Supporting Statement
Disclosures Required of Certain Hospitals and Critical Access Hospitals Regarding Physician Ownership

The purpose of this statement is to support a request from the Centers for Medicare and Medicaid Services (CMS) to the Office of Management and Budget (OMB) for a proposed new collection, under the Paperwork Reduction Act and 5 CFR 1320.6. The information request relates to proposed required third party disclosures by certain Medicare-participating hospitals and critical access hospitals (CAH's) to their patients. The policy is contained in the FY 2009 Inpatient Prospective Payment System Final Rule. Because this information request is closely related to the previously approved collection burden under CMS 10225, we have included a discussion of both the approved provisions and the new provisions in this supporting statement.

A. Background

Section 5006(a)(1) of the Deficit Reduction Act of 2005 (DRA), enacted on February 8, 2006, required the Secretary to develop a "strategic and implementing plan" to address certain issues relating to physician investment in "specialty hospitals, " and to submit this plan to the Congress. We indicated in the required report, submitted in August, 2006, that a well-crafted disclosure requirement, which, at a minimum, would require hospitals to disclose to patients whether they are physician-owned and, if so, the names of the physician-owners, is consistent with the agency's general approach that hospitals should be transparent as to their pricing and quality outcomes. A well-educated consumer is essential to improving the quality and efficiency of our healthcare system. Accordingly, We implemented a change to its regulations at §489.20(u) governing provider agreement requirements, to require physician-owned hospitals to disclose their ownership status to all patients at the beginning of their inpatient stay or outpatient visit, and to make a list of physician owners available upon request. This collection is approved under OMB 0938-1034.

Since the report also found that a less than half of specialty hospitals have emergency departments, compared to roughly 92% of short-term acute care hospitals, We also addressed issues related to safety of patients that develop emergency medical conditions in hospitals that do not have a physician on the premises at all times. Following the principle of increased transparency of hospital operations to patients, We revised its regulations at §489.20(v) governing provider agreements to require all hospitals and critical access hospitals that do not have a physician on the premises at all times to disclose this to its patients upon admission or registration for both inpatient and outpatient services. At the same time, these hospitals would be required to indicate to the patient how the hospital/CAH meets the clinical needs of any patient who develops an emergency medical condition at a time when a physician is not present in the facility. This collection is also approved under OMB 0938-1034.

In addition to these two existing collections, we are revising §489.3 to define a physician-owned hospital as a hospital in which a physician, or an immediate family member of a physician has an ownership or investment interest in the hospital. Because of this change to the definition of a

physician owned hospital, new §489.20(u)(1) will require that hospitals with ownership or investment interests by a physician or immediate family member disclose this information to all their patients. Additionally, We revised §489.20(u) by creating §489.20(u)(1) that requires any physician-owned hospital to furnish patients with written notice that the hospital is physician-owned and provide the list of physician owners (including immediate family members) to the patient at the time the patient or someone on the patient's behalf requests it.

We also require three new collections which are the primary focus of this supporting statement. First, we have added new §489.20(u)(2) to require a hospital to require all physicians who are members of the hospital's medical staff to agree, as a condition of continued medical staff membership or admitting privileges, to disclose in writing to all patients they refer to the hospital any ownership or investment interest in the hospital held by themselves or by an immediate family member. The burden associated with this requirement is two-fold and pertains to both hospitals and physicians. First, hospitals are required to update by-laws and policies and procedures to reflect that as a condition of medical staff membership or admitting privileges, physicians must agree to disclose ownership or investment interests to patient. In addition, physicians are required to develop disclosure notices, distribute them to patients and maintain these disclosure the in patients' medical records.

Finally, we are including new language under §489.20(v) to provide for an exception to the disclosure requirements for a physician-owned hospital that does not have at least one referring physician who has an ownership or investment interest in the hospital (or who has an immediate family member with an ownership or investment interest in the hospital), provided that the hospital attests, in writing, to that effect and maintains such attestation in its files. The burden associated with this requirement is limited to those physician-owned hospitals that do not have physician owners who refer patients to the hospital.

We have created new §489.20(u)(1) and (u)(2), and redesignated existing §489.20(v) and (w) as §489.20(w) and (x), respectively, to accommodate the addition of the proposed exception to the requirements in §489.20(v) as discussed above.

