Supporting Statement A
DISCLOSURES REQUIRED REGARDING PHYSICIAN OWNERSHIP AND ON-SITE AVAILABILITY OF AN MD/DO
CMS-10225

A. Background

We are requesting reinstatement of the approval for the data collection CMS-10225. This collection is approved under OMB Control Number 0938-1034.

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 0938-1034.

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).

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 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. <u>Information Users</u>

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

3. <u>Use of Information Technology</u>

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 XX/XX/20X1.

The 30-day Federal Register notice published on XX/XX/2021.

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)

There are currently 107 physician-owned hospitals and CAHs. For CY 2018, there were approximately 36,333,333 inpatient admissions to all hospitals in the U.S, of which 10,791,977 were Medicare beneficiaries. In FY 2018, there were approximately 10,303,000

hospital outpatient surgeries. These two figures added together equates to a total of 46,636,333 annual claim.

a. §489.20(u)(1) - Providing Disclosure to Patients.

Section 489.20(u)(1) requires a physician owned hospital to furnish written notice to each patient at the beginning of the patient's hospital stay or outpatient visit that the hospital is a physician-owned hospital, in order to assist the patient in making an informed decision regarding his or her care, in accordance with §482.13(b)(2) of this subchapter. The notice should disclose, in a manner reasonably designed to be understood by all patients, the fact that the hospital meets the Federal definition of a physician-owned hospital specified in §489.3. For purposes of 489.20(u)(1), the hospital stay or outpatient visit begins with the provision of a package of information regarding scheduled preadmission testing and registration for a planned hospital admission for inpatient care or an outpatient service."

i. Time & Cost Burden Associated with Preparation of the Notice.

This burden would only apply to new physician owned hospitals that have not yet developed the required notice. We estimate that there are approximately 5 new physician owner hospitals established per year.

We estimate that it would take **4 hours** for a new physician owned hospitals to develop the required disclosure form. We further estimate that the total annual time burden across all new physician owned hospitals per year would be **20 hours**.

- 4 hours x 5 new physician owned hospitals per year = 20 hours ***across all*** new physician owned hospitals

We believe that the person who would develop the disclosure form would be an attorney. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for an attorney is **$69.86** (See: https://www.bls.gov/oes/current/oes231011.htm). This wage, adjusted for the employers overhead and fringe benefits, would be **$139.72**

We estimate that the cost burden for the preparation of ***each*** disclosure statement would be **$558.88**.

- 4 hours per each task x $139.72 per hour = $558.88 per each task

We further estimate that the total annual cost burden across all new physician owned

hospitals would be **$2,794.40**

- 20 hours annually x $139.72 per hour x = $2,794.40 annually

ii. <u>Time & Cost Burden Associated with Providing the Disclosure Notice to Patients.</u>

In CY 2018, there were approximately 36,333,333 inpatient admissions to all hospitals in the U.S (out of which 10,791,977 were Medicare beneficiaries). In FY 2018, there were approximately 10,303,000 hospital outpatient surgeries. These two figures added together equals a total of 46,636,333 inpatient and outpatient surgical admissions.

There are currently 4,181 hospitals in the U.S. We estimate that approximately 107 of these hospitals qualify as physician-owned. Only the physician owned hospitals are required to make such disclosures mandated by §489.20(u)(1).

We estimate that the physician owned hospitals constitute 2.56 % of all hospitals in the U.S.

- 107 divided by 4,181 = 0.256 or 2.56%

There were approximately 46,636,333 hospital inpatient and hospital outpatient surgical admissions to all hospitals per year. We estimate that ***all*** 107 physician owned hospitals would be account for approximately 2.56% of these 46,636,333 admission, or approximately **1,193,890** of the annual hospital inpatient and outpatient surgical admissions.

- 46,636,333 divided by 100 = 466,363.33(1%)

- 466,363.33 x 2.56 = 1,193,890 (2.56%) claims across all 107 physician owned hospitals

We further estimate that ***each*** physician owned hospital would account for **11,158** out of the total of all 46,636,333 hospital inpatient and hospital outpatient surgical admissions per year.

  - 1,193,890 divided by 107 = 11,158 claims per ***each*** physician owned hospital

In addition, we estimate that it would take approximately **5 minutes** to provide and explain the disclosure to each patient and also add a copy of the notice to the patient's medical record.

We estimate that the total annual time burden per each physician owned hospital, associated with the distribution of the disclosures required by §489.20(u)(1), would be **930 hours**.

