

Supporting Statement
DISCLOSURES REQUIRED OF CERTAIN HOSPITALS AND CRITICAL ACCESS HOSPITALS
REGARDING PHYSICIAN OWNERSHIP AND ON-SITE AVAILABILITY OF AN MD/DO
CMS-10225, OCN 0938-1034

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 approval, under the Paperwork Reduction Act and 5 CFR 1320.6, of the revised burden estimate set forth below. The 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, the CY 2011 Outpatient Prospective Payment System Final Rule, and the CY 2012 Outpatient Prospective Payment System Final Rule.

Background

(1) Section 5006(a)(1) of the Deficit Reduction Act of 2005 (the 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 the hospitals 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 revised the 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.

Because the report also found that less than half of specialty hospitals have emergency departments (compared to roughly 92% of short-term acute care hospitals), we also addressed issues that arise when patients 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 the 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 patients upon admission or registration for both inpatient and outpatient services. This collection is also approved under OMB 0938-1034.

Further, §489.20(u)(2) provides that physician-owned hospitals must 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, 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 disclosures in the patients' medical records. This collection is approved under OMB 0938-10236.

(2) 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 (rural provider exception). 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 sections 1877(d)(2) and (d)(3) of the Act to impose additional restrictions on hospitals seeking 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 disclosure requirements set forth in section 6001(a) of 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 implemented this requirement in §411.362(b)(3)(ii)(C). Hospitals are 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 chapter 42) of the physician. We implemented this requirement in §411.362(b)(3)(ii)(A). Hospital legal staff are required to develop, draft, and implement changes to the hospital's medical staff bylaws and policies governing admitting privileges, and hospitals are required to provide a list of physician owners or investors to all of their staff physicians. Referring physicians in turn are 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, the hospital must obtain a signed

acknowledgment from the patient stating that the patient understands that no physician is available for that period. We implemented this requirement in §411.362(b)(5)(i) and in §489.20(w)(2). All hospitals (not merely physician-owned hospitals) were 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. However, in the CY 2012 Outpatient Prospective Payment System final rule, published on November 30, 2011, we revised the general disclosure requirement (originally adopted as §489.20(v), but subsequently renumbered as §489.20(w)) related to disclosures a hospital must make when it does not have an MD or DO on site 24 hours/day, 7 days/week. As revised, §489.20(w) requires hospitals to make required disclosures to fewer patients than previously; specifically, individual written disclosures would need to be made to all inpatients, and only to those outpatients receiving observation services, surgery, and other procedures requiring anesthesia. For patients in the emergency department, posting of signs suffices in place of issuing individual disclosure notices. For hospitals with multiple campuses providing inpatient services, a separate determination is required for each campus as to whether a notice is required. In light of the requirements at §411.362(b)(5), the more comprehensive disclosure requirement continues to apply to physician-owned hospitals, but other hospitals experienced a reduced reporting burden as a result of the revisions to §489.20(w).

A. 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 factor(s) 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 informed of a hospital's physician ownership, whether 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 DRA required 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 we would explore changes to our regulations to require hospitals to disclose to patients, investment interests of physicians who make referrals to the hospitals.

Sections 1861(e)(1) through 1861(e)(8) of the 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) of the Act subjects CAHs to the requirements of section 1861(e), with certain specified exceptions.

Section 6001 of the Affordable Care Act 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 in order to avail itself of the whole hospital and rural provider exceptions to the physician self-referral law.

2. Information Users

The intent of the disclosures is to increase transparency regarding hospital ownership and operations as patients make decisions regarding where to receive care.

3. Use of Information Technology

There are no specified forms to be used for the disclosures. The required disclosures to patients must be in writing and are 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

As further discussed below, we believe that the majority of affected physician-owned hospitals will have already developed and reviewed the content of the disclosures that identify themselves as physician-owned. However, for the remaining 10 percent of hospitals that still have to develop the necessary disclosures, we have been advised by industry representatives that physician-owned hospitals already routinely disclose that fact to their patients. Therefore, it is likely that hospitals that currently make such disclosures could use their current disclosure, with limited modification, to satisfy the 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.

