Supporting Statement (Revised)

DISCLOSURES REQUIRED REGARDING PHYSICIAN OWNERSHIP AND ON-SITE AVAILABILITY OF AN MD/DO

CMS-10225

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 this collection, 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 this collection, 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 for as long as the medical record is kept by the facility. This collection is approved under a separate collection, OMB 0938-10236.

(2) Section 1881 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 1881(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 1881(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 1881(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 1881(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.

There are 3 parts to this information collection request (ICR), which are set forth in section 6001(a) of the Affordable Care Act. These requirements 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).

As further discussed below, we believe that the majority of established hospitals and CAHs, both physician-owned and non-physician owned, will have already developed and reviewed the content of the disclosures that identify whether they are physician-owned. We believe that only those new hospitals and CAHs that are established each year would need to develop the required web-based disclosures and patient disclosure statements.

We estimate that the 5 year average number of hospitals between 2013 and 2017 was 4,882. We estimate that the 5 year average number of CAHs between 2013 and 2017 was 1,346. Therefore, we estimate that the total number of hospitals and CAHs per year is 6,228.
We further estimate that the average number of new hospitals between 2013 and 2017 was 73 and the average number of new CAHs during this time frame was 8. Therefore, we estimate that there is an average of 81 new hospitals and CAHs per year that would have to develop the necessary disclosures.

We further believe that approximately 10% of hospitals and CAHs are physician-owned. This means that approximately 623 of the 6,228 existing hospitals are physician owned and approximately 8 out of the 81 new hospitals/CAHs per year would be physician owned.

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.

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 it 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 1881(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

These data collection requirements do not duplicate any of other information collection that is specific to the hospital program.

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

The requirement that the disclosure statement be maintained in the medical records for as long as the facility maintains the medical record may qualify as a special circumstance.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice published on May 10, 2017 (82 FR 21817). There were no public comments.

The 30-day Federal Register notice published on July 17, 2017 (82 FR 32708). There were no comments were received.

9. Payments/Gifts to Respondents

There are no gifts provided

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)
489.20(u)(1) disclosure rev/review (attorney)	Creating disclosure TPD	8 (10% of 81)	4.0	1	8	32
489.20(u)(1) inpatient disclosure	Presenting disclosure to patients TPD	81	0.008 (30 sec)	2,550	206,550	1,721
489.20(u)(1) inpatient (copy and record)	Record keeping		0.008 (30 sec)		206,550	1,721
489.20(u)(1) outpatient disclosure	Presenting disclosure to patients TPD	81	0.008 (30 sec)	20,486	1,659,366	13,828
489.20(u)(1) outpatient copy and record	Record keeping		0.008 (30 sec)		1,659,366	13,828
489.20(u)(1) disclosure of physician owners/investors	Creating disclosure TPD	81	1.0	1	81	81
489.20(u)(1) disclosure of physician owners/investors to staff physicians	Creating disclosure TPD	81	1.0	1	81	81

411.362(b)(3)(ii)(A) and 489.20(u)(2) medical staff by-laws and policies (attorney)	Creating disclosure TPD	8 (10% of 81)	2.0	1	8	16
411.362(b)(3)(ii)(A)[1]						
489.20(u)(1) attestation of non-referring status (attorney)		8181)	1.0	1	81	81
CFR Section	**Response Type**	**# Respondents**	**Time (hr per response)**	**# Responses (per respondent)**	**Total Responses (all respondents)**	**Total Annual Time (all respondents)**
489.20(w)(1) – (5) disclosure	Presenting disclosure to patients TPD	2,479	0.008 (30 sec)	2,304	5,711,616	47,597
489.20(w)(4) patient signature	patient signature TPD		0.008 (30 sec)		5,711,616	47,597 4
489.20(w)(1) – (5) copy and record	Record keeping		0.008 (30 sec)		5,711,616	47,597
411.362(b)(5)(i) disclosure	Presenting disclosure to patients TPD	81	0.008 (30 sec)	3,992	291,416	2,428
411.362(b)(5)(i) patient signature	Pt signing disclosure TPD		0.008 (30 sec)		291,416	2,428
411.362(b)(5)(i) copy and record	Record keeping		0.008 (30 sec)		291,416	2,428
411.362(b)(3)(ii)(C)	Staff updating disclosures on website/advertising TPD	81	0.5	1	81	41
	TOTAL	**3,062**	**--**	**--**	**21,741,260**	**181,505**

TPD = Third-party disclosure.