- 5 minutes x 11,158 admissions per each PO hospital/yr. = 55,790 min.
- 55,790 minutes divided by 60 minutes per hour = 930 hours

We believe that the person who would provide the disclosure required by 489.20(u)(1) would be a Medical Records and Health Information Technician. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a Medical Records and Health Information Technician is $21.16. (See: https://www.bls.gov/oes/2018/may/oes292071.htm). This wage, adjusted for the employers overhead and fringe benefits, would be **$42.32**

We estimate that the cost for providing ***each*** disclosure would be **$3.55**.

- $42.32 per hour divided by 60 min = $0.71 per min
- $0.71 per min. x 5 min. = $3.55

We further estimate that the total annual cost ***across all*** inpatient and outpatient surgical admissions to ***each*** physician owned hospital per year would be **$39,357.60.**

- $42.32 per hour x 930 hours = $39,357.60

b. §489.20(u)(1) – Provide List of Owners & Investors that are Physicians On Staff to Patient Upon Request.

Pursuant to §489.20(u)(1), physician owned hospitals are required to ensure "that the list of the hospital's owners or investors who are physicians or immediate family members (as defined at §411.351 of this chapter) of physicians is available upon request of the patient. This physician list must be provided to the patient at the time the request is made by or on behalf of the patient.

We estimate that there are 1,193,890 hospital inpatient and outpatient surgical admissions to all physician owned hospitals per year. This would equate to 11,158 admissions per each physician owned hospital per year.

- 1,193,890 divided by 107 = 11,158

We further estimate that only 5% of the patients admitted to each physician owned hospital would actually read the disclosure form thoroughly and request this list of physicians. This would equate to approximately **558 requests** being made annually for the physicians list.

- 11,158 admissions annually divided by 100% = 111.58 (1%)
- 111.58 (1%) x 5% = 558 (5% of total annual admissions)

We estimate that it would take approximately **5 minutes** for: (1) the patient to make their request for a list of the hospital's owners or investors who are physicians or immediate family members known to the appropriate hospital staff person; (2) for the staff person to retrieve a copy of the list and provide it to the patient; (3) for the staff person to answer any questions the patient may have about the list; and (4) for the staff person to document in the patient's medical record that this list was requested by the patient and provided as requested.

We further estimate that the total annual time burden ***per each*** physician owned hospital for the provision of the physician list to patients that request it would be **47 hours.**

- 5 minutes per request x 558 requests annually = 2,790 minutes
- 2,790 minutes divided by 60 minutes per hour = 47 hours annually

We believe that the person who would provide the disclosure list required by §489.20(u)(1) would be a Medical Records and Health Information Technician. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a Medical Records and Health Information Technician is **$21.16**. (See: https://www.bls.gov/oes/2018/may/oes292071.htm).
This wage, adjusted for the employers overhead and fringe benefits, would be **$42.32**.

We estimate that the cost for providing ***each*** disclosure would be **$3.55**.

- $42.32 divided by 60 minutes = $0.71 per minute

- $0.71 per minute x 5 minutes = $3.55

We further estimate that the total cost ***across all*** requests for physicians lists made by patients annually would be **$1,989.04.**

- $42.32 per hour x 47 hours annually = $1,989.04

c. §489.20(u)(2) – Disclosure of Physician's & Immediate Family Member's Ownership or Investment Interests in Physician Owned Hospital (§411.362(b)(3)(ii)(A).)

Section 489.20(u)(2) requires that each physician owned hospital require each physician who is a member 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 the physician refers to the hospital, any ownership or investment interest in the hospital that is held by the physician or by any immediate family members (as defined at §411.351 of this chapter) of the physician. Disclosure is required at the time the referral is made.

i. Time & Cost Burden Related to Incorporating this Requirement into the Hospital By-Laws

In the previous PRA package, burden was included for this task. However, we believe that the requirement that physician owned hospitals require that each physician who is a member of the hospital's medical staff to agree, as a condition of continued medical staff membership or admitting privileges, to provide the required disclosure to their patients that are referred to the hospital was a one-time requirement and would no longer imposes any time or cost burden on the physician owned hospitals. We say this

because this requirement has been implemented for some time now. We believe that the required changes to the hospital's by-laws should have already been completed by all existing physician owned hospitals.

We further believe that this requirement would not impose any additional time or cost burden for new physician owned hospitals that are creating their bylaws because hospitals are required to have by-laws that comply with the CMS requirements. Therefore, they would have to include this requirement in their by-laws in the normal course of business and as a requirement for participation in the Medicare program.

ii. Time and Cost Burden Associated With Preparation of Physician's Disclosure of the

Physician's and Immediate Family Member's Ownership or Investment Interests in Physician Owned Hospital

We estimate that the burden related to the preparation of the disclosure required by §489.20(u)(2) by each physician was a one-time burden that would have already been completed by all of the existing physicians that have an investment or ownership interest or have immediate family members with an investment or ownership interest in one or more physician owned hospitals. Therefore, we do not assess any time or cost burdens for this task for these existing physicians or their immediate family members.

