is not the case.

CURRENT REPORTING RULES DO NOT SUPPORT THE DFRR

In explaining its request for a three-year authorization, CMS effectively recognizes that its current reporting regulations do not support the DFRR. The agency includes the need for rulemaking if it decides to apply the DFRR to the hospital field. The need for rulemaking applies equally to the current use of the DFRR, as it would to application of the DFRR to the whole field.

Under the current rule, routine mandatory reporting is not required. In fact, it was included in the proposed rule on reporting. And, after hearing from the field that it would be unduly burdensome, CMS made a conscious decision not to use that approach. It also made clear that it was not developing any forms or record-keeping requirements specific to reporting. The DFRR, therefore, would circumvent CMS' own rulemaking decision.

There is nothing in the regulations to support imposition of the broad-based, all-encompassing demand of the DFRR. While CMS reserved the right to make requests on an individual basis, that is not what it is doing with the DFRR. This is a wholesale mandatory request. An individual request would have to be justified on grounds specific to the circumstances of the entity from which the information was requested. The DFRR is not a reasonable exercise of

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agency discretion and is outside the scope of the current rule, whether judged as a mandatory reporting system or an individual request.

The effect of the DFRR is more like a subpoena for records in an investigation (authority that CMS does not have), only with none of the safeguards that would apply to a subpoena. There are no standards against which to judge CMS' request and no process to challenge relevance and undue burden. CMS is trying to do by survey what it is not authorized to do by regulation, and without meeting any of the conditions that would undoubtedly be included in a reporting obligation established through a notice and comment rulemaking.

The AHA urges the Office of Management and Budget to deny CMS authorization to proceed with the DFRR as proposed.

If you have any questions, please feel free to contact me or Maureen Mudron, Washington counsel, at (202)626-2301 or mmudron@aha.org.

Sincerely,

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Rick Pollack

Executive Vice President

cc: Susan Dudley, Administrator
Office of Information and Regulatory Affairs, OMB

Kerry Weems, Acting Administrator
Centers for Medicare & Medicaid Services