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# EpsteinBeckerGreen Submits Comments on Required Disclosure of Hospital-Physician Financial Relationships

**by Beth Essig, David E. Matyas and Carrie Valiant**

**January 2009**

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EpsteinBeckerGreen, on behalf of a number of clients, submitted comments in January, 2009, to the Office of Management and Budget ("OMB") concerning the new Disclosure of Financial Relationships Report ("DFRR"), which requires 400 hospitals to disclose their financial relationships with their respective physicians.

The DFRR was implemented to collect information that will be used to analyze investment or compensation arrangements between each of the 400 hospitals selected by the Centers for Medicare & Medicaid Services ("CMS") and the Department of Health and Human Services ("HHS") to determine whether they are in compliance with the Stark law.

On December 19, 2008, CMS published a notice that the OMB would be accepting comments concerning the DFRR.

The DFRR requires, among other things, that hospitals disclose information regarding direct and indirect physician investment and ownership in the hospital, payments to the hospital by physician owners and each rental, personal service and recruitment arrangement between the hospital and physicians. The DFRR also contains a series of questions targeting information on other types of compensation arrangements between the hospital and physicians, including non-monetary compensation to physicians, medical staff incidental benefits that exceed published limits and charitable donations by physicians to the hospital.

The text of letter containing comments by EpsteinBeckerGreen is below.

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**VIA FACSIMILE (202.395.6974)**
**AND ELECTRONIC MAIL**

Office of Management and Budget
Office of Information and Regulatory Affairs
Attention: CMS Desk Officer
New Executive Office Building
Room 10235
Washington, D.C. 20503

**Re: Form Number CMS – 10236 (OMB# 0938 – New)**
**Disclosure of Financial Relationships Report**

To Whom It May Concern:

This letter is submitted in response to the notice that was published in the December 19, 2008 Federal Register by the Centers for Medicare and Medicaid Services (referred to herein as "CMS") that the Office of Management and Budget ("OMB") was accepting comments regarding the Disclosure of Financial Relationship Report ("DFRR").[1] We are submitting these comments on behalf of a number of our clients that are hospitals and health systems across the country.

At the outset, we would like to state that the title of the survey – "Disclosure of Financial Relationships Report" – is a misnomer in that it is less a "disclosure form" and more an audit tool. The numerous hospitals that receive the request will be required to complete up to eight (8) separate worksheets that require the hospitals to provide information about not only physician

[1] On January 14, an EBG Attorney (Tina Rao) spoke to Margaret Malanoski (with OMB's Office of Information and Regulatory Affairs) by telephone (and confirmed by electronic mail) that because the original deadline for the submission of comments to OMB was Tuesday, January 20, which was Inauguration Day and that because the Federal Government's offices were to be closed that day, we could submit comments on or prior to January 23.

owners but also about each and every compensation arrangement the hospital may have with any physician (e.g., service, leases, recruitment, non-monetary compensation, incidental medical staff privileges). In addition, the hospitals are required to submit copies of every contract (unless the hospital has entered into "uniform" contracts, which is discussed in more detail below), and to certify whether and why each of the relationships is Stark compliant.

After conferring with a number of our hospital clients, we have determined that CMS continues to significantly underestimate the time and costs that hospitals will incur in completing these forms. While CMS might argue that this disclosure requirement does not require any additional burden on the industry because hospitals must otherwise ensure that they do not violate the Stark Law, the compliance obligation undertaken pursuant to the DFRR is very different from ordinary compliance because it requires an officer of the hospital to attest to the accuracy and thoroughness of a report being submitted to the Government, and significant penalties could be assessed against the officer (as well as the institution) if the submission is not 100% complete and accurate. This additional administrative task, combined with the already crushing burden of complex and ever-changing and proliferating regulatory requirements, will place further stress on hospitals nationwide that are struggling to remain solvent in a faultering economy. These costs are ultimately passed on to consumers.

As such, CMS is imposing an obligation on hospitals very similar to that imposed on organizations that have entered into corporate integrity agreements with the Office of Inspector General ("OIG") and must submit annual reports, at significant expense, attesting to their compliance. In those circumstances, however, compliance attestations are agreed to in consideration for OIG foregoing any action to exclude the organization from participating in the federal health care programs. However, in this circumstance, these obligations are being imposed on organizations based solely on their status as hospitals participating in the Medicare program, where there is not even any allegation of non-compliance on the part of the hospital.

