

**Supporting Statement A for CMS-10705**  
**Information Collection Requirements Associated with the New Regulations For Accrediting  
Organization Change of Ownership Requirements at 42 CFR 488.5(f)**

**A. Background**

This final rule adds regulatory requirements and a specified process to address changes of ownership as they relate to the sale, transfer, and/or purchase of assets of Accrediting Organizations (AOs) with CMS-approved accreditation programs. This change will provide CMS the ability to receive notice when an AO is contemplating undergoing or negotiating a change of ownership (CHOW), and the ability to review the AO's capability to perform its tasks after a change in ownership has occurred, in order to insure the ongoing effectiveness of the approved accreditation program(s) and to minimize risk to patient safety.

**B. Justification**

**1. Need and Legal Basis**

CMS is responsible for providing continued oversight of the national Accrediting Organizations (AOs) to ensure that providers or suppliers accredited by the AOs meet the required quality and patient safety standards. CMS must ensure that the AOs have formalized procedures to ensure healthcare facilities accredited under their accreditation programs meet the AO's accreditation standards. CMS is also responsible for ensuring that the AO's accreditation standards and practices for surveying providers and suppliers meet or exceed CMS's standards and practices for granting approval.

Any national AO seeking approval of an accreditation program in accordance with section 1865(a) of the Social Security Act ("the Act") must apply for and be approved by CMS for a period not to exceed 6 years. (See 42 CFR 488.5(e)(2)(i)). The AO must also reapply for renewed CMS approval for its accreditation program(s) before the date its existing approval period expires. This allows CMS to continue to ensure that the accreditation provided by these AOs continue to indicate that the providers or suppliers accredited are meeting or exceeding Medicare standards. The CMS regulations for the approval and oversight of AOs that accredit Medicare certified providers and suppliers are set forth at 42 CFR 488.1 through 488.9.

CMS has an established process for the change of ownership of Medicare-certified providers and suppliers set forth at 42 CFR §489.18 and in Chapter 2, section 2005E of the State Operations Manual (SOM). However, the provider and supplier change of ownership process outlined under section 42 CFR §489.18 does not apply to the sale and transfer of AOs. Currently, the regulations governing AOs do not include a process for notifying CMS of pending changes of ownership or other procedures which would allow CMS to review information about the transfer of ownership of accreditation program(s) and the authority for CMS to approve or deny the transfer of the existing CMS approval for the accreditation program(s) to be transferred. Under our current regulations, CMS does not typically become aware of a sale/transfer of an accrediting organization until an AO applies for renewal of CMS approval of its accreditation program(s) or unless voluntarily notified by the AO. CMS

## **Supporting Statement A for CMS-10705**

### **Information Collection Requirements Associated with the New Regulations For Accrediting Organization Change of Ownership Requirements at 42 CFR 488.5(f)**

has the regulatory authority to conduct comparability or validation surveys in accordance with section 488.8. However, we do not believe that we have the explicit regulatory authority to prospectively review and approve or deny the transfer of the existing Medicare-approval of accreditation programs being transferred in a change of ownership transaction.

#### **2. Information Users**

The prospective buyer/transferee will be required by 42 CFR §488.5(f)(2) to submit the following information to CMS in support of their request for approval of the CHOW: (1) the name and address of the legal entity that would be the owner of the new AO after the transfer was completed; (2) the three most recent audited financial statements of the organization that demonstrate that the organization's staffing, funding, and other resources would be adequate to perform the required surveys and related activities; (3) a transition plan that would summarize the details of how the accreditation functions will be transitioned to the new owner.

Section 488.5(f)(2)(iii)(C) will require that the prospective new AO's transition plan include the following information: (1) changes to management and governance structures including current and organizational charts; (2) a list of the CMS-approved accreditation programs that will be transferred to the purchaser/buyer/transferee; (3) employee changes, if applicable; (4) anticipated timelines for action; (5) plans for notification to employees; and (6) any other relevant information that CMS finds necessary.

