

Supporting Statement A

Accrediting Organization Change of Ownership Requirements (CMS-10705)

A. Background

This proposed rule would add 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 is intended to 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 proposed 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 has the regulatory authority to

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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.

We believe that the current situation whereby a change in ownership of CMS-approved accreditation program(s) may occur without the notice to CMS, does not provide an opportunity for CMS to review and approve or deny the transfer of the existing CMS-approval of the accreditation programs to be transferred. This is a scenario that should be addressed so that there is assurance that the standards and conditions for surveying facilities will continue to be met by the accreditation programs that are transferred under new ownership. We believe it is possible that the AO, after a change of ownership transaction, may not be viable or equipped to accredit facilities under the transferred CMS approved CMS accreditation programs, due to the new owner's inability to enforce the health and safety requirements of CMS. Without the authority to require AOs to provide CMS with notice when they are contemplating or negotiating a change of ownership, and the authority to review the ability of the prospective new owner's capability to perform the required accreditation tasks, after a change of ownership, CMS is unable to confirm the ongoing effectiveness of the transferred CMS-approved accreditation program(s). We believe that we need the regulatory authority to ensure that after a change of ownership, the AO can continue to ensure that the entities it accredits meet or exceed CMS requirements, which is required in order to be granted CMS approval of its program(s).

2. Information Users

AOs that are contemplating undergoing or negotiating a Change of Ownership would be required to provide the information required by the proposed new regulations to be added at 42 CFR §488.5(f)

3. Improved Information Technology

The required information must be submitted to CMS by email or sent by U.S. mail. 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 proposed new regulations to be added to 42 CFR 488.5(f).

5. Small Business

Approximately 10% of the existing AOs are small businesses. These requirements would 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

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ownership to retain the existing CMS approval for the accreditation programs that are transferred. These paperwork requirements are minimal and are necessary to meet the participation requirements of the proposed new regulations.

6. Less Frequent Collection

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

7. Special Circumstances for Information Collection

There are no special circumstances associated with this collection.

8. Federal Register and Outside Consultation

A 60 day Federal Register Notice for the Accrediting Organization Change of Ownership Requirements proposed rule published on May 2, 2019 (84 FR 18748).

9. Payments or Gifts

There are no payments or gifts associated with this collection.

10. Confidentiality

No confidential or personally identifiable patient information will be collected.

11. Sensitive Questions

There are no questions of a sensitive nature associated with this form.

12. Estimate of Burden

To estimate the burden associated with proposed new regulations at 488.5(f), we will discuss each section of the proposed 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 2016 National Occupational Employment and Wage Estimates for all salary estimates (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.

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TABLE 1: NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

BLS Occupation Title	Occupation Code	Mean Hourly Wage (\$/hr)	Adjusted Hourly Wage (\$/hr)
Medical or Health Services Manager https://www.bls.gov/oes/current/oes119111.htm	11-9111	\$53.69	\$107.38
Medical Secretary https://www.bls.gov/oes/2017/may/oes436013.htm	43-6013	\$17.25	\$34.50

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. Proposed §488.5(f)(1):

We have proposed to add 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. §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.

1. Time Burden Associated with Proposed §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.

2. Cost Burden Associated with Proposed §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 is **\$17.25**.

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We estimate that the cost burden associated with this task would be **\$8.62** per respondent.

(15 minutes x \$17.25 per hour = \$4.31 wages + \$4.31 for fringe benefits & overhead = \$8.62 per respondent)

B. Proposed §488.5(f)(2)

Proposed §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. Proposed §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 proposed 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.

1. Time Burden Associated With Proposed §488.5(f)(2)

We estimate that it would take each respondent (i.e. - the buyer/transferee) approximately **8 hours** to prepare their request for approval for transfer of the existing Medicare approval for the accreditation programs to be transferred in the

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change of ownership transaction. This time estimate includes the time required to gather the required information to be submitted with the request and the time required to prepare the transition plan.

2. Cost Burden Associated With Proposed §488.5(f)(2)

We believe that these tasks would be performed by 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 is **\$53.69**.

