Comments Summary for Disclosure of Financial Relationships Report (DFRR)

CMS Form/Collection # CMS-10236

The 60-day public comment period for the DFRR ended July 17, 2007. We received six comments, predominantly from national or State hospital associations. The comments fell into several different types of categories, which include: general comments, burden estimates associated with completing the DFRR, comments concerning the number and types of hospitals that should be required to complete the DFRR, and comments that address the content of the DFRR, including legal and confidentiality issues related to the DFRR.

General Comments

Comments: Multiple commenters voiced a need for the instructions and worksheets that compose the DFRR to provide clear guidance on what is being requested and how the form should be completed. One commenter suggested that CMS test the DFRR with a pilot group of hospitals so that any ambiguities can be identified and resolved before the Report is rolled out widely.

Response: We do not believe that testing the DFRR with a pilot group of hospitals is necessary. As noted in the supporting statement, the DFRR builds upon information that was previously requested in the voluntary DRA 2006 survey. In addition, as a result of public comments, we have revised the DFRR instructions and worksheets to help address ambiguities.

Comment: One commenter recommended that CMS not send the DFRR by electronic mail, but rather encouraged CMS to send it by certified mail (return receipt requested) to the designated official on the relevant Medicare enrollment form. In that transmittal, CMS could identify a website link for the spreadsheet so hospitals could download an electronic file if they wish.

Response: CMS has created a process to obtain and verify the accuracy of the e-mail addresses of the CEO, CFO, or other comparable official of each of the 500 hospitals, which we believe will function well. This process involves not only ensuring the accuracy of the e-mail addresses, but verifying that the e-mail has been received. At the present time, there is a small number of hospitals (fewer than 10) for whom we have not received and verified an e-mail address. These entities will receive their DFRR request via certified mail (return receipt requested). In addition, we will post information concerning the DFRR on the CMS website. This will include a highlight on the hospital page and a list of the 500 hospitals. We are also considering whether to e-mail a notice to those entities that are registered on the list-serve, and whether to discuss the DFRR at an open door forum.

Comment: One commenter recommended that throughout the DFRR, we replace the word "stock" with the term "investment interests."

Response: We believe the term "investment interests" is a much broader term than is appropriate. However, in order to minimize confusion, we have substituted the term "stock" to "stock/share" throughout the DFRR. We noted this change in the instructions that accompany the Report.

Comment: One commenter recommended that we include the question from the DRA survey that was designed to capture the percentage of hospital revenues that come from referrals by physician owners.

Response: Section 5006(a) of the Deficit Reduction Act of 2005 (DRA) required the Secretary to address certain issues related to physician investment in "specialty hospitals." The purpose of the DFRR is to analyze the investment and ownership interests and compensation arrangements between 500 hospitals and their physicians, not to analyze the percentage of revenues that come from referrals by physician owners.

DFRR Form, Instructions, and Cover Note

Comment: One commenter stated that Worksheets 2 and 3 might not provide the information needed to ensure that there is a proportional return on investment (ROI) for individual physicians, and for physicians relative to other owners. The commenter asserted that whereas the DFRR captures information regarding the investment shares of physician and non-physician owners, parallel information is not included for the ROI for different types of owners and for the organization as a whole.

Response: We believe that the revisions that we have made to the DFRR now capture information for different types of owners and for the organization as a whole (See Worksheet 8).

Comment: Two commenters requested that we revise the first general instruction to read: "The requested disclosures on Worksheets 1 - 5 pertain only to hospitals with physician ownership."

Response: We are revising this general instruction to incorporate the suggested language. In addition, our revision references the new numbering sequence for the applicable Worksheets.

Comment: One commenter asserted that on Worksheet 1, question 27 was not consistent with the first general instruction. The commenter suggested that we move question 27 to immediately after Question 11, and clarify that the "disclosures" on Worksheet 1 are required only for hospitals with physician owners, as noted in the instructions.

Response: We are moving Question 27 to Question 12, and clarifying that the disclosures on Worksheet 1 are required only for hospitals with physician owners.