For any new physicians, that would now or in the future, acquire an investment or ownership interest or have immediate family members that acquire an investment or ownership interest in one or more physician owned hospitals, we estimate that it would take ***each*** the physician approximately **1 hour** to develop the notice and make copies for distribution to patients.

However, we are not able to estimate a time burden across all new physicians and their immediate family members, because we have no way to accurately estimate the number of new physicians and immediate family members that do currently or would in the future acquire an investment or ownership interest in a physician owned hospital.

According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a Family Practice Physician is $102.53 (See: https://www.bls.gov/oes/current/oes291215.htm). This wage, adjusted for the employer's overhead and fringe benefits, would be **$205.06.**

We estimate that the cost for the preparation for ***each*** physician disclosure would be **$205.06.**

- 1 hour x $205.06 per hour = $205.06

However, we are not able to estimate a cost burden across all physicians for the preparation of the physician's disclosure required by §489.20(u)(2), because we have no way to accurately estimate the number of new physicians and immediate family members that would currently or in the future have an investment or ownership interest in the hospital.

iii. Time and Cost Burden Associated With Distribution of the Physician's Disclosure of

the Physician's and Immediate Family Member's Ownership or Investment Interests in Physician Owned Hospital to Patients Referred to Hospital for Admission.

We estimate that it would take **5 minutes** to provide the disclosure by §489.20(u)(2) to ***each*** patient referred to a physician owned hospital for admission, and record proof of the provision of the disclosure to the patient in each patient's medical record.

However, as indicated in RIN 0938–AP15 (CMS-1390-P and -F), we are unable to estimate the total time burden across all physicians that are required to provide this disclosure because we have no way to accurately estimate the number of physicians and immediate family members that would have an investment or ownership interest in the hospital.

According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a Family Practice Physician is $102.53 (See: https://www.bls.gov/oes/current/oes291215.htm). This wage, adjusted for the employer's overhead and fringe benefits, would be $205.06.

We estimate that the cost for the preparation for ***each*** physician disclosure would be **$17.09.**

- $205.06 divided by 60 minutes = $3.417 per minute
- $3.417 per minute x 5 minutes = $17.09

However, we are not able to estimate a cost burden ***across all*** applicable physicians for the preparation of the physician's disclosure, because we have no way to accurately estimate the number of new physicians and immediate family members that would currently or in the future have an investment or ownership interest in the hospital.

d. §489.20(v) – Attestation Statement for Physician Owned Hospitals That Do Not Have at Least One Referring Physician or the Physician's immediate Family Member Who Has an Ownership or Investment Interest in the Hospital.

Section 489.20(v) states that the requirements of paragraph (u) of this section do not apply to any physician-owned hospital that does not have at least one referring physician who has an ownership or investment interest in the hospital or who has an immediate family member who has an ownership or investment interest in the hospital. However, the hospital must sign an attestation statement to that effect and maintains such attestation in

its records.

We estimate that only approximately 1% of physician owned hospitals would not have at least one referring physician who has an ownership or investment interest in the hospital or who has an immediate family member who has an ownership or investment interest in the physician owned hospital. There are currently **107** physician owned hospitals in the U.S. Therefore, we estimate that there would be approximately only **11** physician owned hospitals that meet this exclusion criteria.

However, we believe that this was a one-time requirement that no longer imposes any time or cost burden on the affected physician owned hospitals. We say this because this regulation has been in effect for some time now. Therefore, the hospitals that meet the above-stated criteria and would be required by §489.20(v) to prepare and save an attestation statement in their records should have already completed this task.

We further believe that this requirement would not impose any additional time or cost burden for new physician owned hospitals that meet the above-stated criteria because the preparation of this attestation statement is required by the CMS regulations as a requirement of the hospital's participation in the Medicare program. These physician owned hospitals would have to prepare this attestation statement as part of documentation that must be submitted to Medicare, and therefore would be created in the normal course of their business.

e. §489.20(w)(1) through §489.20(w)(5) - Notice to Inpatients and Outpatients for Visits for Observation, Surgery or Any Other Procedure Requiring Anesthesia, if a Doctor of Medicine or a Doctor of Osteopathy is Not Present in the Hospital 24 Hours Per Day, 7 Days Per Week. (See also §411.362(b)(5)(i)).