Details

As stated above, we estimate that approximately 81 new hospitals and CAHs per year would have to develop the necessary web-based and patient disclosures. For CY 2016 there were approximately 15,882,402 inpatient claims submitted to the MACs for payment from hospitals and

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.

CAHs. Based on this submitted claim data we estimate that the average number of new inpatients per year in a hospital/CAHs to be 2,550.

Inpatients: (15,882,402 inpatient claims/6,228 total hospitals/CAHs) = 2,550 average number of new inpatients per year in a hospital/CAH.

For CY 2016 there were approximately 127,585,067 outpatient claims submitted to the MACs for payment from hospitals and CAHs. Based on this submitted claim data we estimate that the average number of outpatients per year in a hospital/CAHs to be 20,486.

Outpatients: (127,585,067 outpatient claims/6,228 total hospitals/CAHs) =20,486 outpatients per year in a hospital/CAHs.

a. Physician-ownership of hospitals- hospital disclosure--§489.20(u)(1).

We estimate that approximately 81 hospitals qualify as physician-owned and would have to make such disclosures. 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.

We estimate each hospital or CAH will conduct 2,550 disclosures per year for inpatient visits. Using published Bureau of Labor Statistics (BLS)[2] wage information the mean hourly wages for an attorney is $113.62 ($56.81/hr and doubled for fringe benefits estimation=$113.62). The average hourly wage for a healthcare support workers[3] is $36.26 ($18.13/hr and doubled for fringe benefits = $36.26).

1. Number of Disclosures
   We estimate that the total number of disclosures made across all hospitals and CAHs is **206,550.**

   - **2,550** disclosures/hospital x **81** hospitals = **206,550**

2. Time Burden Associated With In House Counsel Review of Disclosure
   We estimate that the total amount of time required by in-house counsel for hospitals and CAHs to review the disclosures would be **324** hours.

2 https://www.bls.gov/ooh/legal/lawyers.htm
3 https://www.bls.gov/oes/current/oes319099.htm

- **4** hours/hospital x **81** hospitals x **.10** = **324** hours

3. Cost Associated with In House Counsel Review of Disclosures
   We estimate that the total cost for in-house counsel to review the disclosures would be **$36,813.**

   - **$113.62** x **324**= $**36,813**

4. Time For Staff Presenting Disclosure To Patients
   We estimate each hospital or CAH will conduct **206,550** disclosures per year. We further estimate that the total time burden for staff presenting disclosures to patients across all hospitals and CAHs would be **1,421** hours.

   - **170,478** disclosures x **30** seconds per disclosure = **5,114,340** seconds per all disclosures presented

   - **5,114,340** seconds divided by 60 seconds per min. = **85,239** minutes

   - **85,239** minutes divided by 60 minutes per hour = **1,421** hours

5. Cost Burden Associated With Staff Presenting Disclosures to *Inpatients*
   We estimate that the total estimated annual cost for the time required for staff to present the disclosure to the patient is **$51,525**

   - **$36.26** x **1,421** hours = **$51,525**

6. Time Burden Associated With Record Keeping Requirements for Disclosures to *Inpatients*
   The annual time burden associated with record keeping related to disclosures to inpatients is estimated at **2,842** hours for all inpatient visits.

   - **1421** hours +**1421** hours = **2,842** hours

7. Cost Burden Associated With The Record Keeping Requirements for Disclosures to *Inpatients*
   The estimated cost associated with record keeping related to disclosure to inpatients in **$51,525.**

   - **$36.26** x 1,421 hours = **$51,525**

   .

8. Time Burden Associated with Staff presenting disclosures to *Outpatients*
   We estimate each hospital or CAH will conduct 20,486 disclosures per year for outpatient visits. We further estimate that the total time burden for staff presenting

disclosures to outpatients across all hospitals and CAHs would be **13,828** hours.