Comment: One commenter found some titles on the worksheets misleading, e.g., the titles of the worksheets imply that one type or level of information is being requested and the actual questions on the form dictate another type or level. The commenter specifically referred to Worksheet 3, "Report by Individual Physicians" which seems to imply something different than Question 11 on the same form. Question 11 indicates that the information required is not only for individual physicians, but also for immediate family members.

Response: Based upon concerns from commenters, we carefully reviewed the titles of each worksheet, the information requested, and the instructions for each. We agree with the commenter, and have revised the titles on worksheets (such as previous Worksheet 3) to remove the reference to individual physicians. We believe the new titles for each worksheet more accurately reflect the information requested, and each page of the DFRR reminds the respondent to read the instructions before completing the worksheet. The instructions also clearly state that wherever the term "physician" is employed, "physician" includes "immediate family member" as defined in 42 C.F.R. §411.351.

Targeted Hospital Respondents

Comment: Most commenters believed that CMS should limit the DFRR to the original 290 hospitals that did not respond to the initial DRA voluntary survey. They noted that in implementing the strategic and implementing plan required by the DRA, CMS sought information from 500 hospitals located in markets with a limited service facility, and the agency received responses from 210 entities. The commenters contended that the "sample of 500 hospitals" should provide CMS with adequate data from which to assess the various market implications of physician-owned limited service facilities.

Response: The point of this data collection effort is not to determine market implications of physician-owned limited service facilities, but rather to verify that financial relationships between hospitals and their physicians are compliant with the physician self-referral prohibition. We believe that sending the DFRR to 500 hospitals (instead of a lesser number) enables us to monitor the compliance of a large number of hospitals with the physician self-referral law, as well as providing us with as much data as possible given time and budget constraints for the purpose of possibly designing a disclosure process for all hospitals.

Comment: Most commenters urged CMS to remove all questions concerning compensation arrangements unrelated to physician ownership. The commenters contended that the capturing of compensation arrangement activities and compliance activities of 210 additional hospitals is overly expansive and extremely burdensome. In addition, the commenters believe that the expansion of information requested is viewed as being punitive.

Response: We do not believe that the request to capture other information, such as the information on compensation relationships should be viewed as punitive. On page 69 of the Report to Congress, we stated that we would begin a mandatory disclosure process that involved collecting information concerning ownership interests, and compensation relationships. Also, CMS has responsibility for enforcing all prohibitions of the physician self-referral law, not only those associated with ownership and investment interests.

Administrative Burden

Comment: Most commenters stated that CMS had substantially and significantly underestimated the burden associated with the DFRR. They contended that the proposed DFRR would take more time to complete than the DRA 2006 survey. The commenters believed that the burden did not fully recognize the amount of time that would be needed to produce documentation regarding compensation relationships. Commenters also believed that this process requires the involvement of auditors and legal counsel, increasing the expenditure and diversion of financial resources of the hospital. In addition, this task may involve hundreds of contracts.

Response: We are persuaded that we may have underestimated the burden associated with the DFRR and accordingly, we are revising our time estimate to 6 hours. Although one commenter stated that the burden associated with the DFRR is closer to 40 hours, we do not believe that to be the case. The DFRR consists of some information requested on the voluntary DRA survey but does not request information on the DRA survey, such as that concerning capital assets, Medicare and Medicaid utilization, financial data and revenue, and organizational structures. The burden associated with the DRA voluntary survey was 4 hours. We believe that the burden associated with the information requested by the DFRR, including disclosing compensation arrangements and locating supporting documentation for all worksheets, slightly exceeds that associated with the DRA survey. We have factored in the potential need for involvement of auditors and legal counsel. We believe that the number of contracts with physicians may vary greatly, depending upon the size, organizational structure, and the amount of contracting performed by each hospital. We believe hospitals have, or should have, ready access to basic information in all contracts with physicians. Where a hospital has uniform personal services arrangement contracts with physicians, it will be required to note only which physicians are parties to the uniform contract, and whether the contracts are signed, and to transmit one sample copy of that uniform contract to us.