The purpose of this information requirement is to demonstrate that the AO, under the new ownership, will have financial stability and longevity of operations. This information will also be used to determine the prospective new owner's capability to perform the required accreditation tasks after the CHOW takes place and to determine whether CMD should approve the transfer of the existing CMS-approval for the accreditation programs to be transferred in the CHOW to the buyer/transferee.

#### **3. Improved Information Technology**

The required information must be submitted to CMS by email. At this time CMS is not able to accept this information via electronic submission.

#### **4. Duplication of Similar Information**

There is no duplication of information required by the new regulations to be added to 42 CFR 488.5(f).

**Supporting Statement A for CMS-10705**  
**Information Collection Requirements Associated with the New Regulations For Accrediting  
Organization Change of Ownership Requirements at 42 CFR 488.5(f)**

**5. Small Business**

Approximately 30% of the existing AOs are small businesses. The new regulations will have the same effect on all AOs regardless of whether they are small or large businesses. This information collection is necessary for the AOs that have been transferred to new ownership to retain the existing CMS approval for the accreditation programs that are transferred. The paperwork requirements are minimal and are necessary to meet the participation requirements of the new regulations. Also, the documents that must be submitted by the prospective new owner of the AO are similar to but much less extensive than those that must be submitted with an AO's initial or renewal application for CMS-approval of its accreditation programs.

**6. Less Frequent Collection**

The information collection requirements will only arise when there is an anticipated or negotiated change of ownership for an AO and transfer of accreditation programs to new ownership. We anticipate that this will occur on an infrequent basis.

**7. Special Circumstances for Information Collection**

There are no special circumstances associated with this collection.

**8. Federal Register and Outside Consultation**

The Accrediting Organization Changes of Ownership Proposed Rule was published on May 2, 2019 (84 FR 18748). Three comments to the Collection of Information Requirements section of the proposed rule were received. See the attached document which contains these comments and our responses to same.

The Accrediting Organization Changes of Ownership Final Rule published on April 29, 2022 (87 FR 25413).

**9. Payments or Gifts**

There are no payments or gifts associated with this collection.

**Supporting Statement A for CMS-10705**  
**Information Collection Requirements Associated with the New Regulations For Accrediting**  
**Organization Change of Ownership Requirements at 42 CFR 488.5(f)**

**10. Confidentiality**

The prospective buyer/transferee would be required by 42 CFR 488.5(f)(2) to submit information to CMS which demonstrates that the AO, under the new ownership will have

financial stability and longevity of operation, and capability to perform the required accreditation tasks after a CHOW has taken place.

The information submitted by the AOs to CMS will be treated as confidential and CMS will take any steps necessary to maintain the confidentiality of this information.

**11. Sensitive Questions**

The financial documents to be submitted by the prospective new owner of the AO are sensitive in nature.

**12. Estimate of Burden**

To estimate the burden associated with new regulations at § 488.5(f), we will discuss each section of the new regulation that has an associated time or cost burden separately.

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' (BLS) May 2021 National Occupational Employment and Wage Estimates for all salary estimates ([http://www.bls.gov/oes/current/oes\\_nat.htm](http://www.bls.gov/oes/current/oes_nat.htm)). In this regard, the following table presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

**TABLE 1: NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES**

<b>BLS Occupation Title</b>	<b>Occupation Code</b>	<b>Mean Hourly Wage (\$/hr.)</b>	<b>Adjusted Hourly Wage (\$/hr.)</b>
Registered Nurse <a href="https://www.bls.gov/oes/current/oes291141.htm">https://www.bls.gov/oes/current/oes291141.htm</a>	29-1141	\$39.78	\$79.56
Medical or Health Services Manager <a href="https://www.bls.gov/oes/current/oes119111.htm">https://www.bls.gov/oes/current/oes119111.htm</a>	11-9111	\$57.61	\$115.22

