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 new collection, under the Paperwork Reduction Act and 5 CFR 1320.6. The information request relates to the required third party disclosures by certain Medicare-participating hospitals and critical access hospitals (CAH's) and physicians to their patients. The policy is contained in the FY 2009 Inpatient Prospective Payment System Final Rule and in the CY 2011 Outpatient Prospective Payment System Proposed 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.

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.

Section 489.20(u)(2) requires 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. This collection is approved under OMB 0938-10236.

Section 1877 of the Social Security Act (the Act), also known as the physician self-referral law, prohibits a physician from making referrals for certain designated health services (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship unless an exception applies. Section 1877(d) of the Act sets forth exceptions related to ownership or investment interests by a physician in an entity that furnishes certain DHS. Under section 1877(d)(2) of the Act, a physician is permitted to refer patients for DHS furnished by providers in a rural area. Under section 1877(d)(3) of the Act, a physician is permitted to refer patients for the provision of DHS to a hospital in which he or she has an ownership or investment interest if the referring physician is authorized to perform services at the hospital and the physician's ownership or investment interest is in the entire hospital and not merely a distinct part of or a department of the hospital (whole hospital exception).

Section 6001(a) of the Patient Protection and Affordable Care Act (the Affordable Care Act) amended section 1877(d)(2) and (d)(3) of the Act to impose additional restrictions in order to qualify for the rural provider and whole hospital exceptions. Among those restrictions were provisions requiring hospitals to: 1) prevent conflicts of interest by disclosing physician ownership or investment interest to patients and 2) take certain steps to ensure patient safety.

The new disclosure requirements set forth in section 6001(a) the Affordable Care Act are as follows:

1) A hospital must disclose on any public website for the hospital or in any public advertising that it is owned or invested in by physicians. We are implementing this requirement in new §411.362(b)(3)(ii)(C) . Hospitals will be required to develop and place this information on their websites and/or in public advertisements and update such information as needed;

2) A hospital must have procedures in place to require that any referring physician owner or investor in the hospital, as part of his or her continued medical staff membership or admitting privileges, disclose to the patient being referred to the hospital any ownership or investment interest held by the physician or an immediate family member (as defined at §411.351 of this chapter) of the physician, We are implementing this requirement in new §411.362(b)(3)(ii)(A). Hospital legal staff will be required to develop, draft and implement changes to the hospital's

medical staff bylaws and policies governing admitting privileges and hospitals will be required to provide a list of physician owners or investors to all of their staff physicians. Referring physicians in turn will be required to take the hospital-provided list of physician owners or investors and develop a notice to patients , and

3) Following a hospital's disclosure to a patient that it does not have a physician available during all hours that the hospital is providing services to such patient (a current requirement under §489.20(w)), the hospital must obtain a signed acknowledgment from the patient stating that the patient understands that no physician is available for that period. We are implementing this requirement in new §411.362(b)(5)(i) and in new §489.20(w)(2). All hospitals (not merely physician-owned hospitals) will be required to add an acknowledgment line to their existing disclosure forms, obtain the required signature from the patient and include a copy of the notice in the patient's medical record.

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 (Act) 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 Act 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 Act 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.

Section 6001 of the Affordable Care Act, enacted on March 23, 2010, set forth the terms of a new section 1877(i)(1) of the Act under which a hospital, among other things, must comply with certain disclosure requirements to prevent conflicts of interest and comply with certain requirements designed to ensure patient safety.

2. Information Users

The intent of the 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 new disclosures. The required 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 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 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 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 rule, and would result in an inequitable treatment of those beneficiaries and other hospital patients who would not receive the information for disclosure.

7. Special Circumstances

No special circumstances apply to the disclosure requirement.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice for this information collection request published as part of the CY 2011 Outpatient Prospective Payment System proposed rule (75 FR 46436) on August 3, 2010.

The FR notice for this information collection request went on display at the Federal Register on Friday, July 30, 2010.

In addition, the FY 2009 IPPS Final Rule published on August 19, 2008 contained a related information collection request.

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

CMS is not collecting any confidential data.