Comment: Several commenters stated that the proposed 45-day turnaround with a threat of $10,000 per day penalty for late responses is unreasonable and excessive. They expressed concern that the proposed ICR will require hospitals to dedicate more time and resources to complete the expanded survey. The forty-five (45) days allotted for completing the six worksheets and submitting certified responses is too brief to ensure accuracy of the data. They asserted that completing the information request will be particularly burdensome for those hospitals that did not previously receive the DRA survey. The work of auditors and legal counsel will also drive up the cost of compliance

with this survey. One commenter stated that hospital compliance programs will need to be reviewed to ensure that systems are in place to track both the ownership and compensation relationships with physicians. Some programs may need modification in order for the hospitals to provide the information requested by the DFRR. Commenters stated that hospitals will need time to review their current compliance controls and even perform an internal assessment of compliance with the Stark law prior to self-reporting this information to CMS.

Response: We are persuaded that our 45-day completion date is not sufficient, for several reasons, including the internal assessments of compliance that hospital respondents would have to perform. Therefore, we are increasing the time for submission of the DFRR from 45 days to 60 days. We will grant extensions beyond the 60 days to complete the DFRR in appropriate cases.

Comment: One commenter contended that CMS did not raise any concerns about physician ownership or investment interests in non-specialty hospitals at the time of the DRA Strategic and Implementing Plan. Thus, the commenter believes that the disclosure requirement should apply solely to hospitals that meet the definition at section 1877(h)(7) (physician-owned hospitals). The commenter asserted that, by extending this disclosure requirement beyond physician-owned limited service facilities, CMS sought to implement a data collection policy that is inconsistent with the purpose of the Paperwork Reduction Act.

Response: We do not agree with the commenter's contention that we did not raise any concerns about non-specialty hospitals, and we refer the commenter to page 69 of the DRA Report. Therein, we stated that we are interested in knowing the extent to which all hospitals are complying with the physician self-referral law with regard to both ownership/investment interests of physicians and with respect to compensation arrangements with physicians.

Comment: One commenter urged CMS not to institute an annual reporting requirement. The commenter asserted that the costs and burden associated with this reporting activity greatly outweigh the potential benefits to the government, not to mention the significant resources in which the government would need to invest in order to review the large number of annual responses.

Response: In the Supporting Statement accompanying the DFRR, we stated that this was a one time collection effort and that we would issue a notice of proposed rule-making before decisions were made concerning the frequency of any reporting requirements.

Exposure to Legal Liability

Comment: Several commenters argued that the DFRR would require hospitals to submit legal conclusions as to the significance of the information disclosed, and then require senior officers to certify the accuracy of those legal conclusions, "infringing on the due process rights of hospitals." These commenters specifically raised objections to the

design of worksheet 6, which they contend asks hospitals to make legal conclusions about particular arrangements and creates the risk of liability for false claims or false statements if the government disagrees with a hospital's legal conclusion.

Response: We do not agree that the worksheets require hospitals to make new legal conclusions about particular arrangements. All financial arrangements with physicians (or their immediate family members) should have been reviewed to make sure they are compliant with the physician self-referral prohibition law and regulations before billing Medicare. Additionally, Medicare claim forms (CMS-1500 and UB-92), require providers or suppliers to certify that they are compliant with all Medicare coverage and payment rules, which include the physician self-referral rules. We note that the certification statement requires only that the hospital officer believes that the information contained in the DFRR is true and correct to the best of his or her belief and knowledge."

Comment*:* One hospital association asserted that requiring information about all compensation arrangements between hospitals and physicians is overly burdensome and not supported by the stated compliance concerns of CMS. The commenter further stated that CMS incorrectly asserted that section 1877(f) gives CMS the authority to obtain information about compensation arrangements that comply with a compensation exception. Instead, section 1877(f) allows CMS to seek information only about compensation arrangements that do not meet an exception in sections 1877(c), (d), or (e) of the Act. Section 1877(f) states that CMS may require information concerning compensation arrangements that are "described in subsection (a)(2)(B) of [section 1877 of the Act]." Section 1877(a)(2)(B) describes compensation arrangements that do not meet any of the exceptions contained in sections 1877(c), (d), or (e) of the Act. By including certain information that entities must report, Congress effectively excluded other information from CMS's authority.