Similarly, we estimate that the majority of affected hospitals will have already developed and reviewed the content of their disclosures stating that a physician will not be available during all hours that the hospital is providing services to a patient. To the extent that any hospitals still have to develop this disclosure, they could likely use current disclosures, with limited modification, to satisfy the 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 requirements.

6. Less Frequent Collection

The only way in which to conduct the collection less frequently would be to make the required disclosures to select 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 or disclosure.

7. Special Circumstances

No special circumstances apply to the disclosure requirement.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice published on December 13, 2013 (78 FR 75925). No comments were received.

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)

Summary Table

CFR Section	Response Type	# Respondents	Time (hr per response)	# Responses (per respondent)	Total Responses (all respondents)	Total Annual Time (all respondents)
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489.20(u)(1) disclosure dev/review (attorney)	TPD	26.5 (10% of 265)	4.0	1	26.5	106
489.20(u)(1) inpatient disclosure	TPD	265	0.008 (30 sec)	1,092	289,380	2,412
489.20(u)(1) inpatient (copy and record)	Record keeping		0.008 (30 sec)			2,412
489.20(u)(1) outpatient disclosure	TPD	265	0.008 (30 sec)	17,472	4,630,080	38,584
489.20(u)(1) outpatient copy and record	Record keeping		0.008 (30 sec)			38,584
489.20(u)(1) disclosure of physician owners/investors to patients	TPD	265	1.0	1	265	265
489.20(u)(1) disclosure of physician owners/investors to staff physicians	TPD	265	1.0	1	265	265
411.362(b)(3)(ii)(A) and 489.20(u)(2) medical staff by-laws and policies (attorney)	TPD	26.5 (10% of 265)	2.0	1	26.5	53
411.362(b)(3)(ii)(A) ¹						
489.20(u)(1) attestation of non-referring status (attorney)	TPD	26.5 (10% of 265)	1.0	1	26.5	27
489.20(w)(1) - (5) disclosure	TPD	2,597	0.008 (30 sec)	1,966	5,105,702	42,584
489.20(w)(1) - (5) patient signature	TPD		0.008 (30 sec)			42,584
489.20(w)(1) - (5) copy and record	Record keeping	265	0.008 (30 sec)	18,564	4,919,460	42,584
411.362(b)(5)(i) disclosure	TPD		0.008 (30 sec)			40,996
411.362(b)(5)(i) patient signature	TPD	265	0.008 (30 sec)	1	265	40,996
411.362(b)(5)(i) copy and record	Record keeping		0.008 (30 sec)			40,996
411.362(b)(3)(ii)(C)	TPD	265	0.5	1	265	133

1 As further detailed below, we are unable to estimate the number of physicians who have an ownership or investment interest in hospitals. Therefore, we cannot conduct an accurate burden analysis for this information collection requirement at this time.

	TOTAL	2,597	--	--	14,945,476	333,581
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TPD = Third-party disclosure.

Details

For purpose of this request, we continue to assume that the number of physician-owned hospitals is approximately 265.

- a. Physician-ownership of hospitals- hospital disclosure--§489.20(u)(1). We estimate that approximately 265 hospitals 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 assume that in-house counsel will have already developed/reviewed the content of the disclosures for approximately 90 percent of the physician-owned hospitals subject to this requirement. For the remaining 10 percent of hospitals, we assume 4 hours/year/hospital for in-house counsel to develop/review the content of the disclosure. We assume 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 burden is estimated at 4,929 hr (2,411.5 + 2,411.5 + 106) for all inpatient services.