## **Supporting Statement A for CMS-10705**

### **Information Collection Requirements Associated with the New Regulations For Accrediting Organization Change of Ownership Requirements at 42 CFR 488.5(f)**

<b>BLS Occupation Title</b>	<b>Occupation Code</b>	<b>Mean Hourly Wage (\$/hr.)</b>	<b>Adjusted Hourly Wage (\$/hr.)</b>
Medical Secretary <a href="https://www.bls.gov/oes/current/oes436013.htm">https://www.bls.gov/oes/current/oes436013.htm</a>	43-6013	\$19.11	\$38.22
Accountant or Auditor <a href="https://www.bls.gov/oes/current/oes132011.htm">https://www.bls.gov/oes/current/oes132011.htm</a>	13-2011	\$40.37	\$80.74

As indicated, we are adjusting our staff hourly wage estimates by a factor of 100 percent to account for fringe benefits and overhead. We believe that doubling the hourly wage to estimate total cost to the employer, including fringe benefits and overhead is a reasonably accurate estimation method.

**a. §488.5(f)(1):**

We will be finalizing the addition a provision at §488.5(f)(1) that requires any CMS-approved accrediting organization that is contemplating or negotiating a change of ownership to notify CMS of the change of ownership. Section 488.5(f)(1)(ii) would require that this notice be provided to CMS in writing and §488.5(f)(1)(iii) would require that this notice be provided to CMS no less than 90 day prior to the anticipated effective date of the change of ownership transaction.

**i. Time Burden Associated with §488.5(f)(1):**

NOTE: The time and cost burden calculations stated below are for each individual respondent.

We estimate that the initial written notice to be provided to CMS by the AO could consist of an email or letter with 1-2 paragraphs. We estimate that it would take the AO no more than **15 minutes** per respondent to prepare this initial notification and send it to CMS via email or U.S. mail.

**ii. Cost Burden Associated with §488.5(f)(1):**

We believe that this email or letter would be prepared and sent to CMS by a Medical Secretary. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a Medical Secretary, adjusted for the employer's overhead and fringe benefits, is **\$38.22**.

**Supporting Statement A for CMS-10705**  
**Information Collection Requirements Associated with the New Regulations For Accrediting  
Organization Change of Ownership Requirements at 42 CFR 488.5(f)**

We estimate that the cost burden associated with this task would be \$9.55 per respondent.

- \$38.22 per hour x 0.25 hour

**b. §488.5(f)(2)**

Section 488.5(f)(2)(i) would require that the person(s) or organization(s) acquiring an existing CMS-approved accrediting organization or accreditation programs through a change of ownership transaction must seek approval from CMS for the transfer of the existing CMS approval of the accreditation program(s) to be transferred in the change of

ownership event. Section 488.5(f)(2)(iii) would require that the persons or organizations acquiring an existing CMS-approved accreditation programs through a change of ownership transaction submit must the following information in support of their request for approval of the transfer:

- The legal name and address of the new owner;
- The three most recent audited financial statements of the organization that demonstrate the organization's staffing, funding and other resources are adequate to perform the required surveys and related activities;
- A transition plan that summarizes the details of how the accreditation functions will be transitioned to the new owner, including:
  - Changes to management and governance structures including current and organizational charts;
  - A list of the CMS-approved accreditation programs that will be transferred to the purchaser/buyer/transferee,
  - Employee changes, if applicable;
  - Anticipated timelines for action,
  - Plans for notification to employees; and
  - Any other relevant information that CMS finds necessary.

## **Supporting Statement A for CMS-10705**

### **Information Collection Requirements Associated with the New Regulations For Accrediting Organization Change of Ownership Requirements at 42 CFR 488.5(f)**

#### **i. Time Burden Associated With §488.5(f)(2)(iii)**

We believe that this task would likely be performed by three AO staff, including a Registered Nurse (RN), a Medical or Health Services Manager, and an Accountant or Auditor. We estimate that each of these persons will each spend **45 hours** performing this task. Therefore, the total time burden for this task would be **135 hours**.