§489.20(w)(1) requires ***all hospitals*** to "furnish written notice to all patients at the beginning of their planned or unplanned inpatient hospital stay or at the beginning of any planned or unplanned outpatient visit for observation, surgery or any other procedure requiring anesthesia, if a doctor of medicine or a doctor of osteopathy is not present in the hospital 24 hours per day, 7 days per week, in order to assist the patients in making informed decisions regarding their care..." A planned hospital stay or outpatient visit begins with the provision of a package of information regarding scheduled preadmission testing and registration for a planned hospital admission for inpatient care or outpatient service. An unplanned hospital stay or outpatient visit begins at the earliest point at which the patient presents to the hospital.

§489.20(w)(2) states that "in the case of a hospital that is a main provider and has one or more remote locations of a hospital or one or more satellites,….the determination is made separately for the main provider and each remote location or satellite whether notice to patients is required. Notice is required at each location at which inpatient services are furnished at which a doctor of medicine or doctor of osteopathy is not present 24 hours per day, 7 days per week.

§489.20(w)(3) provides that "the written notice must state that the hospital does not have a doctor of medicine or a doctor of osteopathy present in the hospital 24 hours per day, 7 days per week, and must indicate how the hospital will meet the medical needs of any patient who develops an emergency medical condition, as defined in §489.24(b), at a time when there is no doctor of medicine or doctor of osteopathy present in the hospital.

§489.20(w)(4) states that "before admitting a patient or providing an outpatient service to outpatients for whom a notice is required, the hospital must receive a signed acknowledgment from the patient stating that the patient understands that a doctor of medicine or doctor of osteopathy may not be present during all hours services are furnished to the patient.

§489.20(w)(5) requires that "each dedicated emergency department, as that term is defined in §489.24(b), in a hospital in which a doctor of medicine or doctor of osteopathy is not present 24 hours per day, 7 days per week must post a notice conspicuously in a place or places likely to be noticed by all individuals entering the dedicated emergency department. The posted notice must state that the hospital does not have a doctor of medicine or a doctor of osteopathy present in the hospital 24 hours per day, 7 days per week, and must indicate how the hospital will meet the medical needs of any patient with an emergency medical condition, as defined in §489.24(b), at a time when there is no doctor of medicine or doctor of osteopathy present in the hospital.

§411.362(b)(5)(i) states that "If the hospital does not have a physician available on the premises to provide services during all hours in which the hospital is providing services to the patient, the hospital must disclose this information to the patient. Before providing services to the patient, the hospital must receive a signed acknowledgment from the patient stating that the patient understands that a physician may not be present during all hours services are furnished to the patient."

Supporting Statement A

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

CMS-10225

The requirements of §489.20(w)(1) to §489.20(w)(5) as set forth above impose the following tasks on hospitals:

- Creation of a written notice for patients which states that the hospital does not have a physician present in the hospital 24 hours per day, 7 days per week, and which indicates how the hospital will meet the medical needs of any patient who develops an emergency medical condition, at a time when there is no doctor of medicine or doctor of osteopathy present in the hospital.

- Providing this notice to all patients admitted to the hospital as an inpatient and patients presenting for planned or unplanned outpatient visit for observation, surgery or any other procedure requiring anesthesia. If a hospital has more than one location, such notice is required at each location at which inpatient services are furnished at which a doctor of medicine or doctor of osteopathy is not present 24 hours per day, 7 days per week.

- Receiving a signed acknowledgment from the patient stating that the patient understands that a physician may not be present during all hours services are furnished to the patient.

- Posting a conspicuous notice in the Emergency Departments (ED) of hospitals that do not a physician present 24 hours per day, 7 days per week, that indicates this fact and states how the hospital will meet the medical needs of any patient with an emergency medical condition, at a time when there is no doctor of medicine or doctor of osteopathy present in the hospital.

It is important to note that the regulations at §489.20(w)(1) through §489.20(w)(5), §411.362(b)(5)(i), and §489.20(w)(1) to §489.20(w)(5) apply to all hospitals and not just physician owned hospitals.

There are currently 4,181 hospitals and CAHs in the U.S. We estimate that approximately 5% of hospitals and CAHs would not have a physician on site at all times, and will be required to perform the above-stated tasks. In other words, we estimate that approximately **210 hospitals and CAHs** would have to perform the tasks stated above.

- 4,181 divided by 100 = 41.81 (1%)
- 41.81 x 5 = 209.5 (=10%)

In FY2018, there were 36,333,333 hospital inpatient claims. In FY 2018, there were 10,303,000 hospital outpatient observation and surgical claims. This equates to approximately 46,636,333 inpatient and outpatient hospital claims each year across all of the hospitals. However, since these regulatory provisions would apply to only 5% of hospital, they would also apply to only 5% of the total number of admissions. We estimate that that 5% of the total number of admission would be **2,331,817**.