B. Justification

1 . Need and Legal Basis

There is no Medicare prohibition against physician investment in a hospital or CAH. Likewise, there is no Medicare requirement that a hospital or CAH have a physician on-site at all times, although there is a requirement that they be able to provide basic elements of emergency care to their patients. Medicare quality and safety standards are designed to provide a national framework that is sufficiently flexible to apply simultaneously to hospitals of varying sizes, offering varying ranges of services in differing settings across the nation. At the same time, however, patients might consider an ownership interest by their referring physician and/or the presence of a physician on-site to be important factors in their decisions about where to seek hospital care. A well-educated consumer is essential to improving the

quality and efficiency of the healthcare system. Accordingly, patients should be made aware of the physician ownership of a hospital, whether or not a physician is present in the hospital at all times, and the hospital's plans to address patients' emergency medical conditions when a physician is not present.

Section 5006(a)(1) of the Deficit Reduction Act of 2005 (DRA), enacted on February 8, 2006, requires the Secretary to develop a "strategic and implementing plan" to address certain issues relating to physician investment in "specialty hospitals." In that plan we indicated it would explore changes to its regulations to require hospitals to disclose to patients investment interests of physicians who make referrals to the hospital.

Sections 1861(e)(1) through 1861(e)(8) of the Social Security Act (SSA) define the term "hospital" and list the requirements that a hospital must meet to be eligible for Medicare participation. Section 1861(e)(9) of the SSA specifies that a hospital must also meet such other requirements as the Secretary of Health and Human Services finds necessary in the interest of the health and safety of the hospital's patients.

Section 1820 of the SSA provides for the establishment of Medicare Rural Hospital Flexibility Programs (MRHFPs), under which individual states may designate certain facilities as critical access hospitals (CAHs). Section 1820(c)(2)(B)(iv) subjects CAHs to the requirements of Section 1861(e), with certain specified exceptions.

2. Information Users

The intent of the proposed disclosures is to increase the transparency of the hospital's ownership and operations to patients as they make decisions about receiving care at the hospital.

3. Use of Information Technology

There are no specified forms to be used for the proposed disclosures. The proposed disclosures to patients must be in writing and would be generic rather than patient-specific. Accordingly, hospitals and CAHs are free to use pre-printed standard disclosure notices of their own design, and also have the discretion to generate the notices electronically. There is no required reporting to CMS associated with these disclosures. Therefore, issues of electronic collection or acceptance of electronic signatures by CMS are not relevant.

4. Duplication of Efforts

Industry representatives have advised CMS that physician-owned hospitals routinely disclose that fact to their patients. It is likely that hospitals that currently make such disclosures could use their current disclosure, with limited modification, to satisfy the proposed new regulatory requirements. For example, to the extent ownership or investment interests on the part of a physician's immediate family member are not reflected in the disclosures, they should be

updated.

We do not have information on whether or not hospitals that do not have a physician present on-site at all times currently disclose that fact, as well as how they would handle emergencies when a physician is not present on-site, to patients. Any hospitals that currently make such disclosures, however, could likely use, with limited or no modification, their current disclosures to satisfy the new regulatory requirement.

5. Small Businesses

The proposed disclosures entail a minimal burden in general, since the same disclosure statement could be used by a hospital or physician for all of their respective patients, and could be integrated into existing processes for registering/admitting patients. Accordingly, it is not possible to reduce the burden further and still accomplish the goal of the proposed regulatory requirement.

6. Less Frequent Collection

The only way in which to conduct the collection less frequently would be to make the required disclosures to selected patients only. That would not be compliant with the proposed rule, and would result in an inequitable treatment of those beneficiaries and other hospital patients who would not receive the information proposed for disclosure.

7. Special Circumstances

No special circumstances apply to the proposed disclosure requirement.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice for this information collection request published as part of the proposed rule (73 FR 23528) on April 30, 2008.

In addition, the IPPS NPRM went on display at the Federal Register on Friday, April 11, 2008.
In preparing the August, 2006 Report to Congress on the Strategic and Implementing Plan for Specialty Hospitals we consulted with a wide range of stakeholders. There was general support for the need for increased transparency to patients of physician investments in hospitals to which they make referrals.

9. Payments/Gifts to Respondents

N/A

10. Confidentiality

N/A

11. Sensitive Questions

None of the proposed required disclosures would be of a sensitive nature.