- 45 hours x 3 staff persons = 135 hours

#### **ii. Cost Burden Associated With §488.5(f)(2)(iii)**

According to the U.S. Bureau of Labor Statistics, the average hourly wage for an RN, adjusted for the employers overhead and fringe benefits is **\$79.56**. We estimate that the cost burden for the work performed by the RN would be **\$3,580**.

- 45 hours x \$79.56 = \$3,580.20

According to the U.S. Bureau of Labor Statistics, the average hourly wage for a Medical or Health Services Manager, adjusted for the employers overhead and fringe benefits is **\$115.22**. The cost burden for the work performed by the Medical or Health Services Manager would be **\$5,185**.

- 45 hours x \$115.22 = \$5,184.90

According to the U.S. Bureau of Labor Statistics, the average hourly wage for an Accountant or Auditor, adjusted for the employers overhead and fringe benefits is **\$80.74**. The cost burden for the work performed by the Accountant or Auditor would be **\$3,633.30**.

- 45 hours x \$80.74 = \$3,633.30

We estimate that the total cost burden for this task would be **\$12,398**.

- \$3,580 + \$5,185 + \$3,633 = \$12,398

#### **c. Burden Associated With §488.5(f)(2)(iii)(C)(6)**

##### **i. Time Burden Associated With §488.5(f)(2)(iii)(C)(6)**

Section 488.5(f)(2)(iii)(C)(6) requires the prospective new owner of the AO to submit any other relevant information that CMS finds necessary. This task would involve the following: (1) review of CMS' request for information regarding the CHOW; (2)

**Supporting Statement A for CMS-10705**  
**Information Collection Requirements Associated with the New Regulations For Accrediting  
Organization Change of Ownership Requirements at 42 CFR 488.5(f)**

collecting and preparing this information for sending to CMS; and (3) sending the requested information to CMS. In the proposed rule we estimated the time burden for this task to be **1 hour**. However, in response to a public comment received, in the final rule, we increased the time burden for this task to **3 hours**.

**ii. Cost Burden Associated With §488.5(f)(2)(iii)(C)(6)**

We believe that this task would be performed by a clinician such as RN, as is generally the case in AO applications seeking deeming authority. We estimate that the total cost burden incurred by the AO for this task would be **\$238.68**.

- 3 hours x \$79.56 = \$238.68

**d. §488.5(f)(3)**

Section 488.5(f)(3) would require the purchaser/transferee to provide a written acknowledgement to CMS which states the following: (i) that, if the application for the transfer of the existing CMS-approval for the accreditation program(s) to be transferred in the change of ownership transaction is approved by CMS, said purchaser/transferee shall assume complete responsibility for the operations (i.e. – managerial, financial, legal, etc.) of the CMS-approved accreditation programs transferred, immediately upon the finalization of the change of ownership transaction; (ii) that the purchaser/transferee agrees to operate the transferred CMS-approved accreditation program(s) under all of the CMS imposed terms and conditions, to include program reviews and probationary status terms, currently approved by CMS; and (iii) the purchaser/transferee shall not operate the accreditation program(s) it acquired in the change in ownership transaction as a CMS approved accreditation programs, until the effective date set forth within the notice of approval from CMS.

**i. Time Burden Associated With §488.5(f)(3)**

We estimate that the acknowledgements required by CMS would be a one page document consisting 3 paragraphs. We estimate that it would only take the respondent AO no more than **60 minutes (1 hour)** to prepare the letter containing the required acknowledgements and send it to CMS via email.

**ii. Cost Burden Associated With §488.5(f)(3)**

We believe that the document with the written acknowledgements would be prepared and sent to CMS by a Medical or Health Services Manager. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a Medical Health Services Manager, which has been adjusted for the employer's overhead and fringe benefits, is **\$115.22**.