- **20,486** disclosures per hospital x **81** hospitals = **1,659,366** total disclosures across all hospitals and CAHs

- **1,659,366** x **30** seconds = **49,780,980** seconds

- **49,780,980** seconds divided by **60** seconds per minute = **829,683** minutes
- **829,683** minutes divided by **60** minutes per hour = **13,828** hours

9. Costs Burden Associated with Staff presenting disclosures to *Outpatients*
   We estimate each hospital or CAH will conduct 20,486 disclosures per year for outpatient visits. We further estimate that the total time burden associated with staff disclosures to outpatients across all hospitals and CAHs would be **13,828** hours and the total cost burden would be **$501,403**

   - **$36.26** x **13,828** = **$501,403**

10. Time Burden Associated with Record Keeping for *Outpatients*
    We estimate each hospital or CAH will conduct **20,486** disclosures per year for outpatient visits. We further estimate that the total time burden for record keeping related to staff presenting disclosures to outpatients across all hospitals and CAHs would be **13,828** hours.

    - **20,486** disclosures per hospital x 81 hospitals = **1,659,366** total disclosures across all hospitals and CAHs

    - **1,659,366** x **30** seconds = **49,780,980** seconds

    - **49,780,980** seconds divided by **60** seconds per minute = **829,683** minutes

    - **829,683** minutes divided by **60** minutes per hour = **13,828** hours

11. Cost Burden Associated with Record Keeping for *Outpatients*
    We estimate each hospital or CAH will conduct 20,486 disclosures per year for outpatient visits. We further estimate that the total time burden associated with recordkeeping related to staff disclosures to outpatients across all hospitals and CAHs would be **13,828** hours.

    - $36.26 per hour x 13,828 hours = $501,403

12. Total Time Burden for All Outpatient Services
    The total estimated annual time burden for all services related to patient disclosures to outpatients is **27,656** hours.

- **13,828** hours + **13,828** hours = **27,656** hours

b. Physician-ownership of hospitals – patient disclosure and staff physician disclosure required by §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.

1. Time burden Associated with Patient Disclosure Under §489.20(u)(1)
We estimate that the time burden associated with providing patient disclosures as required by §489.20(u)(1) would be **81 hours** per all provided.

    - 81 hospitals x 1 response/hospital = 81 responses per all hospitals/CAHs

    - 1 hour/response x 81 responses per all new hospitals/CAHs = 81 hours per all patient disclosures performed

2. Cost burden Associated with Patient Disclosure Under §489.20(u)(1)
We estimate that the cost associated with providing patients in hospitals and CAHs with the disclosures required by §489.20(u)(1) to be **$2,937**.

    This task would be performed by a medical clerk. We estimate that this task would take one hour per response. The mean average hourly wage for a medical clerk is $36.26.

    - $36.26 per hour x 81 hospitals and CAHs = $2,937

3. Time burden Associated with Staff Physician's Disclosure By §489.20(u)(1)
We estimate that the time burden associated with providing the disclosure about the physician's on staff as required by §489.20(u)(1) would be **81 hours** per all staff physician disclosures provided.

    - 81 hospitals x 1 response/hospital = 81 responses per all hospitals/CAHs

    - 1 hour/response x 81 responses per all new hospitals/CAHs = 81 hours per all staff physician disclosures performed

4. Cost burden Associated with Staff Physician's Disclosure Under §489.20(u)(1)
We estimate that the cost associated with providing patients in hospitals and CAHs

with the disclosures about physicians on staff required by §489.20(u)(1) to be **$2,937**.

This task would be performed by a medical clerk. We estimate that this task would take one hour per response. The mean average hourly wage for a medical clerk is $36.26.

- $36.26 per hour x 81 hospitals and CAHs = **$2,937**

5. Total Time Burden for Disclosure Required By §489.20(u)(1)
The total time burden associated with the patient disclosures and staff physician disclosures required by §489.20(u)(1) is estimated to be **162 hours**.

Time burden for patient disclosures:	81 hours
Time burden for staff physician disclosures	81 hours
Total time burden under §489.20(u)(1):	**162 hours**

6. Total Cost Burden for Disclosure Required By §489.20(u)(1)
The total time burden associated with the patient disclosures and staff physician disclosures required by §489.20(u)(1) is estimated to be **162 hours**.

Cost burden for patient disclosures:	$2,937
Cost burden for staff physician disclosures	$2,937
Total time burden under §489.20(u)(1):	**$5,874**

c. Physician-ownership of hospitals – medical staff by-laws/policies--§411.362(b)(3)(ii)(A) and §489.20(u)(2).
We estimate that the 5 year average number of hospitals between 2013 and 2017 was 4,882. We estimate that the 5 year average number of CAHs between 2013 and 2017 was 1,346. Therefore, we estimate that the total number of hospitals and CAHs per year is 6,228.