11. Sensitive Questions

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

12. Burden Estimates (Hours & Wages)

The disclosure requirements associated with the following burdens initially used “175” as the number of hospitals that would qualify as physician-owned. That number related specifically

to physician ownership in specialty hospitals only. For the purpose of updating the total universe of physician-owned hospitals, we have recently received information from the Physician Hospitals of America, a trade association representing physician-owned hospitals, that the current number of physician-owned hospitals is approximately 265.

a. Physician-ownership of hospitals- hospital disclosure--§489.20(u)(1). We estimate that there are roughly 265 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 4 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 5883 for all inpatient services.

   (4 hours/hospital) x 265 hospitals = **1060 hours**

   (1092 disclosures/hospital) x 265 hospitals = 289,380 total disclosures

   289,380 disclosures x (30 seconds/disclosure) x (1 minute/60 seconds) x (1 hour/60 minutes) = **2411.5 hours**

   (1092 disclosures/hospital) x 265 hospitals = 289,380 total disclosures

   289,380 disclosures x (30 seconds/disclosure) x (1 minute/60 seconds) x (1 hour/60 minutes) = **2411.5 hours**

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

   (17,472 disclosures/hospital) x 265 hospitals = 4,630,080 total disclosures

   4,630,080 disclosures x (30 seconds/disclosure) x (1 minute/60 seconds) x (1 hour/60 minutes) = **38,584 hours**

   (17,472 disclosures/hospital) x 265 hospitals = 4,630,080 total disclosures

   4,630,080 disclosures x (30 seconds/disclosure) x (1 minute/60 seconds) x (1 hour/60 minutes) = **38584 hours**

   The annual hour burden was assumed to be 77,168 for all outpatient services.

Using published Bureau of Labor Statistics (BLS) wage information for mean hourly wages for attorneys ($62.03) and healthcare support workers ($15.07), we estimate that the total cost nationally would be $1,301,356.16.

b. Physician-ownership of hospitals – patient disclosure and staff physician disclosure--§489.20(u)(1). Pursuant to current §489.20(u)(1), hospitals are required to provide a list of their physician owners/investors to patients upon request at the beginning of their inpatient stay or outpatient visit. 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 and also a minimal burden for hospitals to disseminate such lists to staff physicians However, as indicated in sectionxxxxx. of CMS 1504-FC,, we are unable to estimate the number of requests that a hospital may receive. Therefore, we are assigning 1 burden hour to this requirement until such time that we can conduct an accurate burden analysis for this information collection requirement.

265 hospitals x 1 response/hospital x 1 hour/response = **265 hours** (Patient Disclosure)

265 hospitals x 1 response/hospital x 1 hour/response = **265 hours** (Staff Physician Disclosure)

Using published BLS wage information for mean hourly wages for healthcare support workers, we estimate that the total cost nationally would be $7,987.10.

c. Physician-ownership of hospitals – medical staff by-laws/policies--§411.362(b)(3)(ii)(A) and §489.20(u)(2). We estimate that there are roughly 265 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. Additionally, section 6001(a) of the Affordable Care Act added a requirement that the referring physician disclose to his or her patient if a treating physician has ownership or investment interest in the hospital. We are implementing this requirement in new §411.362(b)(3)(ii)(A). We estimate that each hospital will use in-house counsel and spend 2 hours revising medical staff by-laws and policies governing medical staff membership or admitting privileges.

(2 hours/hospital) x 265 hospitals = **530 hours**

Using published BLS wage information for mean hourly wages for attorneys, we estimate that the total cost nationally would be $32,875.90.

d. Physician-ownership of hospitals – physician disclosure--§411.362(b)(3)(ii)(A). Section 6001(a) of the Affordable Care Act added a requirement that a referring physician with

ownership or investment interest in a hospital must disclose to his or her patient if a treating physician at the hospital also has an ownership or investment interest. 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 an 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 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--§489.20(u)(1). We estimate that 10 percent of the 265 physician-owned hospitals, or approximately 26.5 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 26.5 hospitals = **26.5 hours**

Using published BLS wage information for mean hourly wages for attorneys, we estimate that the total cost nationally would be $1643.80.