$$(4 \text{ hours/hospital}) \times (265 \text{ hospitals} \times .10) = \mathbf{106 \text{ hours}}$$

$$(1092 \text{ disclosures/hospital}) \times 265 \text{ hospitals} = 289,380 \text{ total disclosures}$$

$$289,380 \text{ disclosures} \times (30 \text{ seconds/disclosure}) \times (1 \text{ minute}/60 \text{ seconds}) \times (1 \text{ hour}/60 \text{ minutes}) = \mathbf{2411.5 \text{ hours}}$$

$$(1092 \text{ disclosures/hospital}) \times 265 \text{ hospitals} = 289,380 \text{ total disclosures}$$

$$289,380 \text{ disclosures} \times (30 \text{ seconds/disclosure}) \times (1 \text{ minute}/60 \text{ seconds}) \times (1 \text{ hour}/60 \text{ minutes}) = \mathbf{2411.5 \text{ hours}}$$

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

$$(17,472 \text{ disclosures/hospital}) \times 265 \text{ hospitals} = 4,630,080 \text{ total disclosures}$$

$$4,630,080 \text{ disclosures} \times (30 \text{ seconds/disclosure}) \times (1 \text{ minute}/60 \text{ seconds}) \times (1 \text{ hour}/60 \text{ minutes}) = \mathbf{38,584 \text{ hours}}$$

(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) = **38,584 hours**

The annual burden is estimated at 77,168 hr (38,584 + 38,584) 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 \$1,237,386.40.

- b. Physician-ownership of hospitals – patient disclosure and staff physician disclosure--§489.20(u)(1). Pursuant to §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, we are still unable to estimate the number of requests that a hospital may receive. Therefore, we continue to assign 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 approximately 265 hospitals qualify as physician-owned. These hospitals must 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 whom they refer to the hospital, any physician (including immediate family member) ownership or investment interest in the hospital. Section 6001(a) of the Affordable Care Act added a requirement that a referring physician must disclose to his or her patient if a treating physician has ownership or investment interest in the hospital. We implemented this requirement in §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. We assume that 90 percent of physician-owned hospitals subject to these requirements have already completed their revision of medical staff by-laws and policies governing medical staff membership or admitting privileges.

$$(2 \text{ hours/hospital}) \times (265 \text{ hospitals} \times .10) = 53 \text{ hours}$$

Using published BLS wage information for mean hourly wages for attorneys, we estimate that the total cost nationally would be \$3,287.59.

- d. Physician-ownership of hospitals – physician disclosure--§411.362(b)(3)(ii)(A). As stated above, 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 RIN 0938–AP15 (CMS-1390-P and -F), we are unable to estimate the number of physicians who have an ownership or investment interest in hospitals. Therefore, we are continuing to assign 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.

$$(1 \text{ hours/hospital}) \times 26.5 \text{ hospitals} = \mathbf{26.5 \text{ hours}}$$

Using published BLS wage information for mean hourly wages for attorneys, we estimate that the total cost nationally would be \$1,643.80.

- f. No 24/7 on-site physician--§489.20(w)(1) – (5) and §411.362(b)(5)(i). Building upon the 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 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 added §411.362(b)(5)(i) and §489.20(w)(2) describing this requirement.

With respect to the regulations governing provider agreement requirements, we subsequently revised §489.20(w) to amend §489.20(w)(1), renumber §489.20(w)(2) as §489.20(w)(4), and to add new §489.20(w)(2), (3) and (5), with the result that all inpatients on each campus of a hospital without 24/7 MD/DO coverage must receive and acknowledge a written notice, as well as all outpatients receiving observation services,

surgery or a procedure requiring anesthesia. We estimate that approximately 2,597 hospitals and critical access hospitals that may not have a physician on-site at all times, and that under the revised regulation each will make on average 1,966 disclosures per year. We assumed 4 hours/year/hospital for in-house counsel to develop/review the content of the disclosure (including the 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). We assume, however, that 100 percent of the 2,597 hospitals affected have already conducted this one-time development and review of the content of their disclosures after implementation of the CY 2012 Outpatient Prospective Payment System rule, and that this cost will not be repeated going forward. Consequently, we are removing that estimate from this package.

We continue to assume 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.

