section 307(b)(1).[3] This action relates to the 2009 Endangerment and Cause or Contribute Findings for Greenhouse Gases under Section 202(a) of the Clean Air Act (''2009 Endangerment Finding''), which are nationally applicable, 74 FR 66496 (December 15, 2009). The 2009 Endangerment Finding concerns risks from greenhouse gas pollution and contributions to such pollution that occur across the nation, and the result of the denial of these four petitions is that the existing nationally applicable 2009 Endangerment Finding remains in place and undisturbed. Further, both the 2009 Endangerment Finding and EPA's previous denial of petitions for reconsideration of that Finding were previously reviewed by the D.C. Circuit, *see Coal. for Responsible Regul., Inc.* v. *EPA,* 684 F.3d 102 (D.C. Cir. 2012) (per curiam) (subsequent history omitted). Moreover, the 2009 Endangerment Finding triggered EPA's statutory duty to promulgate motor vehicle standards under section 202(a) of the CAA, for which judicial review is also only available in the D.C. Circuit and which have effects in more than one federal judicial circuit.[4] For these reasons, this final action is nationally applicable or, alternatively, the Administrator is exercising the complete discretion afforded to him by the CAA and hereby finds that this final action is based on a determination of nationwide scope or effect for purposes of CAA section 307(b)(1) and is hereby publishing that finding in the **Federal Register**.

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the District of Columbia Circuit within 60 days from the date this final action is published in the **Federal Register**.

Michael S. Regan,

Administrator.

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BILLING CODE 6560–50–P

[3] In deciding whether to invoke the exception by making and publishing a finding that this final action is based on a determination of nationwide scope or effect, the Administrator has also taken into account a number of policy considerations, including his judgment balancing the benefit of obtaining the D.C. Circuit's authoritative centralized review versus allowing development of the issue in other contexts and the best use of Agency resources.

[4] In the report on the 1977 Amendments that revised section 307(b)(1) of the CAA, Congress noted that the Administrator's determination that the ''nationwide scope or effect'' exception applies would be appropriate for any action that has a scope or effect beyond a single judicial circuit. *See* H.R. Rep. No. 95–294 at 323, 324, reprinted in 1977 U.S.C.C.A.N. 1402–03.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 410, 414, 488, and 493

[CMS–3368–F]

RIN 0938–AT83

Medicare Program; Accrediting Organizations—Changes of Ownership

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule adds new requirements and a specified process to address change of ownership (CHOW) for Accrediting Organizations (AOs) in regard to the transfer of the existing Centers for Medicare & Medicaid Services (CMS) approval for the AO's accreditation programs to the new AO owner. These regulations are intended to provide CMS with the ability to receive notice when an AO is undergoing or negotiating a CHOW, as well as to review the prospective new AO owner's capability to perform its tasks after a CHOW has occurred, in order to ensure the ongoing effectiveness of the transferred accreditation program(s) and to minimize risk to patient safety.

DATES: This final rule is effective June 28, 2022.

FOR FURTHER INFORMATION CONTACT: Caroline Gallaher, (410) 786–8705.

SUPPLEMENTARY INFORMATION:

I. Background

Medicare-certified providers and suppliers participate in the Medicare program by entering into a provider agreement with the Medicare program. Medicare-certified providers and suppliers include hospitals; ambulatory surgical centers (ASCs); skilled nursing facilities (SNFs; home health agencies (HHAs); hospice programs, rural health clinics (RHCs); critical access hospitals (CAHs); comprehensive outpatient rehabilitation facilities (CORFs); laboratories; clinics, rehabilitation agencies and public health agencies; and End Stage Renal Disease (ESRD) dialysis facilities.. To participate in the Medicare program, Medicare-certified providers and suppliers of health care services must among other things, be substantially in compliance with specified statutory requirements of the Social Security Act (the Act), as well as additional regulatory requirements related to, among other things, the health and safety of patients specified by the Secretary of the Department of Health and Human Services (the Secretary). These health and safety requirements are generally called conditions of participation (CoPs) for most providers, requirements for SNFs, conditions for coverage (CfCs) for ASCs and other suppliers, and conditions for certification for RHCs and FQHCs. A Medicare-certified provider or supplier that does not substantially comply with the applicable health and safety requirements risks having its Medicare provider agreement terminated.

Section 1865(a) of the Act allows most types of Medicare-certified providers and suppliers to demonstrate compliance with the applicable health and safety requirements through accreditation by a Centers for Medicare & Medicaid Services (CMS)-approved accreditation program of a national accreditation body, known as an Accrediting Organization (AO). This is referred to as ''deemed'' accreditation, because, if an AO is recognized by the Secretary as having standards for accreditation that meet or exceed Medicare requirements, any provider or supplier accredited by that AO's CMS-approved accreditation program is deemed by CMS to be complying with the applicable Medicare conditions or requirements.

We are responsible for providing continued oversight of national AOs' Medicare accreditation programs to ensure that providers or suppliers accredited by the AO meet the required quality and patient safety standards. We must ensure that the AOs have formalized procedures to determine whether the healthcare facilities deemed under their accreditation programs meet the AO's accreditation standards (which must meet or exceed the applicable Medicare program requirements). We are also responsible for ensuring that the AO's accreditation standards and practices for surveying providers and suppliers meet or exceed our standards and practices for granting approval.

Additionally, while accreditation by an AO is generally voluntary on the part of Medicare-certified providers or suppliers, accreditation is mandated by statute for four supplier-types in order to receive payment from Medicare for the services furnished to Medicare beneficiaries. These four supplier types are Advanced Diagnostic Imaging (ADI) suppliers, Home Infusion Therapy (HIT) suppliers, Diabetic Self-Management Training (DSMT) entities, and Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) suppliers. We describe these supplier types as ''non-certified'' because they are enrolled in the Medicare program

but do not formally enter into a participation agreement with Medicare.

These requirements will affect all of the AOs that accredit providers and suppliers, including those that are enrolled in the Medicare program, and those that enter into a participation agreement with Medicare. We believe that a change of ownership (CHOW) could occur with an AO that accredits any category of provider or supplier.

Any national AO seeking approval of an accreditation program in accordance with section 1865(a) of the Act must apply for and be approved by us 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 of its accreditation program(s) before the date the existing approval period expires. This requirement ensures that accreditation provided by these AOs continue to indicate that the providers or suppliers accredited are meeting or exceeding Medicare standards. Regulations implementing these provisions are found at 42 CFR 488.1 through 488.9.

We have an established process for the CHOW of Medicare-certified providers and suppliers set forth at § 489.18 and in Chapters 2 and 3 of the State Operations Manual (SOM), Publication 100–07. Although the existing provider and supplier CHOW process does not apply to the sale and transfer of AOs, it has served as an appropriate model for what we are requiring for changes of ownership of AOs.

The Medicare regulations at § 489.18, as well as the CMS SOM (CMS Pub. 100–07), outline processes concerning how a CHOW of a Medicare certified provider or supplier affects Medicare participation, such as how a provider agreement is automatically assigned to a new owner unless the new owner rejects assignment of the provider agreement. A CHOW takes place when the responsible legal entity has changed, and typically occurs when a Medicare provider has been purchased (or leased) by another organization.

Section 489.18 and interpretive guidance in the SOM (Chapters 2 and 3) define what constitutes a CHOW, the required notice to be provided by the current provider to CMS and contains a provision regarding the automatic assignment of the provider agreement to the new owner. This regulation also sets out the conditions that apply to assignment of the provider agreement to the new owner. Section 489.18(a)(1) provides that in the case of a partnership, the removal, addition, or substitution of a partner, (unless the partners expressly agree otherwise) as permitted by applicable state law, constitutes a CHOW. Section 489.18(a)(2) provides that in the case of an unincorporated sole proprietorship, the transfer of title and property to another party constitutes a CHOW. Section 489.18(a)(3) provides that, in the case of a corporation, the merger of the provider corporation into another corporation, or the consolidation of two or more corporations, resulting in the creation of a new corporation constitutes a CHOW. Transfer of corporate stock or the merger of another corporation into the provider corporation does not constitute a CHOW. In the new regulations at § 488.5(f), which would govern the CHOW process for AOs, we are incorporating via cross-reference the definitions at § 489.18(a)(1) through (3) of what constitutes a CHOW, and applying them to AOs.

Section 489.18(d) provides that where there is a CHOW, the provider agreement under the new owner is subject to all applicable statutes and regulations, and to the terms and conditions under which it was originally issued. This includes successor liability for Medicare overpayments and penalties.

Generally, under the existing CHOW processes, with certain limited exceptions, if a facility's new owner accepts the assignment of the provider agreement and CMS Certification Number (CCN), the new owner retains all the benefits and liabilities of that agreement. In such a case the provider's Medicare participation continues without interruption. If the purchaser (or lessee) elects not to accept automatic assignment or transfer of the provider agreement, then that rejection is considered to be a voluntary termination of the existing provider agreement. Therefore, the purchaser or lessee is considered a new applicant and must request initial certification as a new provider and obtain a new provider agreement.

It is important to clarify that CMS does not approve the actual business transaction between entities that result in the change of the responsible legal entity. Instead, our role when a provider's or supplier's ownership changes is to ensure that a new owner, who accepts the automatic assignment of the existing provider agreement (a CHOW), is eligible for Medicare participation. If so, we continue to treat the provider as the same entity, with only the owner having changed. If the new owner rejects automatic assignment of the provider agreement, then it must seek initial Medicare enrollment and certification for the facility, which may take several months. Pursuant to § 489.18, a new owner who rejects automatic assignment of the provider agreement, cannot receive payment for any services it may provide for Medicare beneficiaries between the date it acquires the facility and the date we determine that it meets all Medicare requirements (including any of the CoPs, CfCs, or other requirements).

The principles that apply when a Medicare-certified provider or supplier undergoes a CHOW provide a general framework as to how CMS will treat situations involving a CHOW for an AO, though there are some important differences. For example, in a CHOW of a Medicare-certified provider or supplier, CMS approval is not needed to transfer the Medicare agreement of the provider or supplier that undergoes a CHOW, if the new owner decides to accept assignment of the Medicare agreement. The Medicare agreement is automatically transferred to the new owner unless the new owner affirmatively rejects assignment, and the new owner will accept the assigned agreement subject to all applicable requirements, including health and safety standards and liability for overpayments. However, in the case of a CHOW for an AO, under this regulation, CMS' affirmative approval will be needed to transfer the existing CMS approval for the AO's accreditation program to a new owner. This policy reflects CMS' desire to ensure that an AO's CHOW does not adversely impact its survey and accreditation procedures, a change which could impact the health and safety of patients receiving services from providers and suppliers.

