Supporting Statement – Center for Medicare and Medicaid Services Disclosure of Financial Relationships Report ("DFRR")

A. Background

Section 5006 of the Deficit Reduction Act of 2005 ("DRA") required us to consider the issue of annual disclosure of information pertaining to physician ownership and investment interest in specialty hospitals. In the Final Report to the Congress and Strategic and Implementing Plan required under Section 5006 of the DRA released in August 2006, we stated that pursuant to 42 CFR § 411.361, we would require hospitals to provide us information on a periodic basis concerning their ownership and investment interests and compensation arrangements with physicians. In order to obtain a more complete depiction of the proportionality of physician ownership and investment interest in specialty hospitals, we created a voluntary DRA survey instrument that was sent to both specialty and competitor hospitals. Because we are unable to determine whether the hospitals that did not respond to our DRA survey questions on ownership and investment interests and compensation arrangements had tainted relationships or whether their non-response was for other reasons, we will begin our disclosure initiative with those 290 hospitals. We will select an additional 210 hospitals, for a total of 500 hospitals.

There is no central repository for the information that CMS needs to conduct its analysis. The purpose of the mandatory disclosure instrument ("Disclosure of Financial Relationships Report" or "DFRR") is to collect information that will be subsequently used to analyze any ownership and investment interest or compensation arrangement between each of the 500 hospitals and the physicians.

B. Justification

1. Need and Legal Basis

Section 1877(f) of the Social Security Act requires that each entity providing covered items or services for which payment may be made shall provide the Secretary with information concerning the entity's ownership and investment interests, and compensation arrangements, in such form, manner, and at such times as the Secretary shall specify.

2. <u>Information Users</u>

The DFRR is a new collection instrument that will be used by CMS to obtain information necessary to analyze each hospital's compliance with Section 1877 of the Act ("the physician self-referral law"), and implementing regulations (42 CFR, Subpart J).

3. Use of Information Technology

The mandatory DFRR, which consists of an Excel spreadsheet and instructions, will be emailed by CMS to 500 hospitals. We have explored various methods of data collection;

however, due to the level of detail, we have concluded that electronic completion and submission of the report is not feasible. Therefore, hospital respondents will be required to submit, in paper format, the original and one copy of the complete DFRR (which consists of the signed certification statement, all applicable worksheets, and all accompanying documentation). Respondents may submit the DFRR via certified mail supplemented with return receipt, but are not required to do so. CMS will require that the DFRR be signed by the Chief Financial Officer, Chief Executive Officer or other appropriate official. The CFO, CEO or other appropriate official will also certify the accuracy of the information submitted in the DFRR. One of the Program Safeguard Contractors ("PSCs") will be tasked with compiling and reviewing the DFRRs submitted by the 500 hospitals and will coordinate its review findings with CMS.

4. <u>Duplication of Similar Information</u>

The DFRR will be sent to hospitals that did not complete the voluntary DRA survey. Although there is some similarity between the types of information requested in the DFRR and the previous voluntary DRA survey, the DFRR does request additional information, personal identifiers, and completion is mandatory. This information collection does not duplicate any other effort and the information cannot be obtained from any other source.

5. Small Business

These information collection requirements do not impact small businesses.

6. Less Frequent Collection

The DFRR will be used to evaluate the compliance of 500 hospitals with the physician self-referral law and regulations. The data also will be used to assist us in proposing a regular financial disclosure process that would apply to all Medicare participating hospitals. We have not yet designed the process, but will consider such issues as whether we should (1) survey all hospitals annually, (2) stagger our survey so that all hospitals are queried but not all in the same year, and/or (3) focus our inquiry on certain types of relationships or certain hospitals. We will also consider whether, having once provided information, hospitals need submit only updated information on a yearly or other basis. In a future notice of proposed rulemaking, we will ensure that our proposals minimize any reporting burden, and that our final regulation carefully considers all public comments.

7. <u>Special Circumstances</u>

There are no special circumstances.

8. Federal Register/Outside Consultation

A 60-day Federal Register notice was published on May 18, 2007.

There is no Federal Register Notice that specifically references the proposed DFRR. However, the DFRR requests much of the same information that was requested in the voluntary DRA survey and approved by OMB (Control Number 0938-0995).

For purposes of the voluntary DRA survey, we consulted with the accounting firm of Figliozzi & Company at (516) 745-6400 and the Law Offices of Kevin McAnaney at (202) 457-0494. In addition, CMS held multiple meetings and open door forums to solicit input from both community and specialty hospital associations regarding the availability of data, data elements, and reporting formats for the voluntary DRA survey.

Much of the same type of information is now required as part of the DFRR. CMS contracted with Figliozzi & Company on the proposed DFRR. It has provided suggestions for improvements to both the DFRR and the accompanying instructions.

9. Payment/Gift to Respondents

There will be no payments/gifts to respondents.

10. Confidentiality

DFRRs from the 500 hospital respondents will be kept in a physically secured area. The PSC computer system and related database(s) will be password protected for electronic information. Files containing hardcopies of the actual DFRR or information from the DFRR will be safeguarded in a physically secured area.

The information collected from the DFRR will be used in analyzing physician ownership and investment interests in hospitals and compensation arrangements, and may be shared with other federal agencies and with Congressional committees. Additionally, we are prevented by the Trade Secrets Act, 18 U.S.C. § 1905, from releasing to the public confidential business information, except to the extent permitted by law. We intend to protect from public disclosure, to the fullest extent permitted by Exemptions 4 and 6 of the Freedom of Information Act, 5 U.S.C. § 552(b)(4) and (6), any individual-specific information collected.

11. Sensitive Questions

There are no sensitive questions included in the DFRR.

12. Burden Estimate (Hours & Wages)

There will be 500 hospitals that will be required to complete the DFRR. We estimate that it will take approximately six (6) hours to complete the DFRR. Therefore, the burden estimate is 3000 hours (500 x 6). We believe that accounting personnel will be responsible for gathering the data and completing the DFRR. We estimate that, on average, the salary for such personnel is \$50 per hour; thus, the total cost is estimated to be \$150,000 (\$50 x 6 hours x 500 hospitals).

13. Capital Costs

There are no capital costs for the respondents this data collection.

14. Cost to the Federal Government

CMS will contract with a Payment Safeguard Contractor to collect and analyze all data from the DFRRs. The estimated cost for this contract is \$1,635,000. The PSC will complete eight different tasks, which, in total, are estimated to take 14,226 hours to complete. Please see the attached Independent Government Cost Estimate that has been prepared as part of the Request for Task Order.

15. Program/Burden Changes

This is a new information collection.

16. Publication and Tabulation Duties

CMS will require that the DFRR be completed and a hard copy submitted to CMS within 60 days of receipt. The Program Safeguard Contractor must complete its tasks no later than February 14, 2008. At this time, there are no plans for publication.

17. Expiration Date

CMS will be requesting a three year regular approval, to provide sufficient time to use the current DFRR for the 500 hospitals, to issue a notice of proposed rulemaking, evaluate all public comments and issue a final rule before this authorization expires.

18. Certification Statement

No exceptions apply.

C. Collections of Information Employing Statistical Methods

This collection of information will not employ any statistical methods. This collection of information involves a determination as to whether each of the 500 hospitals is compliant with the physician self-referral law and implementing regulations.