- 46,636,333 divided by 100 = 466,636.33 (1%)
- 466,636.33 x 5 = 2,331,816.65 (5%)

We will discuss the burden discuss related to each of the above-stated tasks separately below

i. Time & Cost Burden Related to Preparation of Written Notice of Lack of Physician Coverage Present in the Hospital 24/7.

We believe that there would be no time or cost burden to existing hospitals associated with this requirement. We say this because this regulation imposed only a one-time

burden requirement. As this requirement has been implemented for some time now, we believe that all hospitals that meet the criteria of not having 24/7 physician coverage should have already prepared the required written notice.

We also believe that there would be no time or cost burden to new hospitals associated with the requirement. We say this because the new hospitals would have to meet this requirement in the normal course of their business in preparing to participate in the Medicare program.

ii. Time & Cost Burden Related to Providing the Required Notice to Inpatients & Outpatient About Lack of Physician Coverage in the Hospital 24/7.

This requirement applies to all hospitals in the U.S. and not only to physician owned hospitals. This requirement also applies to all patient being admitted for an inpatient stay or as an outpatient for observation, outpatient surgery or other procedures requiring anesthesia.

However, we estimate that only about 5% of hospitals and CAHs would not have a physician on site at all times, and will be required to perform the above-stated tasks. We estimate that approximately **210 hospitals and CAHs** would have to perform the tasks stated above.

- 4,181 divided by 100 = 41.81 (1%)
- 41.81 x 5 = 209.5

Also, since these regulatory provisions would apply to only 5% of hospital, they would also apply to only 5% of the total number of admissions. We estimate that that 5% of the total number of admission would be **2,331,817**.

- 46,636,333 divided by 100 = 466,636.33 (1%)
- 466,636.33 x 5 = 2,331,816.65 (5%)

We believe that it would take no more than **1 minute** for a hospital staff person to present the required disclosure statement to ***each*** patients that presents to the hospital for inpatient admission, are admitted as an outpatient for observation, or have outpatient surgery or other procedures requiring anesthesia. We believe that this disclosure statement would typically be presented to the patient during the admission registration process.

We further estimate that the total time burden disclosure ***across all*** inpatient and outpatient admissions annually, for the presentation of the required disclosure would be **38,864 hours**.

- 1 minute x 2,331,817 total claims in FY2018 = 2,331,817 minutes
- 2,331,817 minutes divided by 60 minutes = 38,864 hours

We believe that the person who would present the required disclosure to the patient would be a Medical Records and Health Information Technician. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a Medical Records and Health Information Technician is **$21.16**. (See: https://www.bls.gov/oes/2018/may/oes292071.htm). This wage, adjusted for the employers overhead and fringe benefits, would be **$42.32.**

We estimate that the cost for providing each disclosure to ***each*** patient would be **$0.71.**

- $42.32 divided by 60 minutes = $0.71 per minute
- $0.71 per minute x 1 minute = $0.71

We further estimate that the total cost ***across all*** inpatient admissions and outpatient registrations for observation, surgery and other procedures involving anesthesia would be **$1,644,724.48.**

- $42.32 per hour x 38,864 hours annually = $1,644,724.48

iii. Time & Cost Burden Related to Obtaining Signature of Patients on Notice to Inpatients & Outpatient About Lack of Physician Coverage Present in the Hospital 24/7.

We believe that it would take no more than **1 minute** for a hospital staff person to explain the disclosure to ***each*** patients that present to the hospital for inpatient admission, are admitted as an outpatient for observation, or have outpatient surgery or other procedures requiring anesthesia; and obtain the patient's signature on the disclosure form. This process would normally take place during the patient registration process.

Therefore we estimate that the total time burden disclosure ***across all*** inpatient and qualifying outpatient admissions annually, for the presentation of the required disclosure would be **38,864 hours.**

- 1 minute x 2,331,817 total claims in FY2018 = 2,331,817 minutes
- 2,331,817 minutes divided by 60 minutes = 38,864 hours

We believe that the person that would present the required disclosure to each patient would be a Medical Records and Health Information Technician. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a Medical Records and Health Information Technician is $21.16. (See: https://www.bls.gov/oes/2018/may/oes292071.htm). This wage, adjusted for the employers overhead and fringe benefits, would be **$42.32**

We estimate that the cost for providing ***each*** disclosure would be **$0.71.**

- $42.32 divided by 60 minutes = $0.71 per minute
- $0.71 per minute x 1 minute = $0.71

We further estimate that the total cost ***across all*** inpatient admissions and outpatient registrations for observation, surgery and other procedures involving anesthesia would be **$1,644,724.48.**

- $42.32 per hour x 38,864 hours = $1,644,724.48

iv. Time & Cost Burden Related to the Posting of Notice in the ED about Lack of Physician Coverage Present in the Hospital 24/7.