Currently, the regulations governing AOs do not include any provisions related to the CHOW process, including a process for notifying CMS of pending CHOWs for AOs, or other procedures which would allow us to review information about the proposed transfer of ownership of accreditation program(s). The current regulations also do not provide us with the authority to approve or deny the transfer of the existing CMS approval for the accreditation program(s) to be transferred. Under our current regulations, we are not typically made aware of a sale or transfer of an AO until that AO applies for renewal of CMS approval of the accreditation program(s) or unless we are voluntarily notified of the CHOW by the AO (although we retain the right to conduct comparability or validation surveys in accordance with § 488.8).

After review of the existing CMS regulations related to CHOWs, we did not believe that we had the explicit

regulatory authority to prospectively review and approve or deny the transfer of the existing Medicare-approval of accreditation programs. The purpose of such a review would be to ensure that, after transfer, the AO would continue to ensure that the entities it accredits met or exceeded CMS requirements.

On May 2, 2019, we published in the **Federal Register** a proposed rule entitled ''Accrediting Organizations—Changes to Change of Ownership'' (84 FR 18748) (2019 proposed rule). In the proposed rule, we stated that the current situation, whereby a change in ownership of CMS-approved accreditation programs may occur without notice to CMS does not provide an opportunity for us to review and approve or deny the transfer of the existing CMS-approval of the accreditation programs to be transferred. We further stated that this scenario had to be addressed so that we could assure Medicare beneficiaries that the standards and conditions for surveying facilities would continue to be met by the accreditation programs that were transferred to new ownership. We also stated that it was possible that the AO, after a CHOW transaction, might not be viable or equipped to accredit facilities under the transferred CMS-approved accreditation program(s), due to the new owner's inability to enforce the health and safety requirements of CMS. Without the authority to require AOs to provide us with notice when they are contemplating or negotiating a CHOW, and the authority to review the ability of the prospective new owner's capability to perform the required accreditation tasks after a CHOW, we are unable to confirm the ongoing effectiveness of the transferred CMS-approved accreditation program(s).

This final rule adds new requirements and a specified process to address CHOWs for AOs in regard to the transfer of the existing CMS approval for the AO's accreditation programs to the new AO owner. These regulations are intended to provide CMS with the ability to receive notice when an AO is undergoing or negotiating a CHOW, as well as to review the prospective new AO owner's capability to perform its tasks after a CHOW has occurred, in order to ensure the ongoing effectiveness of the transferred accreditation program(s) and to minimize risk to patient safety.

To date, there have been two (2) AO CHOW requests submitted to CMS. One was submitted approximately 20 years ago, and the other was submitted on November 19, 2020. While we cannot predict the frequency with which AO CHOW transactions will occur in the future, we believe that they could occur more frequently than they have in the past.

Requirements for Issuance of Regulations

Section 902 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) amended section 1871(a) of the Act and requires the Secretary, in consultation with the Director of the Office of Management and Budget, to establish and publish timelines for the publication of Medicare final regulations based on the previous publication of a Medicare proposed or interim final regulation. Section 902 of the MMA also states that the timelines for these regulations may vary but shall not exceed 3 years after publication of the preceding proposed or interim final regulation except under exceptional circumstances.

This final rule finalizes provisions set forth in the May 2, 2019 proposed rule. In addition, this final rule has been published within the 3-year time limit imposed by section 902 of the MMA. Therefore, this final rule is in accordance with the Congress' intent to ensure timely publication of final regulations.

II. Provisions of the Proposed Regulations

In the 2019 proposed rule, we proposed new procedures for the CHOW process for accrediting organizations. This proposed procedure would enable CMS to determine whether the new AO would be able to meet the appropriate Medicare requirements to be eligible for transfer of the existing CMS-approval for the accreditation programs to be transferred in the CHOW.

At § 488.5, we proposed to add a new paragraph (f) that would set out the requirements and processes for CMS review and approval or denial of a transfer of the existing CMS-approval for accreditation program(s) in a CHOW event.

We proposed at § 488.5(f)(1)(i) that any CMS-approved AOs negotiating or engaging in a CHOW transaction would have to provide notice of this CHOW transaction to CMS. At proposed § 488.5(f)(1)(ii) and (iii), we would require that this notice be provided to CMS in writing no less than 90 days prior to the effective date of the transfer of ownership. This notice requirement would allow CMS to perform an evaluation of whether the AO, under the new ownership, would (1) be viable or equipped to accredit facilities under its existing CMS approval; (2) be able to enforce the health and safety requirements of CMS for that program; (3) operate effectively; and (4) continue to meet or exceed the Medicare standards.

We would further require the prospective new owner or transferee to submit certain information to CMS in support of their request that the existing CMS-approval for the accreditation programs to be transferred in the CHOW. We proposed at § 488.5(f)(2)(iii) to require the prospective new owner or transferee to submit the following information: (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) would require that the prospective new AO's transition plan include the following information: (1) Changes to management and governance structures including current and proposed 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.

At § 488.5(f)(3)(i), we proposed to require the purchaser or transferee to provide a written acknowledgement, which states that if CMS approves the transfer of the existing CMS-approval of the accreditation programs that are part of the CHOW transaction, the new owner will become managerially, legally, and financially responsible for the operations of all CMS-approved accreditation programs being transferred. Upon the finalization of the CHOW transaction, the purchaser or transferee would be completely responsible for the management of the business operations of the AO, including, but not limited to the day to day business operations, the survey and accreditation processes, the oversight of accredited providers and suppliers, the handling of complaints regarding accredited suppliers, and compliance with all CMS requirements.

Furthermore, we proposed at § 488.5(f)(3)(ii), to require the purchaser or transferee to provide written acknowledgment stating that they agree to operate the transferred CMS-approved accreditation program(s)

under all the terms and conditions found at §§ 488.5 through 488.9.

We proposed at § 488.5(f)(3)(iii), that the purchaser or transferee would be required to provide a written acknowledgement that it would not operate the accreditation program(s) it acquired as CMS-approved accreditation program(s) until it received a notice of approval.

We proposed at § 488.5(f)(4)(i), that the parties to the CHOW would be required to notify the providers and suppliers affected by the CHOW within 15 calendar days after being notified of CMS's approval or disapproval for transfer of the existing CMS-approval for the accreditation program(s) to be transferred in the CHOW. Additionally, we proposed at § 488.5(f)(4)(ii), that if the AO or accreditation program(s) being acquired were under a performance review or under probationary status at the time the CHOW notice was submitted, the purchaser or transferee would have to acknowledge such status in writing. We believe that the purchaser or transferee must understand that when the CMS-approved accreditation program(s) are transferred under the CHOW, all current terms and conditions, and responsibilities are included in the transfer.

We proposed at § 488.5(f)(5), that we would publish a notice in the **Federal Register**, which would acknowledge the transfer of the CMS-approved accreditation program(s) through a CHOW event. This notice would also state that the purchaser would retain this CMS-approval for the transferred accreditation programs under the new ownership. This notice would be only intended to inform the public of the ownership change; therefore, the notice would not solicit public comments. Section 488.5(f)(5) would further provide that we would not publish this notice after we have issued approval for the transfer, without first receiving written confirmation that the CHOW has taken place.

We proposed at § 488.5(f)(6), that in the event we did not approve the transfer of the existing CMS approval for the accreditation programs to be transferred, we would notify all parties to the CHOW transaction in writing. The parties to the CHOW would include the relevant staff of the transferor and the transferee. Therefore, this notice would be sent to the relevant parties at the existing AO and the prospective transferee but not to the providers and suppliers accredited by the AO.

We proposed at § 488.5(f)(7)(i), that, in the event we were not made aware of a CHOW transaction, or did not approve the transfer of the existing CMS approval for the accreditation program(s) that were to be transferred, so long as the CHOW transaction was not completed, the transferor AO (existing AO) would be able to continue operating their accreditation programs under the existing CMS approval for said accreditation programs. The exception to this policy would be in the event that our review of the pending CHOW transaction revealed performance and/or compliance issues with the transferor AO that were previously unknown to CMS.

We also proposed at § 488.5(f)(7)(ii), that CMS would be able to withdraw the CMS approval of an AO's accreditation programs in accordance with § 488.8(c)(3)(ii) and (iii), if a CHOW transaction was completed without notice to CMS and/or without obtaining CMS' approval for the transfer the existing CMS approval of the accreditation program(s) to the new owner.

We proposed at § 488.5(f)(8), that in the event parties completed the CHOW transaction, and the purchaser or transferee attempted to operate the transferred accreditation programs under the CMS-approval granted to the previous owner of the accreditation program(s), notwithstanding CMS disapproval of the request to transfer, CMS would withdraw the approval of the accreditation programs in accordance with the procedures set out at § 488.8(c)(3)(ii) and (iii).

We proposed at § 488.5(f)(9), that, in accordance with § 488.8(g), if CMS withdrew the existing approval of transferred accreditation program(s) because a CHOW transaction was completed without notice to or the approval of CMS, an affected Medicare-certified provider's or supplier's deemed status would continue in effect for 180 calendar days after the removal of the existing CMS accreditation approval, if the provider or supplier took the steps stated in § 488.8(g). First, the Medicare-certified provider or supplier would be required to submit an application to another CMS-approved accreditation program within 60 calendar days from the date of publication of the removal notice in the **Federal Register**. Second, the Medicare-certified provider or supplier would be required to provide written notice to the State Survey Agency (SA) stating that it has submitted an application for accreditation under another CMS-approved accreditation program within the 60-calendar day timeframe specified in § 488.8(g). Failure to comply with the timeframe requirements specified in § 488.8(g) would place the affected Medicare-certified provider or supplier under the SA's authority for continued participation in Medicare and on-going monitoring.

The provisions of § 488.8(g) would not apply to non-certified suppliers, because the statute does not authorize SAs to engage in oversight of these supplier types. Therefore, we proposed at § 488.5(f)(10) that if CMS withdrew the existing approval of transferred non-certified accreditation program(s) because a CHOW transaction was completed without notice to or the approval of CMS, an affected non-certified supplier's deemed status would continue in effect for 1 year after the removal of the existing CMS accreditation approval if the non-certified supplier submitted an application to another CMS-approved accreditation program within 60 calendar days from the date of publication of the removal notice in the **Federal Register** and provided written notice of such application to the CMS within such timeframe. Failure to comply with the timeframe requirements would result in a CMS determination that the provider or supplier was no longer accredited.