We also would like to bring to the attention of OMB that hospitals and health systems cannot simply exit these physician financial relationships to avoid the paperwork burden that will be imposed by the DFRR. Hospitals and health systems must have financial relationships with physicians in order to carry out their health care mission, including interpretation of diagnostic tests, the furnishing of on-call and emergency department physician services, as well as medical direction of various hospital operations, as required by CMS regulation. These relationships are appropriate, pervasive and critical to the delivery of health care. The clinical and programmatic expertise that physicians possess is absolutely essential to a hospital's developing and running a sophisticated clinical program. Various examples of the types of financial relationships that hospitals and health systems may enter into with physicians include agreements to:

- Retain physicians to provide services to the indigent in the hospital's clinics and emergency rooms;
- Contract for anesthesia, pathology and radiology services;

- Compensate physicians to provide administrative, supervisory and training services to medical residents and fellows;
- Retain specialist physicians to provide clinical oversight of specialized hospital programs (i.e., a hospital transplant program);
- Furnish Medical Director Services
- Provide on-call services for hospital trauma centers;
- Lease space and equipment to physicians so that the hospital's patients can be conveniently treated by qualified physicians; and
- Assist physicians in recruiting physicians in order to ensure that the community's health care needs are met.

Accordingly, we request that OMB disapprove the DFRR as not the "least burdensome necessary for the proper performance of the agency's functions to comply with legal requirements and achieve program objectives." See 5 C.F.R. §1320.5(d). Specifically, we believe that CMS should be required to conduct a study of the actual costs that would be incurred by hospitals and health systems to complete the forms. Moreover, we believe that no form should require the disclosure of potentially confidential and privileged information in the form of being required to identify which Stark exception has been satisfied and the process should not require expensive and time-consuming submission of contracts.

**CMS's Underestimate of the Time**

In the original DFRR that CMS submitted to OMB, CMS estimated that it would take a hospital 5 hours to complete the DFRR. Over the last two (2) years, CMS has increased this estimate from 5 to 6 to 31 hours to now stating that "the time required to complete this information collection is estimated to average 100 hours per response, including the time to review instructions, search existing data resources, gather the data needed, complete and review the information collection, and obtain legal review as necessary."

The regulations define the term burden as "the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency" and includes the following:

(i) Reviewing instructions;
(ii) Developing, acquiring, installing, and utilizing technology and systems for the purpose of collecting, validating, and verifying information;
(iii) Developing, acquiring, installing, and utilizing technology and systems for the purpose of processing and maintaining information;
(iv) Developing, acquiring, installing, and utilizing technology and systems for the purpose of disclosing and providing information;
(v) Adjusting the existing ways to comply with any previously applicable instructions and requirements;
(vi) Training personnel to be able to respond to a collection of information;
(vii) Searching data sources;

(viii) Completing and reviewing the collection of information; and
(ix) Transmitting, or otherwise disclosing the information.

*See* 5 C.F.R. 1320.3.

While 100 hours might be reasonable for a hospital to complete Worksheets 1 through 6 (which address general characteristics of the hospital, the nature of the ownership of the hospital and the identification of the physician owners), our hospital clients have informed us that the completion of CMS's Worksheets 7 and 8 (which require information on various compensation arrangements with physicians) would require (depending upon the size of the hospital) potentially thousands of hours to complete in light of the number of compensation arrangements that exist with physicians in a position to refer to the hospital and the complexity of the DFRR itself. Those worksheets require not just disclosure of the facts underlying the arrangement, but a determination by the hospital of which Stark Law exception the arrangement fits in.

In calculating the time of completing the DFRR, we ask that OMB consider the sheer volume of the relationships that a typical hospital has with physicians. For example, a hospital that owns a 7 story medical office building could easily have leases of space with 50-70 physicians/physician groups, and this is only one of the categories of compensation arrangements that must be analyzed and reported on Worksheet 7 of the DFRR.

For example, Worksheet 8 asks whether there were "any non-monetary compensation arrangements and/or medical staff incidental benefits granted to a physician that exceeded published limits?" Many hospitals and health systems have thousands of physician members of their medical staffs. The tracking of each and every physician's non-monetary compensation with sufficient precision to enable a hospital executive to certify that the aggregate non-monetary compensation to each physician in any given year received does not exceed the annual aggregate dollar cap (currently, $355) will be close to impossible and extraordinarily costly. As a result, before an officer of the hospital can certify that no such benefits were conferred on a physician, it will be necessary that each and every item of value provided to a physician be analyzed.

The DFRR asks not only for disclosure of the applicable facts, it also asks for the hospital or health system to classify each of the potentially thousands of arrangements with its physicians by indicating which Stark Law exception the arrangement comes under. The DFRR in effect imposes on the hospital the obligation to identify the specific exception and notify the Government as to which exception it chooses. This requirements converts the certification into an implicit legal opinion as to which of the complex, overlapping and ever-evolving Stark Law exceptions each and every arrangement fits in. It is easy to imagine that the advice of specialized health care counsel will be necessary to evaluate each arrangement and assess which Stark Law exception or exceptions the arrangement falls under.