We believe that this regulation imposed a one-time burden for the creation of the disclosure notice to be posted in the ED. We further believe that since this regulation has been implemented for several years now, the existing hospitals should have already met this requirement. Therefore, this regulation imposes no further burden on the

existing hospitals. Consequently, we are removing this burden estimate from the current PRA package.

We do not believe that this requirement would impose any additional burden on new hospitals because they would be required to comply with this regulation as part of their requirements to participate in the Medicare program.

f. Disclosure On the Hospital Website and in Public Advertising of Physician's and Immediate Family Member's Ownership or Investment Interests in Physician Owned Hospital disclosure-- §411.362(b)(3)(ii)(C).

Section 411.362(b)(3)(ii)(C) requires physician owned hospitals to disclose on any public website for the hospital and in any public advertising for the hospital that the hospital is owned or invested in by physicians. This disclosure must contain language that would put a reasonable person on notice that the hospital may be physician-owned to be deemed sufficient. For purposes of this regulation, a public website for the hospital does not include social media websites; electronic patient payment portals; electronic patient care portals; and electronic health information exchanges.

i. Time and Cost Burden Related to Creation of Website Disclosure.

We believe that this regulation imposed a one-time burden for the creation and posting of the required disclosure notice on the hospital's public websites and advertisements. We further believe that since this regulation has been implemented for several years now, the existing physician owned hospitals should have already met this requirement. Therefore, we believe that this regulation imposes no further burden on the existing physician owned hospitals. Consequently, we are removing this burden estimate from the current PRA package.

We do not believe that this requirement would impose any additional burden on new physician owned hospitals because they would be required to comply with this regulation as part of their requirements to participate in the Medicare program.

ii. Time and Cost Burden Related to Updates to Website Disclosures.

This requirement applies to all hospitals in the U.S. and not only to physician owned hospitals. There are currently 4,181 hospitals. However, we estimate that only about 5% of hospitals and CAHs would not have a physician on site at all times, and would be required to perform the above-stated tasks. We estimate that approximately **210 hospitals and CAHs** would have to perform the tasks stated above.

We believe that all hospitals would need to spend some time each year to update their disclosure notice or add the disclosure notice to new advertisements they post on the hospital website or other public websites.

We estimate that it will take ***each*** hospital **1 hour** annually to review, update, and add disclosure information on it's website to new advertisements that are posted on the hospital or other public websites.

We estimate that the annual time burden ***across all*** hospitals for completing updated to the disclosures on their public website would be **210 hours**.

- 1 hours per year x 210 hospitals = 210 hours per year

We believe that the person that would complete this task would be Web Developer.

According to the U.S. Bureau of Labor Statistics the mean hourly wage for Web Developers and Digital Interface Designers is **$39.60**. (See: https://www.bls.gov/oes/current/oes151257.htm). This wage, adjusted for the employer's overhead and fringe benefits, would be **$79.20.**

We estimate that the cost per ***each*** hospital for updating the disclosure information on their public websites would be **$79.20.**

- $79.20 per hour x 1 hour = $79.20

We further estimate that the cost burden ***across all*** physician owned hospitals for the updating of the disclosure information on their public websites and advertisements would be **$16,632**

- $79.20 per hour x 210 hours = $16,632

g. Summary of Time and Cost Burden

See below for a summary of the time and cost burdens estimates set forth above.

Time Burden for Each Task

Task	Hours
§489.20(u)(1) – Preparation of Disclosure Form	4.000 hours
§489.20(u)(1) – Provide Disclosure Form to Patients	0.083 hours
§489.20(u)(1) - Provide Physician List to Patients	0.083 hours
§489.20(u)(2) – Incorporation into Hospital By-Laws	0.000 hours
§489.20(u)(2) – Preparation of Physician's Disclosure	1.000 hours
§489.20(u)(2) – Distribution of Physician's Disclosure	0.083 hours
§489.20(v) – Attestation Statement for Physician Owned Hospitals	0.000 hours
§489.20(w)(1) – Preparation of Written Notice of Lack of Physician Coverage in Hospital	0.000 hours
§489.20(w)(2) – Distribution of Written Notice of Lack of Physician Coverage in Hospital	0.017 hours
§489.20(w)(4) – Receive Patient Signature on Written Notice of Lack of MD Coverage	0.017 hours
§489.20(w)(5) – Post notice in the Hospital's ER of Lack of MD Coverage	0.000 hours
§411.362(b)(3)(ii)(C) – Posting disclosure notice on hospital's public website	0.000 hours
§411.362(b)(3)(ii)(C) – Updating disclosure notice on hospital's public website	1.000 hours
TOTAL	**6.28 hours (6 hours & 17 min.**