Disclosures—5,105,702 disclosures x (30 seconds/disclosure) x (1 minute/60 seconds) x (1 hour/60 minutes) = **42,548 hours**

2,597 hospitals x (1,966 disclosures/hospital) = 5,105,702 disclosures

Obtain Patient Signature-- 5,105,702 disclosures x (30 seconds/disclosure) x (1 minute/60 seconds) x (1 hour/60 minutes) = **42,548 hours**

Copy and Record-- 5,105,702 disclosures x (30 seconds/disclosure) x (1 minute/60 seconds) x (1 hour/60 minutes) = **42,548 hours**

Using published BLS wage information for mean hourly wages for attorneys and healthcare support workers, we estimate that the total cost nationally for the disclosure requirement at § 489.20(w) would be \$2,551,148.00.

The CY 2012 Outpatient Prospective Payment System final rule did not alter the requirement set forth at § 411.362(b)(5)(i) that physician-owned hospitals that do not have a doctor of medicine or osteopathy on site 24 hours a day, 7 days a week, must provide notice to all inpatients and all outpatients. The burden associated with this requirement was approved under OCN 0938-1034. Because physician-owned hospitals are subject to the more comprehensive disclosure requirement, we estimate that approximately 265 physician-owned hospitals will each make an average 18,564 disclosures per year. We assume that 100 percent of the affected physician-owned hospitals will have already conducted the one-time development and review of the content of their disclosure, and that the cost associated with development will not be repeated. Consequently, we are removing that estimate from this package.

We continue to assume 30 seconds per disclosure to include a standard notice to be

delivered to patients, and another 30 seconds to include a copy of the notice in the patient's medical record.

Disclosures – 265 hospitals x (18,564 disclosures/hospital) = 4,919,460 disclosures
4,919,460 disclosures x (30 seconds/disclosure) x (1 minute/60 seconds) x (1 hour/60 minutes) = 40,995.5 hours

Obtain Patient Signature – 4,919,460 disclosures x (30 seconds/disclosure) x (1 minute/60 seconds) x (1 hour/60 minutes) = 40,995.5 hours

Copy and Record – 4,919,460 disclosures x (30 seconds/disclosure) x (1 minute/60 seconds) x (1 hour/60 minutes) = 40,995.5 hours

Using published BLS wage information for mean hourly wages for attorneys and healthcare support workers, we estimate that the total cost associated with the disclosure requirement for physician-owned hospitals under § 411.362(b)(5)(i) is \$1,919,158.36.

g. Website/public advertising disclosure-- §411.362(b)(3)(ii)(C). We estimate that approximately 265 hospitals qualify as physician-owned. These hospitals are 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. Section 411.362(b)(3)(ii)(C) describes these requirements. We estimate that it will take each hospital 30 minutes annually to review and update the information on its website and/or in public advertisement.

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 \$1,996.78.

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 these required disclosures.

15. Changes to Burden

We are adjusting our burden estimate to reflect the revisions to § 489.20(w) made in the CY 2012 Outpatient Prospective Payment System final rule. As stated above, many hospitals experienced a reduced reporting burden as a result of the revisions to § 489.20(w). The burden associated with this requirement was previously estimated to be 1,196,932.6 hours and \$18,518,082. Under revised § 489.20(w), the burden is estimated to be 127,644 hours and \$2,551,148.

In addition, we are adjusting our burden estimates associated with §§ 489.20(u), 411.362(b)(5)(i), and 411.362(b)(3)(ii)(C), because we believe (1) that in-house counsel will have already developed and reviewed the content of the disclosures concerning physician-ownership and whether there is a 24/7 on-site physician; (2) that approximately 90 percent of affected hospitals will have already revised their medical staff bylaws and policies requiring 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; and (3) that the majority of affected hospitals will have already developed and placed information on their respective websites and/or in public advertisements that they are owned or invested in by physicians. The burden previously estimated for the relevant portion of these regulations was 12,215.5 hours and \$170,369.82 (please note that these numbers are only a subset of the entire burden estimate that was previously approved for these regulations). The burden for the revised portion of these regulations is 291.5 hours and \$11,859.55 (again, these numbers are only a subset of the total burden estimate associated with these regulations).

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

B. Collections of Information Employing Statistical Methods

This collection does not employ statistical methods.