We further estimate that the average number of new hospitals between 2013 and 2017 was 73 and the average number of new CAHs during this time frame was 8. Therefore, we estimate that there is an average of 81 new hospitals and CAHs per year that would have to develop the necessary disclosures.

Hospitals and CAHs 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 further believe that approximately 10% of hospitals and CAHs are physician-owned. This means that approximately 623 of the 6,228 existing hospitals are physician owned and approximately 8 out of the 81 new hospitals/CAHs per year would be physician owned.

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 all existing hospitals and CAHs subject to these requirements have already completed their revision of medical staff by-laws and policies governing medical staff membership or admitting privileges.

1. **Time Burden Associated With In House Counsel Revision of Medical Staff By-Laws and Policies Governing Medical Staff Membership or Admitting Privileges**
   We estimate that the time burden associated with the in house counsel revision of medical staff by-laws and policies governing medical staff membership or admitting privileges is 16 hours

   - 2 hours per disclosure x 81 hospitals = 162
   - 162 x .10 = 16 hours

2. Cost Burden Associated With In House Counsel Revision of Medical Staff By-Laws and Policies Governing Medical Staff Membership or Admitting Privileges
   The time required for this task is 16 hours. According to the U.S. Bureau of Labor Statistics, the mean average hourly wage for an attorney is $113.62. Therefore, we estimate that the cost burden associated with the in house counsel revision of medical staff by-laws and policies governing medical staff membership or admitting privileges is **$1,818**

   - $113.62 x 16 hours = $1,818

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.

1. Time Burden Associated with Development of Notice And Making of Copies for Disclosure
   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.

2. Cost Burden Associated with Development of Notice And Making of Copies for

Disclosure
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 81 hospitals & CAHs, or approximately 8 hospitals, do not have at least one physician owner (including immediate family member) who refers to the hospital.

1. Time Burden Associated with Development and Signature of Attestation Required By --§489.20(u)(1)
We estimate one hour for each of these hospitals to develop, sign, and maintain an attestation reflecting this non-referring status. We further estimate that the total time burden for the 8 hospitals would be **8 hours**.

- 1 hours/hospital x 8 hospitals = 8 hours

2. Cost Burden Associated with Development and Signature of Attestation Required By --§489.20(u)(1)
The time required for this task is 16 hours. According to the U.S. Bureau of Labor Statistics, the mean average hourly wage for an attorney is $113.62. Therefore, we estimate that the cost burden associated with the development and signature of attestation required by §489.20(u)(1) is **$909**

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 there are approximately 2,479 hospitals and CAHs that may not have a physician on site at all times, and that under the revised regulation each will make on average 2,304 disclosures per year (10% of the inpatient and outpatient visits occurring on

the campus of the hospital/CAH but not in main hospital/CAH

1. Number of Disclosure of Notice Given about Lack of 24/7 on-site physician as Required By §489.20(w)(1) – (5) and §411.362(b)(5)(i).
   We estimate that the number of disclosure notice s regarding the lack of 24/7 on-site physician coverage as required by §489.20(w)(1) – (5) and §411.362(b)(5)(i) would be 2,304.

   - 2,550 + 20,486 = 23,036 x .10 = 2,304.

2. Time Burden Associated with In-House Counsel Review of the Disclosure of Notice Given About Lack of 24/7 on-site physician as Required By §489.20(w)(1) – (5) and §411.362(b)(5)(i).
   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).

   However, we assume, that 100 percent of the 2,479 hospitals/CAHs 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.

3. Time Burden Associated With Presenting the Disclosure of Notice Given of Lack of 24/7 on-site physician as Required By §489.20(w)(1) – (5) and §411.362(b)(5)(i) to Inpatients and Outpatients.
   We estimate that it would take 30 seconds to present the disclosure notice required by §489.20(w)(1) – (5) and §411.362(b)(5)(i) to patients at the time their inpatient stay or outpatient visit begins. We further estimate that it would take another 30 seconds to include a copy of the disclosure notice in the patient's medical record. The estimated time required to present the disclosures across all inpatient and outpatients is 47,597 hours.
   We estimate that there are 2,479 hospitals that would have to provide the disclosure required by §489.20(w)(1) – (5) and §411.362(b)(5)(i). In additional we estimate that there are an average of 2,304 admissions per hospital per year. Therefore, we estimate that the total number of disclosure across all hospitals per year would be **5,711,616**