12. Burden Estimates (Hours & Wages)

a. Physician-ownership of hospitals- hospital disclosure. We estimate that there are roughly 175 hospitals that would qualify as physician-owned and would have to make such disclosures. Information derived from research conducted for the agency by RTI in connection with the Report to Congress mandated by the DRA supports an assumption that such hospitals have an average of three new patients per day/seven days per week for an average of 1092 disclosures per hospital per year. We assumed four hours/year/hospital for in-house counsel to develop/review the content of the disclosure, and 30 seconds per disclosure to include a standard notice to be delivered to patients at the time their inpatient stay or outpatient visit begins, and another 30 seconds to include a copy of the notice in the patient's medical record. The annual hour burden was assumed to be 3885 for all respondents.

(4 hours/hospital) x 175 hospitals = **700 hours**

(1092 disclosures/hospital) x 175 hospitals = 191,100 total disclosures

191,100 disclosures x (30 seconds/disclosure) x (1 minute/60 seconds) x (1 hour/60 minutes) = **1592.5 hours**

(1092 disclosures/hospital) x 175 hospitals = 191,100 total disclosures

191,100 disclosures x (30 seconds/disclosure) x (1 minute/60 seconds) x (1 hour/60 minutes) = **1592.5 hours**

We estimate that each hospital will conduct 17,472 disclosures per year for outpatient visits.

(17,472 disclosures/hospital) x 175 hospitals = 3,057,600 total disclosures

3,057,600 disclosures x (30 seconds/disclosure) x (1 minute/60 seconds) x (1 hour/60 minutes) = **25,480 hours**

(17,472 disclosures/hospital) x 175 hospitals = 3,057,600 total disclosures

3,057,600 disclosures x (30 seconds/disclosure) x (1 minute/60 seconds) x (1 hour/60 minutes) = **25,480 hours**

Using published Bureau of Labor Statistics wage information for mean wages for attorneys and medical records and health care support technicians, we estimate that the total cost nationally would be $81,370.

b. Physician-ownership of hospitals – hospital disclosure. We estimate that there would be a minimal burden imposed upon hospitals that honor requests by or on behalf of patients for lists of physician owners and investors. However, as indicated in section XI. B. 2. c. of CMS 1390-P, we are unable to estimate the number of requests that a hospital may receive. Therefore, we are assigning 1 token burden hour to this requirement until such a time that we can conduct an accurate burden analysis for this information collection requirement.

c. Physician-ownership of hospitals – medical staff by-laws/policies. We estimate that there are roughly 175 hospitals that would qualify as physician-owned. These hospitals would be required to require all physicians who are members of the hospital's medical staff to agree, as a condition of continued medical staff membership or admitting privileges, to disclose in writing, to all patients who they refer to the hospital any physician (including immediate family member) ownership or investment interest in the hospital. We estimate that each hospital will spend 4 hours revising medical staff by-laws and policies governing medical staff membership or admitting privileges.

(4 hours/hospital) x 175 hospitals = **700 hours**

d. Physician-ownership of hospitals – physician disclosure. We estimate that there will be a burden imposed upon physicians to prepare a disclosure notice, provide the notice to patients and maintain record of the disclosures. We estimate that it will take each physician one hour to develop the notice and make copies for distribution to patients. In addition, we estimate that it will take 30 seconds to provide the disclosure to each patient and additional 30 seconds to record the proof of disclosure in each patient's medical record. However, as indicated in section XI. B. 2. c. of CMS 1390-P, we are unable to estimate the number of physicians that have an ownership or investment interest in hospitals. Therefore, we are assigning 1 token burden hour to this requirement until such a time that we can conduct an accurate burden analysis for this information collection requirement.

e. Inapplicability of hospital disclosure. We estimate that 10 percent of the 175 physician-owned hospitals, or approximately 18 hospitals, do not have at least one physician owner (including immediate family member) who refers to the hospital. We estimate one hour for each of these hospitals to develop, sign and maintain an attestation reflecting this non-referring status.

(1 hours/hospital) x 18 hospitals = **18 hours**

Using published Bureau of Labor Statistics mean wage information for attorneys ($55 per hour), we estimate that the total cost nationally would be $990.