For non-certified suppliers such as ADI and DSMT suppliers, CMS-approved accreditation is required as a condition for receipt of CMS reimbursement for the services furnished to Medicare beneficiaries. If these suppliers were suddenly left without CMS-approved accreditation they would have to seek new accreditation from a CMS-approved AO. We estimated that it would take no less than 6 to 9 months for these suppliers to complete the reaccreditation process and obtain new CMS-approved accreditation. We were concerned that during the time that these suppliers were undergoing the reaccreditation process, they would not be able to receive reimbursement from Medicare for any services furnished to Medicare beneficiaries. For many of these suppliers, Medicare beneficiaries make up a large portion of their client population and provides a large source of revenue for them. Therefore, these suppliers would be likely to suffer significant hardship if left without CMS-approved accreditation for a 6 to 9 month period. Also, if these suppliers were not able to provide services to Medicare beneficiaries for an extended period of time, it could create access to care issue for Medicare beneficiaries for the services provided by these suppliers. For this reason, we proposed accreditation for a 1 year period after **Federal Register** notification that CMS's approval of the non-certified supplier's

accreditation organization was being withdrawn. Because we proposed to add the same requirements for ADI, HIT, DSMT suppliers, and clinical laboratories, we would add cross references to the provisions in § 488.5(f) for these suppliers so that they would be subject to the same proposed requirements for a CHOW. Specifically, for DSMT suppliers at § 410.142, we proposed to add a new paragraph (k); for ADI suppliers at § 414.68, we proposed to add a new paragraph (j); for HIT suppliers at § 488.1030, we proposed to add a new paragraph (g); and for laboratories at § 493.553, we proposed to add a new paragraph (e).

III. Analysis of and Responses to Public Comments

We received 8 public comments from an individual, accrediting organizations and a hospital association. We have reviewed all of the public comments received and considered the concerns raised by all stakeholders. As a result, we have made several revisions to the proposed regulation at § 488.5(f) in response to public comments. Specifically, we have modified §§ 488.5(f)(1)(iii) and (iv) and § 488.5(f)(2)(iii)(D). See section IV ''Provisions of the Final Regulations'' for detail description of these changes. A summary of the comments received and our responses to those comments appear in the paragraphs below.

A. Notification Requirements

1. Notice to CMS Requirements—§ 488.5(f)(1)

Comment: One commenter expressed support for the 90-day written notification of intention to change ownership of an AO. The commenter stated that this requirement reflects a reasonable timeframe for the organization to notify CMS of whether negotiation or engagement in the intent to change ownership is taking place.

Response: We thank this commenter for their support on the written notification requirements.

Comment: One commenter recommended that CMS require AOs to notify CMS of any ownership change within 15 days following the effective date of ownership transfer. This commenter stated that, by that point, CMS would have the authority to review characteristics of the new business entity and make decisions regarding whether the new entity has the necessary resources and structure to retain deeming authority.

Response: We thank this commenter for their comment, however, we respectfully disagree with the commenter's position that CMS would not have the authority to review characteristics of the new business entity and make decisions regarding whether the new entity has the necessary resources and structure to retain deeming authority until after the AO is sold or transferred to the new owner. We believe that in the case of a CHOW for an AO, the new owner might have an expectation that CMS's approval of an accreditation program would be a transferable business asset or an intrinsic part of the accreditation program that would automatically transfer, along with the accreditation programs, to the new owner as part of the CHOW process. However, this rule clarifies that CMS approval of accreditation programs is not freely transferable, without regulatory oversight, qualifications or conditions.

CMS approval is not a transferrable business asset, but a governmental regulatory agency approval. Our approval of an accreditation program is granted to the existing owner of the AO based on that AOs ongoing circumstances, as described in the AO's initial and renewal applications for deeming authority. Before we could agree to transfer the existing approval of CMS accreditation program(s) to a new AO owner, we would require information which provides us with the assurance that the AO, under new ownership, would: (1) Be viable or equipped to accredit facilities under its existing CMS approval; (2) be able to enforce the health and safety requirements of CMS for that program; (3) operate effectively; and (4) continue to meet or exceed the Medicare standards. If CMS finds that these conditions are met, then we would approve the transfer of the existing CMS approval for the accreditation programs to be transferred to the new owner. We believe that section 1865(a)(2) of the Act permits us to look at an AO's resources and procedures at any time. Consequently, CMS has the authority to perform a prospective review of the new owner's ability to run the AO prior to the time of sale or transfer. The purpose of this review is to ensure that the AO will have financial longevity, will provide safe and effective accreditation that meets the CMS requirements, and ensure that the providers and suppliers accredited by the AO, under new ownership, will continue to provide safe and effective healthcare to patients.

Further, we note that waiting until after the CHOW has occurred to perform our review of the new owner's circumstances and qualifications will likely be burdensome as well as a disservice to the AO itself. If we were to find that an AO under new ownership was not accrediting facilities in accordance with the CMS requirements, we will terminate our approval for the transferred accreditation programs. Also, we will investigate the providers and suppliers that were accredited between the time that the new owner took over and the time that the CMS approval for the accreditation programs was terminated. We will perform this investigation because these providers and suppliers would have been accredited under accreditation programs during the time the programs were not being properly administered by the AO under the new owner. These additional surveys will be burdensome for the providers or suppliers being surveyed a second time, as well as for CMS and our contractors.

Comment: One commenter suggested that the rule should require the AO to notify CMS when an AO is contemplating undergoing or negotiating a CHOW.

Response: We agree with this commenter. Sections 488.5(f)(1)(ii) and 488.5(f)(1)(iii) require that written notice of the CHOW must be provided by the AO to CMS no less than 90 days prior to the anticipated effective date of the CHOW transaction.

2. Notification Requirements—§ 488.5(f)(4)

Comment: One commenter stated that if CMS approved the transfer of ownership of an AO, the required 15 day notice that providers would receive would be an inadequate amount of time for hospitals to review and enter into new contracts with the new AO owner. This commenter requested that CMS provide at least 3 months' notice to hospitals prior to the change in ownership going into effect, to allow hospitals time to engage with the new owner. This commenter also suggested that CMS should consider both print and electronic communications to satisfy these efforts (that is, U.S. mail, email, voicemail follow up by AOs).

Response: We understand this commenter's concern but respectfully disagree. The purpose of the notice required by § 488.5(f)(4) is to notify the providers and suppliers that have been accredited by that AO that CMS has approved the transfer of the existing CMS-approval for the accreditation programs to be transferred in the CHOW to the new owner. An approved transfer will not terminate any facility's existing accreditation, which will expire at the end of the term set by the transferor AO.

We are hopeful that requirements imposed under these proposed new regulations will not affect the contracts

between the providers and suppliers and the AO. We are also hopeful that the accredited providers and suppliers will not be required to immediately enter into new contracts with the new AO since the new owner will assume ownership of the AO subject to the AO's existing contractual obligations. However, it will be up to the parties involved to examine their own agreements prior to the CHOW. Unless the CHOW agreement between the existing AO and transferee AO states otherwise, we believe the CHOW will not affect the term of accreditation that was granted to the providers and suppliers by the existing AO ownership, provided that CMS does not withdraw approval for the accrediting programs to be transferred. CMS' approval for the transfer of the approval for the accreditation program(s) being transferred in a CHOW will be contingent upon the new AO owners agreement to continue the periods of accreditation for any providers or suppliers accredited under those accreditation programs, prior to the time the CHOW transaction took place. In other words, the new AO owner will be required to assume ownership of the AO subject to the terms of existing accreditations granted by the existing AO.

The caveat to this rule would be if CMS were to not approve the transfer of the approval for the accreditation program to be transferred in the CHOW. In such a case, if the CHOW still occurred, the new AO would not have approval for the transferred accreditation programs and the providers and suppliers accredited by the previous owner of the AO would be required to seek accreditation from another AO. Also, there is a possibility that a transferor's poor performance could trigger withdrawal of the AO's deeming authority in accordance with § 488.8(g). In this case, as in all cases of involuntary termination of an AO's accreditation program, an affected provider's or supplier's deemed status would continue in effect for 180 calendar days after the removal of the approval if the provider or supplier submitted an application to another CMS—approved accreditation program within 60 calendar days from the date of publication of the removal notice in the **Federal Register**.

3. Notification to Parties in the Event That CMS Does Not Approve the Transfer of the Existing CMS Approval—§ 488.5(f)(6)

Comment: One commenter stated that it was important to include this step in the provision; however, they stated that the language of § 488.5(f)(6) was vague. This commenter suggested that § 488.5(f)(6) be revised to include language stating that CMS would notify all providers and suppliers to the CHOW transaction in writing. The commenter stated that the notice to the providers and suppliers should include information about an AO program's current status.

Response: We appreciate the need for providers and suppliers to have transparency about their AO's ownership, but believe that the policies in this rule are sufficient to reach that end. Section 488.5(f)(4) provides that all parties to the CHOW transaction must notify the providers and suppliers affected by such change within 15 calendar days of being notified of CMS's approval to transfer of the existing CMS-approval for the accreditation programs to be transferred in the CHOW transaction. We believe that this notice to providers and suppliers required by § 488.5(f)(4) is adequate because it must be provided within 15 days after CMS has approved the transfer of the CMS approval for the accreditation programs to be transferred in the CHOW.

Also, § 488.5(f)(5) requires that, after CMS receives written confirmation from the new owner that the CHOW has taken place, CMS publishes a notice of approval in the **Federal Register** of the transfer of the existing CMS approval for the accreditation program(s) to a new owner. However, the notice required by § 488.5(f)(5) will be published only after CMS receives written confirmation from the new owner that the CHOW has taken place because providers and suppliers should not be notified by CMS of the CHOW until after it is approved by CMS. If CMS does not approve the transfer of the CMS approval for the accreditation programs or if the parties to the CHOW decide not to proceed with the sale or transfer transaction, such premature notice could cause providers and suppliers to panic or worry unnecessarily.

We believe between these two forms of notice, there is no reason that the affected providers and suppliers would not be notified of the CHOW. In addition AOs contemplating a CHOW may choose to notify providers and suppliers at any time on their own.