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Annual Time Burden Across All Physicians / Physician Owner Hospitals / Hospitals

Task	Hours
§489.20(u)(1) – Preparation of Disclosure Form	20 hours
§489.20(u)(1) – Provide Disclosure Form	930 hours
§489.20(u)(1) - Provide Physician List to Patients	47 hours
§489.20(u)(2) – Incorporation into Hospital By-Laws	0 hours
§489.20(u)(2) – Preparation of Physician's Disclosure	0 hours
§489.20(u)(2) – Distribution of Physician's Disclosure	0 hours
§489.20(v) – Attestation Statement for Physician Owned Hospitals	0 hours
§489.20(w)(1) – Preparation of Written Notice of Lack of Physician Coverage in Hospital	0 hours
§489.20(w)(2) – Distribution of Written Notice of Lack of Physician Coverage in Hospital	38,864 hours
§489.20(w)(4) – Receive patient signature on written notice of lack of MD coverage	38,864 hours
§489.20(w)(5) – Post notice in the Hospital's ER of Lack of MD Coverage	0 hours
§411.362(b)(3)(ii)(C) – Posting disclosure notice on hospital's public website	0 hours
§411.362(b)(3)(ii)(C) – Updating disclosure notice on hospital's public website	210 hours
TOTAL	**78,935 hours**

Cost Burden for Each Task

Task	Cost
§489.20(u)(1) – Preparation of Disclosure Form	$558.88
§489.20(u)(1) – Provide Disclosure Form	$ 3.55
§489.20(u)(1) - Provide Physician List to Patients	$ 3.55
§489.20(u)(2) – Incorporation into Hospital By-Laws	$ 0.00
§489.20(u)(2) – Preparation of Physician's Disclosure	$205.06
§489.20(u)(2) – Distribution of Physician's Disclosure	$ 17.09
§489.20(v) – Attestation Statement for Physician Owned Hospitals	$ 0.00
§489.20(w)(1) – Preparation of Written Notice of Lack of Physician Coverage in Hospital	$ 0.00
§489.20(w)(2) – Distribution of Written Notice of Lack of Physician Coverage in Hospital	$ 0.71
§489.20(w)(4) – Receive patient signature on written notice of lack of MD coverage	$ 0.71
§489.20(w)(5) – Post notice in the Hospital's ER of Lack of MD Coverage	$ 0.00
§411.362(b)(3)(ii)(C) – Posting disclosure notice on hospital's public website	$ 0.00
§411.362(b)(3)(ii)(C) – Updating disclosure notice on hospital's public website	$ 79.20
TOTAL	**$868.75**

Cost Burden Across All Physicians / Physician Owner Hospitals / Hospitals

§489.20(u)(1) – Preparation of Disclosure Form	$ 2,794.00
§489.20(u)(1) – Provide Disclosure Form	$ 39,357.60
§489.20(u)(1) - Provide Physician List to Patients	$ 1,989.04
§489.20(u)(2) – Incorporation into Hospital By-Laws	$ 0.00
§489.20(u)(2) – Preparation of Physician's Disclosure	$ 0.00
§489.20(u)(2) – Distribution of Physician's Disclosure	$ 0.00
§489.20(v) – Attestation Statement for Physician Owned Hospitals	$ 0 00
§489.20(w)(1) – Preparation of Written Notice of Lack of Physician Coverage in Hospital	$ 0.00
§489.20(w)(2) – Distribution of Written Notice of Lack of Physician Coverage in Hospital	$1,644,724.00
§489.20(w)(4) – Receive patient signature on written notice of lack of MD coverage	$1,644,724.00
§489.20(w)(5) – Post notice in the Hospital's ER of Lack of MD Coverage	$ 0 .00
§411.362(b)(3)(ii)(C) – Posting disclosure notice on hospital's public website	$ 0.00
§411.362(b)(3)(ii)(C) – Updating disclosure notice on hospital's public website	$ 16,632.00
TOTAL	**$3,350,220.64**

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

The table below shows the increase in number of responses, time, and cost burden.

	Total Requested	Program Change Due to	Program Change Due to	Due to Adjustment in OPDIV/Office	Change Due to Violation	Currently Approved

		New Statute	OPDIV/Office Discretion	Estimate		
Number of Responses	1,193,890	N/A	N/A	-6,675,398	N/A	7,869,288
Time Burden	78,935 hours	N/A	N/A	-102,570 hours	N/A	181,505 hours
Cost Burden	$3,350,221	N/A	N/A	+$257,588	N/A	$3,092,633

As stated in the above table, there has been a decrease in the total number of responses. In the previous PRA package, the total number of responses was stated to be 7,869,288. However, in the current PRA package, we have estimated the total number of responses to be 1,193,890. This is a 6,675,398 decrease in the number of responses. We believe this decrease is due to several factors.