**Supporting Statement A for CMS-10705**  
**Information Collection Requirements Associated with the New Regulations For Accrediting  
Organization Change of Ownership Requirements at 42 CFR 488.5(f)**

We estimate that the cost burden associated with this task would be **\$115.22** per respondent.

- 1 hour per respondent x \$115.22 per hour = \$115.22

**e. §488.5(f)(4)**

The following written notifications are required after the change of ownership transaction has been approved by CMS:

- All parties to the change of ownership transaction must notify the providers and suppliers affected by such change within 15 calendar days after being notified of CMS's approval of the transfer of the existing CMS-approval for the accreditation programs to be transferred in the change of ownership transaction.
- If applicable, the purchaser/buyer/transferee must acknowledge in writing to CMS that the accrediting organization or accreditation program(s) being acquired through a purchase or transfer of ownership was under a performance review or under probationary status at the time the change of ownership notice was submitted.

**i. Time Burden Associated with §488.5(f)(4)(i)**

We estimate that it would take each AO approximately **45 minutes** to prepare and the notice required by §488.5(f)(4)(i) that is to be sent to each of the AOs accredited providers and suppliers. We believe that this task would be performed by a Medical Secretary

We further estimate that it would take an additional **3 hours** for each AO to prepare an individual printed letter to be sent to each of the AO's accredited providers and suppliers, put each letter into envelopes, affix the correct amount of postage to each letter and put the letters into the outgoing mail. We believe that these tasks would also be performed by a Medical Secretary.

We estimate that the total time burden related to these tasks would be **3.75 hours**

- 0.75 hours + 3.00 hours = 3.75 hours

**ii. Cost Burden Associated with §488.5(f)(4)(i)**

We believe that these tasks would be performed by a Medical Secretary. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a Medical Secretary, which has been adjusted for the employer's overhead and fringe benefits, is **\$38.22**.

**Supporting Statement A for CMS-10705**  
**Information Collection Requirements Associated with the New Regulations For Accrediting  
Organization Change of Ownership Requirements at 42 CFR 488.5(f)**

We estimate that the cost burden associated with the preparation of the notice to be sent by email to each of the AO's accredited providers and suppliers pursuant to §488.5(f)(4)(i) would be **\$28.66** per respondent.

- \$38.22 per hour divided by 60 min/hour = \$0.637 per min
- \$0.637 per min x 45 minutes = \$28.66

We further estimate that the cost burden associated with the preparation of the notice to be sent by regular mail to each of the AO's accredited providers and suppliers pursuant to §488.5(f)(4)(i) would be **\$114.66** per respondent.

- \$38.22 x 3 hours = \$114.66

Therefore, we estimate that the total cost burden associated with the tasks required by §488.5(f)(4)(i) would be **\$143.32**.

- \$28.66 + \$114.66 = \$143.32

**iii. Time Burden Associated with §488.5(f)(4)(ii)**

We believe that the required written acknowledgment that must be submitted to CMS stating that the accrediting organization or accreditation program(s) being acquired through a purchase or transfer of ownership was under a performance review or under probationary status at the time the change of ownership notice was submitted would take no more than **20 minutes** (per respondent) for the AO staff to prepare. This written acknowledgement could consist of several paragraphs in an email or letter.

**iv. Cost Burden Associated with §488.5(f)(4)(ii)**

We believe that these tasks would be performed by a Medical Secretary. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a Medical or Health Services Manager, adjusted for the employer's overhead and fringe benefits, is **\$38.22**.

We estimate that the cost burden associated with the preparation of the written acknowledgement that must be sent to CMS pursuant to §488.5(f)(4)(ii) would be **\$12.74** per respondent.