We estimate that the total cost burden associated with the performance of the tasks required by proposed §488.5(f)(2) would be **\$859.04** per each respondent

(8 hours per each respondent x \$53.69 per hour = \$429.52 + \$429.52 for fringe benefits & overhead = \$859.04 per each respondent)

C. Proposed §488.5(f)(3)

Proposed §488.5(f)(3) would require the purchase/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.

1. Time Burden Associated With Proposed §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 **30 minutes** to prepare this letter containing the required acknowledgements and send it to CMS via email or U.S. mail.

2. Cost Burden Associated With Proposed §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 is **\$53.69**.

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We estimate that the cost burden associated with this task would be **\$53.69** per respondent.

(30 minutes per respondent x \$53.69 per hour = \$26.84 wages + \$26.85 for fringe benefits & overhead = \$53.69 per respondent)

D. Proposed §488.5(f)(4)

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

- i. 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.
- ii. 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.

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

We believe that notice required by §488.5(f)(4)(i) would take approximately **45 minutes** (per respondent) for the AO staff to prepare. We further estimate that it would take an additional **45 minutes** (per respondent) for the AO staff to prepare an individual copy of the notice to be sent to each of the AO's accredited providers and suppliers, put the letter into an envelope, affix the correct amount of postage and put the letter into the outgoing mail. We believe that these tasks would be performed by a Medical Secretary.

2. Estimated Cost Burden Associated with 488.5(f)(4)(i)

We believe that these tasks would be performed by 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 is **\$53.69**.

We estimate that the cost burden associated with the preparation of the notice to be sent by the AO to each of its accredited providers and suppliers pursuant to §488.5(f)(4)(i) would be **\$161.08** per respondent.

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(45 minutes x \$53.69 per hour = \$40.27 wages + \$40.27 for fringe benefits & overhead = \$ 80.54)

(45 minutes x \$53.69 per hour = \$40.27 wages + \$40.27 for fringe benefits & overhead = \$ 80.54)

TOTAL = \$161.08

3. Estimated 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.

4. Estimated Cost Burden Associated with 488.5(f)(4)(ii)

We believe that these tasks would be performed by 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 is **\$53.69**.

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 **\$35.80** per respondent.

(20 minutes x \$53.69 per hour = \$17.90 wages + \$17.90 for fringe benefits & overhead = \$35.80 per respondent)

E. Proposed §488.5(f)(6)

Proposed §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.

1. Time Burden Associated with Proposed §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.

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2. Cost Burden Associated with Proposed §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 Secretary is **\$53.69**.

We estimate that the cost burden associated with this task would be **\$35.80** per respondent.

(20 minutes x \$53.69 per hour = \$17.90 wages + \$17.90 for fringe benefits & overhead = **\$35.80** per respondent)

F. Total Time Burden Associated with Proposed New Regulations at 42 CFR 488.5(f)

Proposed §488.5(f)(1)	0.25 hours
Proposed §488.5(f)(2)	8.0 hours
Proposed §488.5(f)(3)	0.5 hours
Proposed §488.5(f)(4)(i)	1.5 hours
Proposed §488.5(f)(4)(ii)	0.33 hours
<u>Proposed §488.5(f)(6)</u>	<u>0.33 hours</u>
TOTAL:	11 hours

G. Total Cost Burden Associated with Proposed New Regulations at 42 CFR 488.5(f)

Proposed §488.5(f)(1)	\$ 8.62
Proposed §488.5(f)(2)	\$ 859.04
Proposed §488.5(f)(3)	\$ 53.69
Proposed §488.5(f)(4)(i)	\$ 161.08
Proposed §488.5(f)(4)(ii)	\$ 35.80
<u>Proposed §488.5(f)(6)</u>	<u>\$ 35.80</u>
TOTAL:	\$1,154.03

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

This is a new data collection.

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16. Publication and Tabulation Dates

The results of this collection will not be published.

17. OMB Expiration Date

There is no actual data collection form upon which CMS could display an expiration date.