f. No 24/7 on-site physician. We estimate that there are roughly 2504 hospitals and critical access hospitals that may not have a physician on-site at all times. Based on information about presence of an emergency department in a hospital, we assume that all of the 1280 critical access hospitals and 16 religious non-medical institutions; 8% of the 3728 (298) short-term acute care and 8% of the 81 (7) children's hospitals; and 83% of the 479 psychiatric hospitals (397), 83% of the 218 (181) rehabilitation hospitals, and 83% of the 391 (325) long term care hospitals may not have a physician on-site at all times. We know that CAHs are small hospitals, limited to 25 beds and assumed further that the other hospitals without a 24/7 physician on-site would also be small and/or have patients with longer length of stay and less patient turnover. Therefore, relying on the research referenced above regarding specialty hospitals, we also assume that there would be an average of 3 new patients per day in these hospitals, necessitating an average of 1092 disclosures per hospital per year. We assumed four hours/year/hospital for in-house counsel to develop/review the content of the disclosure, and 30 seconds per disclosure to include a standard notice to be delivered to patients at the time their inpatient stay or outpatient visit begins, and another 30 seconds to include a copy of the notice in the patient's medical record. The annual hour burden was assumed to be 55,588 nationally.

(4 hours/hospital) x (2504) hospitals = **10,016 hours**

2504 hospitals x (1092 disclosures/hospital) = **2,734,368** disclosures

2,734,368 disclosures x (30 seconds/disclosure) x (1 minute/60 seconds) x (1 hour/60 minutes) = **22,786 hours**

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2,734,368 disclosures x (30 seconds/disclosure) x (1 minute/60 seconds) x (1 hour/60 minutes) = **22,786 hours**

We estimate that each hospital will conduct 17,472 disclosures per year for outpatient visits. The burden for outpatient visits is 30 seconds for the disclosure and 30 seconds to fulfill the recordkeeping requirement.

(17,472 disclosures/hospital) x 2,504 hospitals = 43,749,888 total disclosures

43,749,888 disclosures x (30 seconds/disclosure) x (1 minute/60 seconds) x (1 hour/60 minutes) = **364,582.4**

(17,472 disclosures/hospital) x 2,504 hospitals = 43,749,888 total disclosures

43,749,888 disclosures x (30 seconds/disclosure) x (1 minute/60 seconds) x (1 hour/60 minutes) = **364,582.4**

Using published Bureau of Labor Statistics wage information for mean wages for attorneys and medical records and health care support technicians, we estimate that the total cost nationally will be $1,151,443.

13. Capital Costs

There are no capital costs anticipated as a result of the proposed required disclosures. Currently, hospitals routinely provide a variety of written materials to patients upon admission/registration and we assume that the required disclosures will be incorporated into their existing processes, utilizing existing equipment.

14. Cost to Federal Government

There is no cost to the Federal Government anticipated, since no reporting to the Federal Government of the information disclosed to patients will occur as part of this proposed required disclosure.

15. Changes to Burden

This collection of information includes several requirements promulgated by the regulation CMS-1533-P and approved under 0938-1034. Specifically, § 489.20(u) required physician-owned hospitals to disclose physician ownership or investment interests to patients and to make the list of physician owners available to patients upon request. In addition § 489.20(v) required that hospitals and CAHs: (1) furnish all patients written notice at the beginning of their inpatient hospital stay or outpatient service if a doctor of medicine or a doctor of osteopathy is not present in the hospital 24 hours per day, 7 days per week; and (2) describe how the hospital or CAH will meet the medical needs of any patient who develops an emergency medical condition at a time when no physician is present in the hospital.

In CMS 1390-P, we have revised §489.20(u) by creating §489.20(u)(1) that would require that the list of physician owners or investors (including immediate family members) be furnished at the time the patient or someone on the patient's behalf requests it. We have also added new §489.20(u)(2) to require a hospital to require all physician who are members of the hospital's medical staff to agree, as a condition of continued medical staff membership or admitting privileges, to disclose in writing to all patients they refer to the hospital any

ownership or investment interest in the hospital held by themselves or by an immediate family member.

We also have included under §489.20(v) new language to provide for an exception to the disclosure requirements for a physician-owned hospital that does not have any physician owners who refer patients to the hospital (and that has no referring physicians who have an immediate family member with an ownership or investment interest in the hospital), provided that the hospital attests, in writing, to that effect and maintains such attestation in its files. In CMS 1390-P, we have redesignated existing §489.20(v) and (w) as §489.20(w) and (x), respectively, to accommodate the addition of the exception to the requirements in §489.20(v) as discussed below. The new burden is limited to the provisions proposed in 489.20(u)(2) and (v).

16. Publication/Tabulation Dates

N/A

17. Expiration Date

This collection does not lend itself to the displaying of an expiration date.

18. Certification Statement

N/A

C. Collections of Information Employing Statistical Methods

This collection does not employ statistical methods.