   - 2,479 hospitals x 2,304 disclosures/hospital) = 5,711,616 disclosures

   i. Time Burden Associated With Obtaining Patient's Signature on the Disclosure Required By §489.20(w)(1) – (5) and §411.362(b)(5)(i)
   We estimate that it would take 30 second to obtain 30 second for a Medical Clerk to obtain the patients signature on the disclosure form required by

§489.20(w)(1) – (5) and §411.362(b)(5)(i**).** We further estimate the total time burden across all applicable hospitals for this task to be **47, 597** hours.

- 5,711,616 disclosures x 30 sec./disclosure = 171,348,480 sec.
- 171,348,480 seconds divided by 60 seconds per minute = 2,855,808 minutes
- 2,855,808 minutes divided by 60 minutes per hour = 47,597 hours

ii. Time Burden Associated With Copying and Recoding the Signed Patient Disclosure Required By §489.20(w)(1) – (5) and §411.362(b)(5)(i)

We estimate that it would take 30 seconds to include a copy of the disclosure notice in the patient's medical record. We further estimate that the time burden for this task across all applicable hospitals would be **47,597** hours

- 5,711,616 disclosures x 30 sec./disclosure = 171,348,480 sec.
- 171,348,480 seconds divided by 60 seconds per minute = 2,855,808 minutes
- 2,855,808 minutes divided by 60 minutes per hour = 47,597 hours

4. Cost Burden Associated with Providing Notice of Lack of 24/7 on-site physician as Required By -§489.20(w)(1) – (5) and §411.362(b)(5)(i).

We estimate that this task would take 30 seconds per disclosure and would be performed by a medical clerk. According to the U.S. Bureau of Labor Statistics, the mean average hourly wage for a medical clerk is $36.26. Therefore, we estimate that the cost for presentation of patients with the notice of lack of 24/7 on-site physician as required by -§489.20(w)(1) – (5) and §411.362(b)(5)(i) is $1,725,867.

- $36.26 per hour x 7,597 hours = $1,725,867

g. Requirements of set forth at § 411.362(b)(5)(i) as Addressed in the CY 2012 OPPS Final Rule.

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 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.

See the time and cost burden estimates for requirements 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 in section 12(f) above

h. Website/public advertising disclosure-- §411.362(b)(3)(ii)(C).
We estimate that there are approximately 81 new hospitals/CAHs each year would have to develop the necessary web-based and written disclosures to provide to its patients. . 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.

1. Time Burden Associated With Review and Update of the Required Disclosure Language on the Hospital Public Facing Website
We estimate that this task would be performed by a health care support worker. According to the U.S. Bureau of Labor Statistics, the mean average hourly wage for a health care support worker is $36.25. We estimate that this task would take 30 minutes per hospital and 41 hours across all hospitals.

    - 81 hospitals x 1 response/hospital = 81 responses across all hospitals
    - 30 minutes per response x 81 = 40.5 hours (rounder up to 41 hours)

2. Cost Burden Associated With Review and Update of the Required Disclosure Language on the Hospital Public Facing Website
We estimate that this task would be performed by a health care support worker. According to the U.S. Bureau of Labor Statistics, the mean average hourly wage for a health care support worker is **$36.25**. We estimate that the cost associated with this task across all hospitals would be **$1,487.**

    - $36.26 per hour x 41 hours= $1,487.

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 changes in the number of physician owned hospitals and CAHs from the previous package which was 265 compared to the current number of 81. Additionally, for CY 2016 there were changes in the number of inpatient and outpatient claims submitted to the MACs for payment from hospitals and CAHs. This current

claim information was used to calculate burden associated with the estimated inpatients and outpatients that are required to receive disclosure notices. These changes decreased the estimated burden hours from 333,583 to 181,505.

There have been no regulatory changes since the last package to change the estimated burden.

16. Publication/Tabulation Dates
There are no publication dates.

17. Expiration Date
CMS will publish a notice in the Federal Register to inform the public of both the approval and the expiration date. In addition, the public will be able to access the expiration date on OMB's website by performing a search using the OMB control number.

B. Collections of Information Employing Statistical Methods

This collection does not employ statistical methods.