We believe that the writer of the previous PRA package used the incorrect metric for measuring the total number of annual responses, and therefore, used too high a number of responses. In the previous Supporting Statement A, it was estimated that there were approximately 15,882,402 hospital inpatient claims, and approximately 127,585,067 hospital outpatient surgical claims, which equated to a total of 143,467,469 claims ***across all*** hospital in 2016. We believe that the approved number of responses might be based on a percentage of the total number of all claims ***across all*** hospitals and CAHs in 2016. For example, 5.5% of 143,467,469 = 7,890,711.

It is important to note that in the current PRA package, we have asserted that the number of claims across all physician-owned hospitals/CAHS is the correct metric to be used to identify the total number of responses. We did this because while most of the regulations that are the subject of this PRA package affect physician owned hospitals only, several of these regulations involve all hospitals and CAHs. Since the majority of the regulations affect physician owned hospitals only, we believe that the correct number of responses should be based on the total number of annual inpatient admissions and outpatient surgical admissions across all physician owned hospitals only. To attempt to blend the numbers for the claims associated the regulations that affect physician owned hospitals only and those that affect all hospitals/CAHs would be unnecessarily complicated and could introduce inaccuracy in the calculations.

We also believe that the number of claims stated in the previous PRA package was over-estimated. We say this because, according to Statista.com (https://www.statista.com/statistics/459718/total-hospital-admission-number-in-the-us/) there were only 36,110,000 hospital inpatient admissions in the U.S. for 2016. Also, according to the Medicare inpatient claims data for 2016, there were only 37,637,173 hospital inpatient claims in 2016 (https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CMSProgramStatistics/2016/Downloads/UTIL/2016_CPS_MDCR_INPT_HOSP_7.pdf . We also obtained this information from the Medicare claims data (https://www.cms.gov/research-statistics-data-systems/cms-program-statistics/2018-medicare-utilization-and-payment) and Statista.com (https://www.statista.com/statistics/459718/total-hospital-admission-number-in-the-us/).

In addition, in the current PRA package, we have estimated that there were approximately 46,636,333 total admissions across all hospitals in 2018. The writer of the previous PRA package estimated that there were 143,467,469 admissions in 2016. There is little likelihood that the number of hospital admissions decreased by 96,831,136 per year since 2016. Therefore, it is highly likely that the writer of the previous PRA package overestimated the number of claims.

In addition, we believe that the estimates contained in the previous PRA package for the number of claims is incorrect because it was calculated using an incorrect estimate of the number of hospitals/CAHs. For example, in the previous PRA package it was estimated that there were 15,882,402 total hospital inpatient claims and 127,585,067 total hospital outpatient surgery claims, for a total of 143,467,469 claims for FY 2016. It was further calculated that the average number of hospital inpatient claims per each hospital/CAH was 2,214 and the average number of hospital outpatient surgical claims per each hospital/CAH was 17,784.

These figures were obtained by dividing the total number of claims by the total number of hospitals/CAHs (see calculations below).

- 15,882,402 claims / 7,174 total hospitals/CAHs = 2214
- 127,585,067 hospital outpatient surgery claims / 7,174 total hospital/CAHs =17,784

However, we found that there were actually only a total of 6,195 active hospitals/CAHs in CY

2016, not 7,174 as stated in the previous PRA package. This means that the writer of the previous PRA package over estimated the number of providers by 979 (7,174 – 6,195 = 979). This also means that the figures for the number of claims was calculated using an incorrect figure for the number of hospitals and therefore would not be correct.

The total burden cost has increased by only $257,588. We believe this increase is attributable to two factors. First, we used a revised burden calculation in this PRA package, which is detailed but more reader friendly than that used in the previous package. In the previous PRA package, a table was provided that was very difficult to understand. We believe that the difference in the method used for the burden calculation in this PRA package could account for some of these differences.

Second, we have used updated wage rates for the staff required to perform the tasks required by the applicable regulations. We have doubled the wage rates used in the burden calculations to account for the employer's overhead and fringe benefits. This is standard practice for all

PRA packages and is required by the PRA analyst in the Office of Strategic and Regulatory Affairs (OSORA) at CMS. We believe that the increased wage rates could account for most, if not all, of the increased cost burden.

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.

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B. Collections of Information Employing Statistical Methods

This collection does not employ statistical methods.