Supporting Statement
Disclosures to Patients by Certain Hospitals & Critical Access Hospitals

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 proposal is contained in the FY 2008 Inpatient Prospective Payment System Notice of Proposed Rulemaking.

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. CMS 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, CMS has proposed a change to its regulations 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.

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, CMS also proposes to address 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. There has also been significant Congressional interest in how CMS assures the safety of patients experiencing medical emergencies. Following the same principle of increased transparency of hospital operations to patients, CMS has proposed a change to its regulations 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.

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 CMS 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 are 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 is no specified form to be used for the proposed disclosure. The proposed disclosure 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 or no modification, to satisfy the proposed new regulatory requirements.

CMS does 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 disclosure entails a minimal burden in general, since the same disclosure statement could be used by a hospital for all of its 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 on April 27, 2007.

In addition, the IPPS NPRM went on display at the Federal Register on Friday, April 13, 2007.
In preparing the August, 2006 Report to Congress on the Strategic and Implementing Plan for Specialty Hospitals CMS 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. CMS estimates 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**

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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. No 24/7 on-site physician. CMS estimates 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 would 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 would 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 would occur as part of this proposed required disclosure.

15. Changes to Burden

This is a new collection of information promulgated by the regulation CMS-1533-P (72 FR 24680).

In addition, we revised the information collection after the publication of the 60-day FR notice based on public comments we received. One commentor stated that it believed CMS's estimate of burden associated with this requirement was grossly understated and appears to be based solely on inpatient admissions, with no estimate for outpatient visits. We have adjusted

the PRA burden estimate for both the physician-ownership disclosure and the physician-availability disclosure to include outpatient visits as well as inpatient admissions.

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.