We further disagree with this commenter's suggestion that the notice required by § 488.5(f)(6) should include information about the current status of the AOs' programs. The purpose of this notice is to inform the parties to the CHOW that CMS has disapproved the transfer of the approval for the accreditation programs to be transferred in the CHOW. This is outside the purpose of the notice required by § 488.5(f)(6). Also, we believe that it would not be CMS's place to provide information about the AO's current status to its accredited providers and suppliers; CMS generally does not maintain current information on accreditation organizations' client lists.

B. Documentation Requirements

Comment: One commenter stated that a transition plan plays no role in the contemplated business negotiation and may not be readily available 90 days prior to the effective date of ownership transfer.

Response: We thank the commenter for their input but respectfully disagree. We believe that the new owner should have a transition plan fully developed at least 90 days prior to the time that the CHOW takes place so that it can be put into place immediately upon the sale or transfer of the AO. We believe that it will be shortsighted of the new owner to not develop a transition plan well in advance of the anticipated effective date of the CHOW. We also believe that it will have potentially negative consequences, not only for the AO but for the providers and/or suppliers it accredits, for the new owner to wait until after the CHOW takes place to develop the transition plan. If this were the case, the AO under new ownership would lack organization and direction until the transition plan was developed and implemented.

Comment: One commenter stated that the development of a transition plan will engage employees in both the business operations and accreditation operations departments within the AO(s).

Response: We agree with this commenter regarding this aspect of the request for approval process and thank them for their comment.

C. Written Acknowledgements

1. Written Acknowledgement From the Purchaser/Buyer/Transferee—§ 488.5(f)(3)(ii)

Comment: One commenter stated that the requirement of § 488.5(f)(3)(ii) that requires the purchaser/buyer/transferee to agree 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) is an important step. This commenter supports the expectation of the purchaser or transferee to provide full disclosure of the understanding of specific conditions related to operating a CMS-approved AO.

Response: We thank this commenter for their support of the written acknowledgement provision.

2. Written Acknowledgement From the Purchaser/Buyer/Transferee—§ 488.5(f)(3)(iii)

Comment: This commenter stated that the requirement of § 488.5(f)(3)(iii) that requires the purchaser/buyer/transferee to agree not to operate the accreditation program(s) it acquired in the CHOW as CMS approved accreditation programs until the effective date set forth within the notice of approval from CMS expands on the importance of full disclosure. The commenter supported the continued protection of the process included in the transfer of ownership of an AO.

Response: We thank this commenter for their support of the proposed written acknowledgement provision.

D. Proposed Regulatory Requirements

1. General Comments About the Proposed Regulatory Requirements

Comments: Several commenters expressed full support for our proposal to establish the regulations at § 488.5(f). One commenter stated that being certain a process is in place so that CMS approves new ownership of AOs is essential to mitigating risks to patients and that proposal will establish even greater accountability for the AO and will highlight CMS' role in the oversight of AOs. This commenter further stated that our proposals exemplify the ongoing efforts CMS has in order to safeguard patients by guaranteeing AOs are upholding the standards required to maintain an approved accreditation program.

One commenter stated CMS should establish a standard process for review and approval of a CHOW of an accrediting organization and that this rule would provide important clarity for accrediting organizations seeking to undergo an ownership change. Another commenter stated that, generally, the proposed changes provide for increased oversight and strengthen the program without placing extraordinary burden on AOs and prospective merger or acquisition partners.

Response: We thank these commenters for their support of our proposals.

Comment: One commenter did not support our proposal to establish regulations related to CHOW of AOs. This commenter stated that the proposed notification requirements regarding contemplated ownership changes amount to unwarranted regulatory interference.

Response: We thank the commenter for sharing their concern but respectfully disagree that this regulation amounts to unwarranted interference. It is important to note that transfer of the CMS approval of the accreditation programs held by the original owner of an accreditation program is not a right that could automatically accrue to the new owner of an AO. It is also not something that could be sold or transferred to another owner like a piece of property or business asset. Such CMS approval is granted to the original owner of the AO accreditation programs based on the circumstances of the AO that exist at the time of approval.

Therefore, transfer of the CMS approval for the accreditation programs being transferred in a CHOW must be approved by CMS. In order to give this approval, CMS must receive assurance that the AO under the new ownership will be financially viable, and have long term stability of operations. CMS must also ensure that the accreditation provided by the AO, under new ownership, meets the CMS standards to ensure that the healthcare providers and suppliers accredited by that AO are providing safe and effective healthcare. This means that CMS would need to be provided with specific information about the proposed new ownership in order to obtain such assurance prior to the CHOW taking place.

The regulations at § 488.5(f) allow CMS to obtain information prior to the CHOW that will allow us to determine whether the AO, under the new ownership, will maintain continuity of operations, will be able to accredit facilities using the CMS accreditation standards, and whether the facilities accredited by the new AO will provide safe and effective patient care. CMS is finalizing these regulations in order to create fair and transparent standards for the transfer of the CMS approval for the accreditation programs to be transferred in a CHOW and avoid any potential lapses in deeming authority that may come from a post-transfer review. Without this regulatory authority, the new AO would not be allowed to operate using the existing CMS approval for the accreditation programs that were transferred in the CHOW. The new AO owner/transferee will be required to submit an application to CMS seeking approval of the transferred accreditation programs. During the time frame that the application was pending CMS approval, the new AO owner/transferee would not be able to provide accreditation services to any providers or suppliers. The requirements of § 488.5(f) will enable us to decide whether to approve the transfer of the existing CMS approval for the accreditation programs to be transferred, thus avoiding a lapse in the CMS approval for these accreditation programs.

Comment: A commenter stated that CMS is inappropriately inserting itself into the AO's financial transactions, which would interfere with the AOs' ability to conduct business.

Response: We thank the commenter for their concern but respectfully disagree. The purpose of this regulation is not to approve or deny the sale or transfer transaction that takes place. The purpose of these regulations is (1) to receive documents from the prospective new owner of the AO, prior to the time that the CHOW takes place, in order for CMS to determine whether the AO's accreditation programs under new ownership would meet or exceed the CMS requirements; (2) to make a prospective determination as to whether the AO, under the new ownership, can assure us that the providers and suppliers accredited by the AO, are providing safe and effective care; and (3) to determine whether to transfer the existing CMS approval for an AO's accreditation program to the prospective new owner of the AO. We believe these functions are integral to CMS' ability to effectively regulate AOs and ensure quality in Medicare-certified suppliers and providers. Beyond ensuring accreditation program integrity and adherence to CMS' requirements under the new ownership, we will have no part in AO financial business.

Comment: One commenter stated that this proposed notification process could create unnecessary work for CMS. They explained that not all negotiations end in a successful transaction and that in the event that a potential ownership change never came to fruition, CMS would have spent resources reviewing documentation for a transaction that was never finalized.

Response: We appreciate this commenter's concern on CMS' behalf. We are primarily concerned with making sure there are assurances that an AO's accreditation programs under new ownership would meet or exceed our requirements and determine whether the providers and suppliers accredited by that AO provide safe and effective care. If a sale or transfer for the AO were to fall through, we expect the existing or prospective new owner of the AO to notify CMS as soon as possible. This will allow us to cease our review of the documents as early as possible and thus limit any unnecessary work.

2. Deadline Requirement—§ 488.5(f)(1)

Comment: One commenter suggested that CMS specify in the final regulation whether the timeframes are measured in business or calendar days.

Response: We agree with this commenter and believe that the distinction between calendar and business days has a significant impact on the amount of time allowed.

In reviewing § 488.5(f)(1)(iii) in the 2019 proposed rule, we noted that only the 90 day deadline was listed but did not specify whether this deadline was for calendar or business days. However, the remainder of the deadlines contained in § 488.5(f) did specify whether these deadline are for calendar or business days. Therefore, we have revised the requirement at § 488.5(f)(1)(iii) by adding ''calendar days'' to the 90 day deadline.

Comment: One commenter pointed out that the proposed regulations do not include a timeline related to the CMS review and approval or denial of the proposed transfer. This commenter requested that CMS amend the proposal to add that CMS will notify the parties of approval or denial no more than 30 days after receipt of a complete application for approval of transfer of the existing Medicare approval.

This commenter stated that a timeline should be in place because, should the AO contemplate a CHOW arrangement, there would be implications on planning, forecasting, and budgeting. The AO would face significant costs throughout the duration of transition planning including ongoing accounting, public relations, legal, and other professional fees. In addition, in a CHOW, an AO may have other operational issues to consider, including staffing requirements and support before and after the ownership change.

Response: We agree with this commenter that having a deadline for CMS' review of their request for approval of the CHOW would be helpful for the planning, forecasting, and budgeting process related to a CHOW and also for transitioning the AO to the new ownership. Therefore we have added a provision at § 488.5(f)(1)(iv) which requires that CMS will complete their review of the AO's request for approval for the transfer of the existing CMS approval for the accreditation programs to be transferred in the CHOW within 90 days from receipt of said request.

3. Federal Register Notice Requirement—§ 488.5(f)(5)

We received no comments in regards to this section of the proposed regulation, and are therefore adopting it without change.

4. Withdrawal of CMS Approval Due to Failure To Notify CMS of Intent To Transfer Accreditation Programs—§ 488.5(f)(7).

Comment: One commenter stated that the provisions of § 488.5(f)(7) serve an important role. This commenter further expressed their support for the provision at § 488.5(f)(7)(i) regarding CMS' authority to withdraw approval if further review of the pending transaction reveals issues with performance and/or compliance. This commenter stated that if an AO does not notify CMS of the CHOW, but has started the process, the AO may continue to operate under their current approval but that this violation should prompt a CMS review of their current approval status.

Response: We thank this commenter for their support regarding the requirements in § 488.5(f)(7). We further note that there are several types of reviews that CMS can use when an AO attempts to or does complete a CHOW without notice to and approval from CMS.

First, proposed § 488.5(f)(7)(i) will allow CMS to perform a review of a pending CHOW transaction of which CMS has not been made aware. As in the case of other CHOW reviews, per § 488.5(f)(7)(ii), if our review revealed issues with the AO that were previously unknown to CMS, CMS would take action accordingly.

Second, proposed § 488.5(f)(8) provides that in the event that the parties complete the CHOW, notwithstanding CMS disapproval, and the purchaser/buyer/transferee attempts to operate the transferred accreditation program(s) under the CMS-approval granted to the previous owner, CMS will withdraw the existing approval of the transferred accreditation program(s) in accordance with the procedures set out at § 488.8(c)(3)(ii) and (iii). Existing § 488.8(c) provides the standards for CMS-approved accreditation program review, including the timeline for the AO's probationary period and withdrawal of CMS approval at § 488.8(c)(3)(ii) and (iii).