Response: We do not believe that the estimated time of 6 hours to complete the Report is overly burdensome. We also do not agree that the information required does not pertain to our stated compliance concerns. Section 5006 of the DRA, enacted on February 8, 2006, directed the Secretary to develop a "strategic and implementing plan" to address certain issues relating to physician investment in specialty hospitals. In the Final Report to the Congress and Strategic and Implementing Plan released in August 2006, HHS stated that it would require all hospitals to provide information on a periodic basis concerning their investment and compensation relationships with physicians pursuant to 42 CFR §411.361.

The purpose of this new mandatory disclosure instrument, the DFRR, is to collect information that will be subsequently used to analyze all investment interests and compensation arrangements between each of the 500 hospitals and their respective referring physicians.

We believe that it is impossible to fully analyze the ownership interests of physicians in hospitals without also taking into account the compensation relations of hospitals with their referring physicians. That is, although a physician may be highly motivated to refer

patients to a hospital in which he or she has an ownership interest, the physician may be just as likely – or even more likely -- to refer patients to a hospital with which he or she has compensation relationships. For example, a physician may have an ownership interest in an MRI or a lithotripter, refer patients to a hospital for these services, provide these services under arrangements with the hospital, and furnish the professional component of the services. Similarly, although neither a physician nor anyone else can have an ownership or investment interest in a hospital that qualifies as a charitable institution under section 503(c) of the Internal Revenue Code (IRC), the IRC does not prohibit highly lucrative compensation arrangements between a referring physician and a charitable institution.

In addition, we believe that Congress did not intend to limit our ability to capture information about compensation arrangements that meet an exception. Section 1877(f) states that "each entity . . . shall provide the Secretary with the information concerning entity's . . . compensation arrangements . . . *including* the names and [UPINS] of all physicians with a compensation arrangement (as described in subsection (a)(2(B)…" (emphasis added). We believe Congress's use of the word "including" meant that it was providing only examples of the type of information that we may require. To read the statute otherwise would effectively negate our ability to make fully informed decisions about the compliance of hospitals and instead allow hospitals to report only information about those compensation relationships that they self-determine are out of compliance.

Confidentiality Protections

Comment: One commenter expressed appreciation for CMS' representation that information will be held confidentially. The commenter noted that the supporting statement indicates that CMS is prevented by the Trade Secrets Act from releasing to the public confidential business information, except to the extent "permitted" by law. The commenter encouraged CMS to only release information under the Trade Secrets Act to the extent "mandated" by law. In addition, the commenter requested that a footnote be added to all pages of the DFRR indicating that CMS will abide by both the Trade Secrets Act and Freedom of Information Act (FOIA) protections.

Response: The Trade Secrets Act, 18 USC §1905, forbids us from releasing confidential business information unless authorized by law. In addition to releasing information contained in the DFRR to the extent mandated by law, we will also release such information, where appropriate, to federal law enforcement agencies such s HHS's Office of Inspector General and the Department of Justice. We will not release information contained in the DFRR as matter of course to law enforcement agencies, but rather will do so only where we believe a specific referral to the OIG, DOJ, or other agency is warranted. Our policy is to not release any confidential business information or FOIA-protected personally identifiable information to the public. We do not believe it is necessary to include the type of footnote suggested by the commenter (and in any event spacing limitations would prevent us from doing so); rather, our disclosure policy will be set forth in the general instructions.

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Indirect Financial Relationships

Comment: Two commenters expressed concern that the DFRR does not reach far enough in requiring hospitals to disclose their indirect financial arrangements with physicians. One of the commenters also recommended that CMS must be required to disclose employment-like relationships with physicians. Some states do not allow hospitals to directly employ physicians. However, in some states, such as Texas, physicians are able to form organizations which employ physicians, and through which the hospital retains the physicians' services. CMS should be clear in requiring hospitals to disclose all personal services arrangements even when they are not a direct agreement with a physician.

Response: We recognize that physician referrals may be significantly influenced by the presence of either a direct or an indirect financial ownership or investment interest, similar to the effect of a compensation arrangement. Therefore, we are persuaded to capture information on indirect financial arrangements and have revised the DFRR accordingly.