f. No 24/7 on-site physician--§411.362(b)(5)(i) and §489.20(w)(2). Building upon the current requirement in §489.20(w) that a hospital must disclose to a patient if a physician will not be available during all hours that the hospital is providing services to such patient, section 6001(a) of the Affordable Care Act added a new requirement that the hospital must obtain a signed acknowledgment from the patient stating that the patient understands that no physician is available for that period. We have added §411.362(b)(5)(i) and new §489.20(w)(2) describing the new requirement. We estimate that there are roughly 2557 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 1306 critical access hospitals and 16 religious non-medical institutions; 8% of the 3637 (291) short-term acute care and 8% of the 78 (6) children's hospitals; and 83% of the 495 psychiatric hospitals (411), 83% of the 224 (186) rehabilitation hospitals, and 83% of the 411 (341) 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 (including the new requirement that a hospital must add an acknowledgment line to the current disclosure form and obtain a signed acknowledgement from the patient stating that the patient understands that a physician may not be available at all times), 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 1,196,932.6 nationally.
Development-- (4 hours/hospital) x (2557) hospitals = **10,228 hours**
2557 hospitals x (1092 disclosures/hospital) = **2,792,244** disclosures

Disclosures-- 2,792,244 disclosures x (30 seconds/disclosure) x (1 minute/60 seconds) x (1 hour/60 minutes) = **23,269 hours**

2557 hospitals x (1092 disclosures/hospital) = 2,792,244 disclosures

Obtain Patient Signature-- 2,792,244 disclosures x (30 seconds/disclosure) x (1 minute/60 seconds) x (1 hour/60 minutes) = **23,269 hours**

Copy and Record-- 2,792,244 disclosures x (30 seconds/disclosure) x (I minute/60 seconds) x (1 hour/60 minutes) = **23,269 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 2557 hospitals = 44,675,904 total disclosures

44,675,904 disclosures x (30 seconds/disclosure) x (1 minute/60 seconds) x (1 hour/60 minutes) = **372,299.2 hours**

(17,472 disclosures/hospital) x 2557 hospitals = 44,675,904 total disclosures

44,675,904 disclosures x (30 seconds/disclosure) x (1 minute/60 seconds) x (1 hour/60 minutes) = **372,299.2 hours**

Copy and record—44,675,904 disclosures x (30 seconds/disclosure) x (1 minute/60 seconds) x (1 hour/60 minutes) = **372,299.2 hours**

Using published BLS wage information for mean hourly wages for attorneys and healthcare support workers, we estimate that the total cost nationally would be $18,518,082.

g. Website/public advertising disclosure-- §411.362(b)(3)(ii)(C). We estimate that there are roughly 265 hospitals that would qualify as physician-owned. These hospitals would be required to disclose on any public website for the hospital or in any public advertising that the hospital is owned or invested in by physicians. We estimate that it will take each hospital 1 hour to develop and place this information on its website and/or in a public advertisement and an additional 30 minutes annually for a hospital to review and update such information. We have added §411.362(b)(3)(ii)(C) describing the new requirements.

Development-- 265 hospitals x 1 response/hospital x 1 hour/response = **265 hours**

Review and Update—265 hospitals x 1 response/hospital x 30 minutes/response = **132.5 hours**

Using published BLS wage information for mean hourly wages for healthcare support workers, we estimate that the total cost nationally would be $5990.32.

13. Capital Costs

There are no capital costs anticipated as a result of the 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 required disclosure.

15. Changes to Burden

This collection of information includes several requirements that we have included in the CY 2010 OPPS Final Rule that implements, among other things, the disclosure requirements set forth in section 6001(a) of the Affordable Care Act.

First, a hospital will now be required to disclose on any public website for the hospital or in any public advertising that it is owned or invested in by physicians. We are implementing this requirement in new §411.362(b)(3)(ii)(C).

Second, a hospital must have procedures in place to require that a referring physician owner or investor in a hospital, as part of his continued medical staff membership or admitting privileges, disclose to the patient being referred to the hospital any ownership or investment interest by the patient's treating physician(s). We are implementing this requirement in new §411.362(b)(3)(ii)(A.

Finally, following a hospital's disclosure to a patient that it does not have a physician available during all hours that the hospital is providing services to such patient (a current requirement under §489.20(w)), the hospital must obtain a signed acknowledgment from the patient stating that the patient understands that no physician is available for that period. We are implementing this requirement in new §411.362(b)(5)(i) and in new §489.20(w)(2).

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.