Therefore, in addition to the ability to cite the AO's failure to meet Medicare's conditions and requirements under § 488.5(f)(7)(i), CMS can also initiate a program review under proposed § 488.5(f)(8). We do not believe that any additional review processes are necessary.

5. Withdrawal of CMS Approval for Accreditation Programs Which Are Transferred Notwithstanding CMS' Disapproval of the Transfer—§ 488.5(f)(8)

Comment: One commenter supported the provision for the withdrawal of CMS' approval for the accreditation program if the transfer is disapproved, as proposed at § 488.5(f)(8).

Response: We thank this commenter for their support of the proposed withdrawal provision.

Comment: One commenter suggested that the notice of withdrawal of an AO's Medicare approval should be provided directly to affected providers by CMS and the AO. This commenter stated that this would make this notice process consistent with the notice requirement when a CHOW is approved.

Response: We understand this commenter's concern. We would like to point out that if CMS does not approve a CHOW, we will not withdraw or terminate an AO's Medicare participation, but instead will withdraw the CMS approval for that AO's accreditation programs to be transferred in the CHOW. If the transferee were to proceed with the CHOW, the AO, under new ownership, will be permitted to file a new application seeking CMS approval for these accreditation programs.

We do not believe that it is necessary to modify the regulations at § 488.5(f) to require CMS to provide notice of the disapproval of the CHOW directly to the affected providers and suppliers for several reasons. First, if the transferee elected not to proceed with the CHOW, then the CMS approval would remain unchanged as per § 488.5(f)(7)(i) Second, there are other AO oversight regulations which require that such notice be given to providers and suppliers when CMS withdraws approval for an AO's accreditation program. Existing § 488.8(g)(1) provides that we will publish a notice in the **Federal Register** if we were to withdraw the CMS approval of an AO. Also, existing § 488.8(e) provides that an AO whose CMS approval has been withdrawn must notify, in writing, each of its accredited providers or suppliers of the withdrawal and the implications for the providers' or suppliers' deemed status no later than 30 calendar days after the notice is published in the **Federal Register**. We believe that the notice provided pursuant to §§ 488.8(e)(1) and 488.8(g) are adequate to ensure providers and suppliers receive timely notification of the withdrawal of an AO's CMS approval.

We are therefore finalizing § 488.5(f)(8) without change.

6. Requirements for Continuation of a Deemed Status Accreditation of Medicare-Certified Providers and Suppliers After CMS Withdraws the Existing Approval of the Transferred Accreditation Program(s)—§ 488.5(f)(9)

Comment: One commenter stated that if CMS proceeds in codifying this process, it should extend the proposed timeframes for providers, to allow sufficient time for providers to negotiate new contracts and have orderly transitions from one AO to another AO, or to a SA.

Response: We appreciate this commenter's concern. The timeframes set forth in § 488.5(f)(9) are the same as those that are set forth in § 488.8(g) entitled ''*Continuation of deemed status*'' which provides that ''[a]fter CMS removes approval of an accrediting organization's accreditation program, an affected provider's or supplier's deemed status continues in effect for 180 calendar days after the removal of the approval if the provider or supplier submits an application to another CMS-approved accreditation program within 60 calendar days from the date of publication of the removal notice in the **Federal Register**.'' We believe that having different timeframes in § 488.5(f)(9) for the same activities that are set forth in § 488.8(g) for Medicare-certified providers and suppliers would be inconsistent and confusing to providers and suppliers.

Comment: One commenter noted that the proposed rule provided that if an AO did not appropriately seek approval from CMS prior to a change in ownership, providers accredited by the now-former AO would only have 180 days of deemed status remaining. As an example, a hospital may have only recently gone through their AO's survey process and could have just recently been reaccredited for 3 years. Through no fault of their own, they would have only 6 months prior to their loss of Medicare certification status. By contrast, the proposed rule would provide 1 year of accreditation status to non-certified suppliers. This commenter recommended that CMS grant Medicare-certified providers and suppliers at least the same amount of time as non-certified suppliers (that is, 1 year) and allow for an extension process if additional time is needed. This commenter further stated that the Ligature Risk Extension Request process in CMS' draft guidance, DRAFT–QSO–19–12-Hospitals—Clarification of Ligature Risk Interpretive Guidelines, released April 19, 2019, may provide a helpful model for seeking an extension.

Response: We appreciate this commenter's concern. The timeframe set forth in § 488.5(f)(9) for Medicare-certified providers and suppliers are the same as those that are set forth in § 488.8(g) titled ''*Continuation of deemed status.*'' In fact, § 488.8(g) are referenced in § 488.5(f)(9)(iii). As noted previously, we believe using different timeframes would be inconsistent and confusing.

We proposed at § 488.5(f)(10) that if CMS withdrew AO approval of transferred non-certified accreditation program(s) because a CHOW was completed without notice to CMS or receipt of CMS approval, an affected non-certified supplier's deemed status would continue in effect for 1 year after the removal of the existing CMS accreditation approval if the non-certified supplier submitted an application to another CMS approved accreditation program within 60 calendar days from the date of publication of the removal notice in the **Federal Register** and provided written notice of such application to the CMS within such timeframe. Failure to comply with the timeframe requirements would result in a CMS determination that the supplier was no longer accredited.

We proposed a 1 year period of time for the continuation of accreditation for non-certified suppliers for several reasons. First, the provisions of § 488.8(g) do not apply to non-certified suppliers. Second, in our view, giving non-certified suppliers additional time compared to Medicare-certified provider and suppliers (1 year as opposed to 180 days of continued accreditation status, respectively), is appropriate due to the different circumstances of Medicare and Medicare certified providers and suppliers as compared to those of the non-certified suppliers. More specifically, non-certified suppliers are not subject to inspection by the SA, because there is no legal authority for the SA to do so. Therefore, they are not able to use the SA for approval to participate in Medicare in the event that they cannot obtain accreditation from an AO. We believe it is necessary to grant the non-certified suppliers a longer period of extended accreditation in which to achieve reaccreditation from another AO, since they do not have the safety net of being certified by the state.

For non-certified suppliers such as ADI, DSMT, and HIT suppliers, the accreditation process typically takes longer because it's usually performed by a ''desk audit'' process. With a desk audit, the non-certified supplier would be given a period of time in which to collect and submit the information required for the desk audit. For example, ADI suppliers must submit images for specific ADI procedures. They must either gather images from procedures that have already been performed or perform new procedures to obtain these images.

After the ADI supplier has obtained all of the images required for accreditation, they would submit their accreditation package to the AO. We estimate that the ADI AO's review the ADI supplier's accreditation package takes up to one to several weeks, depending on the AO's workload. Whereas, for Medicare-certified providers and suppliers, accreditation is based on an on-site survey, which can be scheduled and performed within a short period of time. Therefore, the accreditation can be completed more quickly.

In addition, accreditation is a condition for receipt of Medicare payment for non-certified suppliers, while this is not the case for Medicare certified providers and suppliers. If their Medicare accreditation lapses, the non-certified suppliers would no longer be eligible to receive payment for services furnished to Medicare beneficiaries. This could lead to financial hardship for these non-certified suppliers that could cause them to refuse to serve Medicare beneficiaries or cause them to go out of business. Both of these scenarios would result in an access to care issues for Medicare beneficiaries. For these reasons, we believe it is important that we allow the non-certified suppliers a longer period of time in order to obtain re-accreditation from another AO.

Comment: One commenter suggested that both the 60-day timeframe to submit an application to a new AO and the 120-day timeframe to be surveyed be extended. Another commenter expressed the belief that an affected provider's or supplier's deemed status should continue for longer than 180 days to allow sufficient time for them to make decisions, establish budgets, prepare for and address findings on the path to an accreditation determination by a new AO.

Response: This commenter seems to suggests that §§ 488.5(f)(9) and 488.8(g) provide for 2 separate and distinct periods of time or deadlines, consisting of an initial 60 day period in which the provider or supplier must submit their application to another AO and second and subsequent 120 day period in which the provider or supplier must be surveyed.

We note that providers and suppliers actually have 180, rather than 120, days in which to receive accreditation. Section 488.5(f)(9) provides that ''an affected Medicare-certified provider or supplier's deemed status will continue in effect for 180 calendar days if the Medicare-Certified provider or supplier takes the following steps set forth is § 488.8(g).'' Those steps include the provider or supplier is required to file an application with another AO and provide notice to the SA of the filing of this application within 60 days of the date of receipt of notice of the withdrawal of the AOs CMS approval. This deadline does not separate the 180 day period of continued accreditation into two separate and distinct periods. Rather, healthcare provider or supplier can file their application with another AO as soon possible after being notified of withdrawal of their AO's CMS approval. Conceivably, this application could be filed the day after the provider or supplier received such notification. We believe that if a provider or supplier has filed an AO application in the past, they should be familiar with the information and documentation required and therefore, should not wait until near the 60 day deadline to notify the SA of the filing of their application with another AO.

We further believe that the 180-day timeframe is an adequate amount of time for a Medicare-certified provider or supplier to obtain reaccreditation from a new AO. In fact, the timeframes in § 488.8(g) are referenced in § 488.5(f)(9)(iii).

E. Change of Ownership of AOs

Comment: One commenter suggested that, CMS should also require written disclosure of any potential or actual conflicts of interests related to the new owner, as part of the documentation required to request approval of a transfer to a new owner. This commenter expressed the opinion that requiring this information would do the following: (1) Give CMS the authority to review conflicts and, if necessary, require corrective action as a condition of approval; (2) be an opportunity to consider conflicts based on paid consultative services (the subject of the Request for Information published in December 20, 2018, ''Accrediting Organizations Conflict of Interest and Consulting Services'', CMS–3367–NC (83 FR 65331)); and (3) help CMS ensure that the primary focus of accreditation by the new owner is to recognize quality and that accreditation decisions will continue to be made in an objective manner independent of the new owner's other financial or programmatic interests.

Response: We agree with this commenter. Therefore, we have added a requirement at § 488.5(f)(2)(iii)(D) that requires the prospective new owner of the AO to provide policies and procedures to avoid conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys or participate in accreditation decisions, as required by § 488.5(f)(10) with the information to be submitted with the AO's request for approval.