Then, in addition to the "yes/no" answers in Worksheet 8, any affirmative responses will require the hospital to provide an explanation. In other words, the hospital will be required to make a disclosure to CMS that it has, in fact, violated the Stark Law, and it is hard to believe that any affirmative response that might be identified would not otherwise require at least 100 hours of the hospital executives' (and outside counsel's) time before making any such disclosure. In addition, given the complex relationships between hospitals and physicians, coupled with the well recognized complexity of the Stark Law, many relationships exist that the hospital "believes" in good faith to be compliant. Unfortunately, hospitals and health systems cannot always predict with certainty what position the Government may take with respect to the applicability of the Stark Law exceptions to a particular relationship. As a consequence, if a hospital or health system is forced to certify that a particular relationship fits into a particular Stark Law exception with a "yes/no" answer, many hospital and health system executives may feel compelled to include a detailed analysis even with a "yes" answer so as not to risk a *post-facto* determination by the Government that the executive has made a false certification.

The time-consuming nature of this exercise is further exacerbated by the fact that, every few years, CMS has rewritten the Stark regulations so as to completely revise the longstanding analytical framework for compliance, twice in 2008 alone. Imposing a substantial disclosure exercise while hospitals are in the midst of ascertaining which of the many financial relationships warrant restructuring under the new Stark law interpretations simply is overly burdensome.

**CMS's Underestimate of the Costs**

According to CMS and its most recent figure of 100 hours for a hospital to complete the DFRR, CMS broke this estimate down into two buckets: 60 hours of accounting and administrative personnel time at the rate of $30 per hour and 40 hours of attorney time at the rate of $57 per hour.

However, even if CMS were correct that the number of hours is correctly set at 100 (which we dispute for the reasons set forth above), CMS significantly underestimated the costs associated with these professional hours. Thirty dollars per hour is woefully low to cover the costs associated with administrative and accounting personnel. The estimate of the hourly rate for attorneys was again significantly underestimated. While attorney hourly rates are dependent upon the law firm and the office location(s), we are unaware of any attorneys who specialize in health regulatory issues and in particular Stark who charge $57 per hour. Instead, we would estimate (and our clients have confirmed) that the range of fees for outside counsel who might be called upon to assist hospitals in this task could range between $225 to $675 per hour, and therefore, on average would be more like $400 per hour. Even if the legal tasks were carried out by in-house attorneys, they require senior level attorneys whose salaries are well in excess of $57 per hour.

**CMS's Burdensome Request for Copies of All Documents Related to Financial Relationships**

Another significant factor that CMS did not take into consideration when it provided OMB with a cost estimate is that the DFRR requires submission of numerous contractual documents as part of the response. This means that hospitals and health systems will incur substantial costs in making copies and shipping the numerous space and equipment rental agreements, personal service contracts and recruitment arrangements. As stated above, hospitals and health systems could easily have thousands of such agreements and it will be necessary that a hard copy be provided. We acknowledge that, in its most recent version, CMS has modified the instructions for Worksheet 7 by stating a hospital or health system can simply provide a "uniform agreement," which CMS defines as an agreement in which "all of the elements present in the arrangements are materially the same." However, CMS does not define what the relevant elements are or what it means if they are "materially" the same. For instance, is the inclusion of a non-compete in one agreement but not in others considered to be "materially" the same? As a result, we anticipate that hospitals and health systems will likely still be required to provide copies of each and every one of these agreements.

Moreover, we fail to understand why is it even necessary for CMS to receive copies of these documents. Even the OIG does not require submission of each and every physician financial relationship for providers under a corporate integrity agreement. Rather, appropriate certifications suffice. Nor do we expect that CMS is intending to micromanage the details of these hospital/physician arrangements, commenting upon and giving helpful guidance to hospitals and health systems.

Further, we doubt that CMS would seek to collect this quantity of information if it was simply attempting to track information. Rather, the only possible reason for CMS to gather this information is to audit compliance. In fact, CMS explains that the purpose of the DFRR is to collect information that would permit CMS to "analyze" the types of financial relationships involving hospitals and physicians, the structure of various compensation arrangements and "trends therein," and "potentially whether the hospitals are in compliance with the physician self-referral law and implementing regulations."[2] We question whether this latter purpose is within the statutory authority granted to CMS. If CMS intends to move forward with a disclosure tool, it should return to the original intent of the tracking provision and adopt a far more streamlined approach by eliminating the certification requirement, the identification of the Stark exception into which each agreement fits, and the submission of supporting documents.

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[2] 73 Fed. Reg. at 23697.

We appreciate the opportunity to provide these comments on the DFRR, and we hope that OMB takes the necessary action to limit CMS's ability to impose this tremendous and unwarranted burden on hospitals. If you have any questions or would like to discuss these issues in greater detail, please feel free to contact any of the following attorneys if you have any questions or require further information:

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Sincerely,

Epstein Becker & Green, PC /dem

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