- \$38.22 divided by 60 minutes per hour = \$0.637 per minute
- \$0.637 x 20 min. = \$12.74

## **Supporting Statement A for CMS-10705**

### **Information Collection Requirements Associated with the New Regulations For Accrediting Organization Change of Ownership Requirements at 42 CFR 488.5(f)**

**f. §488.5(f)(6)**

§488.5(f)(6) provides that in the event that CMS does not approve the transfer of the existing CMS approval for the accreditation programs subject to the change of ownership event, CMS will notify all parties to the change of ownership transaction of such in writing. This notice would be sent to the relevant parties at the existing AO and the prospective transferee.

**i. Time Burden Associated with §488.5(f)(6)**

The burden associated with this regulatory provision is the time required for the parties at the AO to review the CMS notice. We believe that this notice would consist of no more than 1-2 pages and would take no more than **20 minutes** per respondent for the AO staff review.

**ii. Cost Burden Associated with §488.5(f)(6)**

We believe that the person at the AO that would review the CMS notice would be a Medical or Health Services Manager. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a Medical or Health Services Manager, adjusted for the employer's overhead and fringe benefits is \$115.22.

We estimate that the cost burden associated with this task would be **\$38.40** per respondent.

- \$115.22 per hour divided by 60 min/hour = \$1.92 per min.
- \$1.92 per min. x 20 min. = \$38.40

**g. Total Time Burden Associated with New Regulations at 42 CFR §488.5(f)**

§488.5(f)(1)	0.25 hours
§488.5(f)(2)	135.00 hours
§488.5(f)(2)(iii)(C)(6)	3.00 hours
§488.5(f)(3)	1.00 hours
§488.5(f)(4)(i)	3.75 hours
§488.5(f)(4)(ii)	0.33 hours
<u>§488.5(f)(6)</u>	<u>0.33 hours</u>
<b>TOTAL:</b>	<b>144.00 hours</b>

**Supporting Statement A for CMS-10705**  
**Information Collection Requirements Associated with the New Regulations For Accrediting**  
**Organization Change of Ownership Requirements at 42 CFR 488.5(f)**

**h. Total Cost Burden Associated with New Regulations at 42 CFR §488.5(f)**

§488.5(f)(1)	\$ 9.55
§488.5(f)(2)	\$12,398.00
§488.5(f)(2)(iii)(C)(6)	\$ 238.68
§488.5(f)(3)	\$ 115.25
§488.5(f)(4)(i)	\$ 143.32
§488.5(f)(4)(ii)	\$ 12.74
§488.5(f)(6)	\$ 38.40
<b>TOTAL:</b>	<b>\$12,955.94</b>

**13. Capital Costs**

There are no anticipated capital costs associated with this collection.

**14. Federal Cost Estimates**

There is no anticipated costs to the Federal Government.

**15. Burden Changes/Program changes**

The regulations being established are new and therefore the time and cost burden associated with these new regulation would be new burden.

In the proposed rule information collection request (ICR), we requested approval for 11 burden hours and burden costs in the amount of \$1,154.03. In this final rule ICR, we are requesting first time approval for 144 burden hours and \$12,955.94 in burden costs associated with the regulations being finalized at 42 CFR § 488.5(f). The increase in the burden costs between the previous and current ICR is due, in part, to increases in the time and cost burdens estimates we made in response to public comments received on the proposed rule. The increase in the cost burden is also attributable in part to the use of updated wage rates from the U.S. Bureau of Labor Statistics for 2021 in the current ICR. In the proposed rule we had used the wage rates for 2018.

**16. Publication and Tabulation Dates**

The results of this collection will not be published.

**Supporting Statement A for CMS-10705**  
**Information Collection Requirements Associated with the New Regulations For Accrediting  
Organization Change of Ownership Requirements at 42 CFR 488.5(f)**

**17. OMB Expiration Date**

There is no actual data collection form upon which CMS could display an expiration date. However, CMS will display the expiration date on the CMS.gov website on the QSOG webpage.

**Supporting Statement A for CMS-10705**  
**Information Collection Requirements Associated with the New Regulations For Accrediting  
Organization Change of Ownership Requirements at 42 CFR 488.5(f)**