Comment: Several commenters expressed concern regarding the confidentiality of proprietary merger/acquisition information and the open-ended review timeline. Other commenters expressed concerned that the proposed regulation did not include provisions protecting against disclosure of sensitive information related to the potential CHOW.

Another commenter explained that parties to a merger or acquisition have significant interest in maintaining the confidentiality of related deliberations because uncontrolled disclosure could cause significant harm to the interests of the parties involved and other stakeholders, including CMS. This commenter expressed concern that if the CHOW information is disclosed prematurely, it could create concern amongst customers, potentially impacting the transaction, and creating operational issues for both the accreditation organization and CMS who may not yet be ready to field customer inquiries about the pending change.

Another commenter expressed concern that the proposed rule contains no explicit guarantee of the confidentiality of proprietary information and intellectual property shared with CMS. This commenter stated that as part of the valuation process in any ownership change, AOs will share proprietary information and intellectual property that must remain protected. Another commenter recommended that CMS consider confidentiality concerns of the involved parties in any rulemaking that requires advance notice to CMS. Several other commenters requested that CMS modify the proposal with consideration for these concerns.

Response: We understand the concern expressed by these commenters. We will make every effort to keep the information submitted by the buyer/transferee in support of their request for transfer of the existing CMS approval for the accreditation programs strictly confidential. There is a possibility that CMS could receive a Freedom of Information Act (FOIA) request for this information, however the FOIA contains several statutory exemptions that allow agencies to withhold records in responding to a FOIA request. Exemption 4 protects ''trade secrets and commercial or financial information'' that is ''privileged or confidential.'' *See* 5 U.S.C. 552(b)(4). CMS will withhold or release information in accordance with applicable federal law and its regulations at 45 CFR subpart D.

Comment: One commenter stated that CMS should consider ''change of control'' principles in addition to ''CHOW'' as part of the proposed rule.

Response: We thank the commenter for their input. We note that the term ''change of control'' could refer to a change in the day-to-day AO management activities, or a change to the managing control of the AO. This term could also refer to a change in the ownership or partnership interests in the AO. A change of management or managing control could involve a change in the day-to day management staff, board of director members or managing partners of the AO. A change in the ownership interest in the AO could involve a change in the number of persons who own an interest in the AO and/or a change in their percentage of ownership of interest in the AO. A change in a partnership interest in an AO could involve the addition of or removal of partners or a change in the percentage of their partnership interest.

We do not believe that change of control should be included in the regulations at § 488.5(f) because, if a change of control issue were to occur, we would not expect the daily operations of the AO to change. We say this because, an AO undergoes a change of control they are required to notify CMS of this change. Also if, as a result of the change of control, the AO were to decide to make changes to its accreditation standards and/or survey processes, the AO will be required to submit these revised accreditation standards and/or survey processes to CMS for a comparability review and CMS approval pursuant to § 488.8((b)(2). In addition, the AO will be required by § 488.5(a)(19) to provide, with their initial or renewal application, a statement that, in response to a written notice from CMS to the organization of a change in the applicable conditions or requirements or in the survey process, the organization will provide CMS with proposed corresponding changes in the organization's requirements for its CMS approved accreditation program to ensure continued comparability with the CMS conditions or requirements or

survey process. These proposed changes must be submitted within 30 days after CMS's written notice and the AO may not implement them without CMS approval. We believe that these requirements will be sufficient to provide notice to CMS of any changes, in the event that an AO undergoes a change of control.

Comment: One commenter suggested that the regulation should set out the criteria CMS uses to assess an AO's ability to perform its tasks after a CHOW has occurred.

Response: We appreciate this commenter's concern but respectfully disagree. The regulation at § 488.5(f)(2) states the specific information the AO must submit to CMS for review. As we have noted throughout this preamble, we review transaction information in order to assess the new AO's financial resources and its ability to perform its tasks after a CHOW has occurred, in order to insure the ongoing effectiveness of the approved accreditation program(s) and to minimize risks to patient safety. We believe that stating the information and documents that will be reviewed and the purpose for this review provides the AOs with enough information about CMS' intent for the review and approval or disapproval of the transfer of the existing CMS-approval for the accreditation programs to be transferred in the CHOW. The review of the application to be submitted by the prospective new owner of the AO is similar to the requirements at § 488.5 in which we request information to be submitted with an AO's initial or renewal application for CMS approval of the AOs accreditation programs. We do not state specific review criteria to be used for this application review.

IV. Provisions of the Final Regulations

In this final rule, we are adopting the provisions in the May 2, 2019 proposed rule, with the following changes:

- Revised § 488.5(f)(1)(iii) to specify that the 90 day deadline refers to calendar days.
- Revised § 488.5(f)(1)(iv) to specify that we will complete our review of the AO's request for approval for the transfer of the existing approval for the accreditation programs to be transferred CHOW within 90 days from receipt of the request.
- Revised § 488.5(f)(2)(iii)(D) to require that the prospective new owner of an AO provide us with policies and procedures to avoid conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys or participate in accreditation decisions, as required by § 488.5(f)(10).

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including the use of automated collection techniques.

We solicited public comment on each of the section 3506(c)(2)(A)-required issues for the following information collection requirements (ICRs).

A. Wage Data

In the 2019 proposed rule, to derive average costs, we used data from the U.S. Bureau of Labor Statistics' (BLS) May 2020 ''National Occupational Employment and Wage Estimates'' for all salary estimates (*http://www.bls.gov/oes/current/oes_nat.htm*). In this final rule we have updated the wage information to reflect the most current wage information from the BLS for the May 2020 ''National Occupational Employment and Wage Estimates'' (*https://www.bls.gov/oes/current/oes_nat.htm*).

In this regard, the following table presents the updated mean hourly wage, the employer's benefits and other indirect costs (calculated at 100 percent of salary), and the adjusted hourly wage.

TABLE—NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

BLS occupation title	Occupation code	Mean hourly wage	Hourly wage adjusted for benefits & other indirect costs
Registered Nurse [1]	29–1141	$38.47	$76.94
Medical or Health Services Manager [2]	11–9111	57.12	114.24
Accountant or Auditor [3]	13–2011	39.26	78.52

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because the employer's benefits and other indirect costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

B. Documentation Requirements

At § 488.5(f)(1), we require that the AO that is the subject of the transaction provide notice to CMS that it intends to request approval for a CHOW. This initial notice will be minimal, such as a coversheet, email, or any type of formal notice and will be included in the additional documentation requirements of § 488.5(f)(2).

At § 488.5(f)(2)(i) and (ii), we specify that the prospective purchaser or transferee provide three most recent audited financial statements of the organization that demonstrate that the organization's staffing, funding, and other resources are adequate to perform the required surveys and related activities. Additionally, we require the name and address of the legal entity that would be the owner of the new AO. We believe that this information is

[1] *https://www.bls.gov/oes/current/oes291141.htm.*

[2] *https://www.bls.gov/oes/current/oes119111.htm.*

[3] *https://www.bls.gov/oes/current/oes132011.htm.*

documentation that will be easily accessible and require minimal time to gather and submit. Therefore, we have considered that the cost burden for the AO to submit the financial statements and other information deemed necessary by CMS will be approximately $76.94. We believe it is likely that the AOs use a registered nurse (RN) to gather information and we estimate the time to gather the financial statements will not exceed 1 hour. The AO will incur a cost burden in the amount of $76.94 for the preparation of the response to CMS (1 hour × $76.94).

At § 488.5(f)(2)(iii), we require the prospective purchaser or transferee to submit a transition plan that summarizes the details of how the accreditation functions will be transitioned to the new owner. While most existing AOs engaged in business transactions such as a CHOW would have already developed a transition plan as proposed under section II of the 2019 proposed rule, this process will be more time consuming. The development of a transition plan will take approximately 45 hours of time to gather, obtain, or prepare all documentation for submission. We estimate that the AO will have a total of three staff work on transition plan. One of these staff persons will likely be clinicians such as a RN. We further believe that the other will be in a management position and serve in a management position. We believe that this person's position will be equivalent to the U.S. Bureau of Labor Statistics job category of Medical and Health Services Manager. We believe that the other staff person working on this task will be accountant or auditor.

We estimate that the RN, medical or health services manager, and accountant or auditor would each spend 45 hours performing this task. We estimate that the total time burden for this task will be 135 hours.

We further estimate that the cost burden for the work performed by the RN will be $3,462.30 (45 hours × $76.94). We believe that the cost burden for the work performed by the Medical and Health Services Manager will be $5,140.80 (45 hours × $114.24 per hour). Also, we estimate that the cost burden for the work performed by the auditor or account will be $3,533.40 (45 hours × $78.52 per hour).

Finally, we estimate that the total cost burden for this task will be $12,136.50 ($3,462.30 + $5,140.80 + $3,533.40).

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) collecting and preparing this information for sending to CMS; and (3) sending the requested information to CMS. In the 2019 proposed rule we had estimate the time burden for this task to be 1 hour. However, in response to a public comment received. We are increasing the time burden for this task to 3 hours.

We believe that this task will be performed be 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 will be $230.82 (3 hours × $76.94).

C. Written Acknowledgements

At § 488.5(f)(3), we specify that the purchasing AO to provide several written acknowledgements. At § 488.5(f)(3)(i), we require the purchaser or transferee to provide written acknowledgement that it understands the financial and legal responsibilities involved with the CHOW process. We believe this written acknowledgement will be developed by a health services manager, as they currently serve in roles for submission of general accrediting approvals. We believe this will not take more than 1 hour to prepare the required written notice.

We estimate that the total cost burden associated with this task will be $114.24. ($114.24 × 1 hour).

At § 488.5(f)(3)(ii), we require the purchasing AO to provide written acknowledgement that it agrees to operate the new AO as defined by CMS' standards under §§ 488.5 and 488.9, as well as include acknowledgements on any program reviews or probationary terms. This will be a minimal cost burden as we are not defining a specific format for the written acknowledgement. We believe that it will take no more than 1 hour to prepare this written notice. We believe that this task will be performed by a medical or health services manager. We estimate that the cost burden associated with this task will be $114.24 (1 hour × $114.24).

At § 488.5(f)(3)(iii), we require the purchasing AO to provide written acknowledgement that would not operate the accreditation program until it received a notice of approval of the transfer of the CMS approved accreditation program from CMS. Given this requirement is minimal and the purchasing AO is already required to include a written acknowledgment as outlined at proposed § 488.5(f)(3)(ii), it is likely that this written notice will include both acknowledgements; therefore, we will include this in the hour of burden and cost described under § 488.5(f)(3)(ii).

At § 488.5(f)(5), we require the purchasing AO to provide documentation within 15 days after the sale confirming the CHOW. We believe that it is a standard business practice that the sale or transfer of a business and its assets be confirmed with some type of documentation such as a bill of sale, deed, or financial documents. Therefore, we believe that the burden to the AO for providing the required proof of the sale of transfer of the AO will be minimal. This will require the AO to provide CMS with a copy of already existing sales documentation. Also, because the existing owner of the AO and prospective new owner will be in the process of negotiating the sale or transfer of the AO, we believe that the AO will have this information readily available and easily accessible.

We estimate that it will require 30 minutes for the staff of the new AO to provide a copy of the existing sales documentation to CMS via an electronic method such as email. We believe that this task will be performed by a medical or health services manager. We estimate that the total cost burden for this requirement will be $57.12 (0.5 hour × $114.24).

We want to emphasize that these anticipated costs and burdens are only subject to those AOs seeking a CHOW. To date, there has been one CHOW request of an AO submitted approximately 20 years and another submitted in November 2020. While we cannot predict the frequency with which AO CHOW transactions will occur in the future, we believe that they should occur more frequently than they have in the past.

The requirements and burden will be submitted to OMB under (OMB control number 0938–New).

D. Description of Time and Cost Burdens

Description of burden	Time per response (hours)	Number of potential respondents per every 3 years	Triennial hour burden per response (hours)	Cost per response	Triennial cost burden
Burden Associated with proposed § 488.5(f)(1) [4] (See footnote 4 below)	0	1	0	$0	$0
Burden Associated with proposed § 488.5(f)(2)(iii)	135	1	135	12,136.50	12,136.50
Burden Associated with proposed § 488.5(f)(2)(iii)(C)(6)	3	1	3	230.82	230.82
Burden Associated with proposed § 488.5(f)(3)(i)	1	1	1	114.24	114.24
Burden Associated with proposed § 488.5(f)(3)(ii) & 488.5(f)(3)(iii)	1	1	1	114.24	114.24
Burden Associated with proposed § 488.5(f)(5)	0.5	1	0.5	57.12	57.12
Total	140.5	1	140.5	12,652.92	12,652.92

E. Response to Public Comments

We received the following public comments in response to the burden estimates:

Comment: One commenter stated that the development of a transition plan will engage employees in both the business operations and accreditation operations departments within the AO(s). This commenter suggested that the estimated time and cost burden of $8,014 to allow for the work performed by business operations.

Response: We agree with this commenter that there could be a business person such as an accountant or auditor involved in the preparation of the transition plan. Therefore, we have revised the burden estimate for this task to include a time burden of 45 hours for an additional person who would be an accountant or auditor. This change increased the hourly burden estimate for the preparation of the transition plan from 90 to 135 hours.

Comment: One commenter suggested that the estimated time burden of 1 hour for a development of a response to a CMS request for additional information be increased to 8 hours. The commenter stated that while one individual will prepare the response, it will require multiple layers of internal review, approval, and communication as well as delivery to CMS.

Response: We appreciate this commenter's input. We agree that there will be layers of administrative review for any documentation requirements. However, we do not believe that this administrative review should be included in the burden estimate, because this is a task that is performed in the normal course of business and therefore will not be considered burden. Given the unpredictable nature of the ''CMS request for additional information'' we believe that the current burden estimate of 1 hour to perform this task is too low.

If the AO provides all of the information required by § 488.5(f)(2)(iii), CMS would need to request little, if any, additional information. However, if the AO fails to provide some of the information required by § 488.5(f)(2)(iii), we believe that the time spent by the AO to provide this information in response to a request from CMS for additional information will still be covered under our initial burden estimate for § 488.5(f)(2)(iii). Therefore, we do not agree with this commenter that the time required for the prospective owner to submit ''additional documentation'' should be increased to 8 hours. This request for additional information and/or documentation would occur only after CMS has received and reviewed the required documentation from the prospective new owner and found that there was missing or incomplete information or that we needed additional clarifying information.

We have increased the estimated time burden for this task to 3 hours. However, we note that this requirement would not be a regularly occurring burden under these regulations but would only be required when and if CMS needs additional information from the AO.

Comment: One commenter stated that the hours assigned for the preparation of the CHOW application was estimated to be two staff (one RN and one health services manager) for 2 hours each for a total of 4 hours. This commenter suggested that the amount of staff working in this task should be increased to three (two RNs and one health services manager), and the time spent on this task should be increased to 8 hours per each person for each a total of 24 hours.

Response: We thank the commenter for their concern. However, we did not provide a specific burden estimate for the task of preparing an application which will be performed by two RNs for a period of 2 hours each. We did provide specific time and cost burden estimates for the gathering and submission of required documentation set forth in § 488.5(f)(1) and § 488.5(f)(2)(iii). We have revised this burden estimate in response to public comments received. We believe that this burden estimates, as revised, provide an accurate estimate of the burden related to the requirements of § 488.5(f)(2).

VI. Regulatory Impact Statement

A. Overall Impact

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A Regulatory Impact Analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This rule does not reach the economic threshold and thus is not considered a major rule.

[4] The time and cost burden related to § 488.4(f)(1) are minimal have been combined with the time and cost burden for § 488.5(f)(2) because the notification required by § 488.5(f)(1) would be submitted together with the documentation required by § 488.5(f)(2).

B. Burden for Change of Ownership Among Accrediting Organizations

The AOs which seek to sell or transfer or purchase another AO and undergo a CHOW will incur time and cost burdens associated with the preparation of the information they submit to CMS to request approval of their new accreditation program under the CHOW. This includes the preparation, gathering or obtaining of all the documentation required at § 488.5(f).

While we recognize that most existing AOs are familiar and have majority of the documentation CMS is requesting at § 488.5(f), we believe that due to the need for the selling or transferring and purchasing AOs to submit documentation for both entities, that this will take approximately 2 hours of time to gather, obtain or prepare all documentation required by § 488.5(f). We believe that this task will take approximately 2 hours because the AOs have previously submitted an application to CMS requesting approval of their accreditation program; therefore, will already be familiar with the application process and requirements and should have the required documentation readily available.

The AOs (selling or transferring and purchasing) will incur costs associated with the preparation and submission of the requested documents, development of the written acknowledgement letters, and submission of the documents. The AO will incur costs for the wages of all AO staff that work on the preparation of the CHOW application. We estimate that the AO will have a total of three staff work on the preparation of the application. We believe that two of the AO staff that perform this task will be clinicians such as RN or medical or health services manager, as they currently serve in roles for submission of general accrediting approvals. We further believe that the third AO staff person will be an accountant or auditor.

We estimate that the RN, medical or health services manager, and accountant or auditor will each spend 45 hours performing this task. The total estimated time burden for this task is 135 hours.

The mean hourly wage for a RN is $38.47 (*https://www.bls.gov/oes/current/oes291141.htm*). This wage, adjusted for the employer's benefits and other indirect costs, is $76.94. We estimate that the total wages incurred by the AO for the 45 hours spent by the RN performing this task will be $3,462.30 ($76.94 × 45 hours).

The mean hourly wage for a medical or health services manager is $57.12 (*https://www.bls.gov/oes/current/oes119111.htm*). This wage adjusted for the employer's benefits and other indirect costs is $114.24. We estimate that the total wages incurred by the AO for the 45 hours spent by the Medical or Health Services Manager performing this task will be $5,140.80 ($114.24 × 45 hours).

The mean hourly wage for an accountant or auditor is $37.89. (*https://www.bls.gov/oes/current/oes132011.htm*). This wage adjusted to include employer's benefits and other indirect costs is $78.52. We estimate that the total wages incurred by the AO for the 45 hours spent by the Accountant performing this task will be $3,533.40 ($78.52 × 45).

We estimate that the total cost burden for this task will be $11,598, which is calculated as follows:

- 45 hours × $76.94 per hour = $3,462.30
- 45 hours × $114.24 per hour = $5,140.80
- 45 hours × $78.52 per hour = $3,533.40

Total = $12,136.50

Furthermore, at § 488.5(e)(8), we require the AOs to provide additional information as requested by CMS to ensure the continuity of oversight for facilities currently accredited. Therefore, there is potential for AOs to incur a cost burden for the wages of the AO staff that are involved with reviewing our additional requests for information and the preparation of the documents and program standards. The AO staff that review information requested by CMS regarding the CHOW will be a clinician such as RN, as is generally the case with the AO's preparation and submission of application materials. We estimate that it will take 3 hours for the RN to perform this task.

As, stated previously, the adjusted wage for an RN is $76.94. We estimate that the AO will incur a cost burden in the amount of $230.82 (3 hours × $76.94 per hour) for the preparation of the response to CMS.

We want to emphasize that these anticipated costs and burdens are only subject to those AOs seeking a CHOW. To date, there has only been one AO CHOW request submitted approximately 20 years ago and another submitted in November 2020. While we cannot predict the frequency with which AO CHOW transactions will occur in the future, we believe that they should occur more frequently than they have in the past.

We solicited comments, specifically from stakeholders and AOs and request AOs to submit their comments to include a breakdown of potential costs they would estimate for this to be completed.

A summary of the comment received and our response to that comment follow:

Comment: One commenter stated that they disagree with the conclusion that the burden would not be substantial for the AO and any other parties involved in a proposed CHOW because the cost estimates provided based on hours are probably low.

Response: We have revised our time and cost burden estimates in section V ''Collection of Information'' and section VI ''Regulatory Impact Statement'' of this rule.

C. Anticipated Effects

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $8.0 million to $41.5 million in any 1 year. Individuals and states are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined, and the Secretary certifies, that this final rule will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2022, that threshold is approximately $165 million. This rule will have no consequential effect on state, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. Since this regulation does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on April 20, 2022.

List of Subjects

42 CFR Part 410

Diseases, Health facilities, Health professions, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 414

Administrative practice and procedure, Biologics, Diseases, Drugs, Health facilities, Health professions Medicare, Reporting and recordkeeping requirements.

42 CFR Part 488

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 493

Administrative practice and procedure, Grant programs-health, Health facilities, Laboratories, Medicaid, Medicare, Penalties, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 1. The authority citation for part 410 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd.

■ 2. Section 410.142 is amended by adding paragraph (k) to read as follows:

§ 410.142 CMS process for approving national accreditation organizations.

* * * * *

(k) *Change of ownership.* An accreditation organization whose accreditation program(s) is (are) approved and recognized by CMS that wishes to undergo a change of ownership is subject to the requirements set out at § 488.5(f) of this chapter.

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 3. The authority citation for part 414 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr(b)(l).

■ 4. Section 414.68 is amended by adding paragraph (j) to read as follows:

§ 414.68 Imaging accreditation.

* * * * *

(j) *Change of ownership.* An accreditation organization whose accreditation program(s) is (are) approved and recognized by CMS that wishes to undergo a change of ownership are subject to the requirements set out at § 488.5(f) of this chapter.

PART 488—SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

■ 5. The authority citation for part 488 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 6. Section 488.5 is amended by adding paragraph (f) to read as follows:

§ 488.5 Application and re-application procedures for national accrediting organizations.

* * * * *

(f) *Change of ownership. What Constitutes Change of Ownership.* A description of what could constitute a change of ownership with respect to a national accrediting organization are those activities described in § 489.18(a)(1) through (3) of this chapter.

(1) *Notice to CMS.* Any CMS-approved accrediting organization that is contemplating or negotiating a change of ownership must notify CMS of the change of ownership.

(i) This notice requirement applies to any national accrediting organization with CMS-approved accreditation program(s) that is the subject of a potential or actual change of ownership transaction, including accrediting organizations for Advanced Diagnostic Imaging (ADI) suppliers; Home Infusion Therapy (HIT) suppliers; Diabetic Self-Management Training (DSMT) entities, and clinical laboratories.

(ii) This notice must be provided to CMS in writing.

(iii) This notice must be provided to CMS no less than 90 calendar days prior to the anticipated effective date of the change of ownership transaction.

(iv) CMS will complete their review of the AO's request for approval for the transfer of the existing CMS approval for the accreditation programs to be transferred in the change of ownership within 90 days from receipt of said AO's request.

(2) *Information submitted with the request for approval for change of ownership transaction.* The person(s) or organization(s) acquiring an existing CMS-approved accrediting organization or accreditation programs (that is, purchaser, buyer or transferee) through a change of ownership transaction must do the following:

(i) Seek approval from CMS for the purchase or transfer of the existing CMS approval for the accreditation program(s) to be transferred in the change of ownership event; and

(ii) Meet the requirements of paragraphs (f)(2)(iii) through (f)(4) of this section to demonstrate that the entities that will be accredited with the transferred accrediting program(s) continue to meet or exceed the applicable Medicare conditions or requirements.

(iii) The following information must be submitted to CMS in the purchaser's/buyer's/transferee's request for approval of a transfer of the existing CMS approval for the accreditation program(s) to be transferred in the change or ownership transaction:

(A) The legal name and address of the new owner;

(B) 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;

(C) A transition plan that summarizes the details of how the accreditation functions will be transitioned to the new owner, including:

(*1*) Changes to management and governance structures including current and proposed 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.

(D) The prospective new AO's policies and procedures to avoid conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys or participate in accreditation decisions, as required by paragraph (f)(10) of this section.

(3) *Written acknowledgements.* The purchaser/buyer/transferee must provide a written acknowledgement to CMS, which states the following:

(i) 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/buyer/transferee must assume complete responsibility for the operations (that is, managerial, financial, and legal) of the CMS-approved accreditation programs transferred, immediately upon the finalization of the change of ownership transaction;

(ii) The purchaser/buyer/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/buyer/transferee must not operate the accreditation program(s) it acquired in the change in ownership transaction as CMS approved accreditation programs, until the effective date set forth within the notice of approval from CMS.

(iv) The purchaser/buyer/transferee agrees to operate the transferred CMS-approved accreditation program(s) under all of the terms and conditions found at §§ 488.5 through 488.9.

(4) *Notification.* 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.

(5) ***Federal Register*** *notice.* CMS will publish a notice of approval in the **Federal Register** of the transfer of the existing CMS approval for the accreditation program(s) to be transferred to the new owner, only after CMS receives written confirmation from the new owner that the change of ownership has taken place.

(6) *Notification to parties in the event that CMS does not approve the transfer of the existing CMS approval.* In the event that CMS does not approve the transfer of the existing CMS approval for the accreditation program(s) to be transferred in the change of ownership transaction, CMS will notify all parties to the change of ownership transaction of such in writing.

(7) *Withdrawal of CMS approval for transferred accreditation programs due to failure to notify CMS of intent to transfer accreditation programs.* In the event that CMS was not made aware of or did not approve the transfer of the existing CMS-approval for the accreditation program(s) to be transferred under a change of ownership:

(i) The existing AO would be permitted to continue operating their existing CMS-approved accreditation programs, if the change of ownership transaction was not completed, unless our review of the transaction revealed issues with the AO that were the subject of the un-finalized change of ownership transaction that was previously unknown to CMS.

(ii) If a change of ownership transaction was completed without notice to CMS or the approval of CMS, CMS would be able to withdraw the existing approval of the AO's accreditation programs in accordance with § 488.8(c)(3)(ii) and (iii).

(8) *Withdrawal of CMS approval for accreditation programs which are transferred notwithstanding CMS' disapproval of the transfer.* In the event that the parties complete the change of ownership transaction, notwithstanding CMS disapproval and the purchaser/buyer/transferee attempts to operate the transferred accreditation program(s) under the CMS-approval granted to the previous owner, CMS will withdraw the existing approval of the transferred accreditation program(s) in accordance with the procedures set out at §§ 488.8(c)(3)(ii) and (iii).

(9) *Requirements for continuation of a deemed status accreditation of Medicare-certified providers and suppliers after CMS withdraws the existing approval of the transferred accreditation program(s).* If CMS withdraws the existing approval of the transferred accreditation program(s) because the change of ownership transaction was completed without notice to CMS or the approval of CMS, an affected Medicare-Certified provider or supplier's deemed status will continue in effect for 180 calendar days if the Medicare-Certified provider or supplier takes the following steps set forth is § 488.8(g).

(i) The Medicare-certified provider or supplier must submit an application to another CMS-approved accreditation program within 60 calendar days from the date of publication of the removal notice in the **Federal Register**; and

(ii) The Medicare-certified provider or supplier must provide written notice to the SA that it has submitted an application for accreditation under another CMS-approved accreditation program within this same 60-calendar day timeframe in accordance with § 488.8(g).

(iii) Failure to comply with the timeframe requirements specified in § 488.8(g) will place the provider or supplier under the SA's authority for continued participation in Medicare and on-going monitoring.

(10) *Requirements for continuation of accreditation for non-certified suppliers when CMS withdraws the existing approval of the transferred accreditation program(s).* If CMS withdraws its existing approval from a transferred non-certified accreditation program for Advanced Diagnostic Imaging (ADI) suppliers; Home Infusion Therapy (HIT) suppliers; Diabetic Self-Management Training (DSMT) entities; or clinical laboratories, because a change of ownership transaction was completed without notice to or the approval of CMS, such affected non-certified supplier's deemed status would continue in effect for 1 year after the removal of the existing CMS accreditation approval, if such non-certified supplier take the steps specified paragraphs (f)(10)(i) and (ii) of this section—

(i) The non-certified supplier must submit an application to another CMS-approved accreditation program within 60 calendar days from the date of publication of the removal notice in the **Federal Register**; and

(ii) The non-certified supplier must provide written notice to CMS stating that it has submitted an application for accreditation under another CMS-approved accreditation program within the 60-calendar days from the date of publication of the removal notice in the **Federal Register**.

(iii) Failure to comply with the above-stated timeframe requirements will result in de-recognition of such provider or supplier's accreditation.

■ 7. Section 488.1030 is amended by adding paragraph (g) to read as follows:

§ 488.1030 Ongoing review of home infusion therapy accrediting organizations.

* * * * *

(g) *Change of ownership.* An accrediting organization that wishes to undergo a change of ownership is subject to the requirements set out at § 488.5(f).

PART 493—LABORATORY REQUIREMENTS

■ 8. The authority citation for part 493 is revised to read as follows:

Authority: 42 U.S.C. 263a, 1302, 1395x(e), the sentence following 1395x(s)(11) through 1395x(s)(16).

■ 9. Section 493.553 is amended by adding paragraph (e) to read as follows:

§ 493.553 Approval process (application and reapplication) for accreditation organizations and State licensure programs.

* * * * *

(e) *Change of ownership.* An accrediting organization that wishes to undergo a change of ownership is subject to the requirements set out at § 488.5(f) of this chapter.

Dated: April 25, 2022.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2022–09102 Filed 4–27–22; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[Docket No. 220425–0104]

RIN 0648–BK43

Fisheries Off West Coast States; West Coast Salmon Fisheries; Federal Salmon Regulations for Overfished Species Rebuilding Plans

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule.

SUMMARY: NMFS is revising regulations that implement the Pacific Fishery Management Council's (Council) Pacific Coast Salmon Fishery Management Plan (FMP). This action removes a rebuilding plan for Sacramento River fall-run Chinook salmon (SRFC) from regulation, as this stock has been rebuilt and is no longer required to be managed under a rebuilding plan; and updates language to reflect the 2013 merger of NMFS' Northwest Region (NWR) and Southwest Region (SWR), which created NMFS' West Coast Region (WCR).

DATES: Effective May 31, 2022.

FOR FURTHER INFORMATION CONTACT: Shannon Penna, Fishery Management Specialist, at 562–676–2148, or *Shannon.Penna@noaa.gov.*

SUPPLEMENTARY INFORMATION: Regulations at 50 CFR part 660, subpart H implement the management of West Coast salmon fisheries under the FMP in the exclusive economic zone (3 to 200 nautical miles (5.6–370.4 kilometers)) off the coasts of the states of Washington, Oregon, and California.

In 2018, NMFS determined that SRFC was overfished under the Magnuson-Stevens Fishery and Conservation Management Act (MSA). The Council developed a rebuilding plan for SRFC, which it transmitted to NMFS on August 14, 2019. The Council recommended as the rebuilding plan the existing control rule for SRFC, which is described in the FMP and referenced in codified regulation at 50 CFR 660.410(c). The Council determined that the existing control rule met the MSA requirement to rebuild the stock as quickly as possible, taking into account the status and biology of any overfished stock and the needs of fishing communities (50 CFR 600.310(j)(3)(i)). NMFS approved and implemented the Council's recommended rebuilding plan for SRFC through rulemaking. 50 CFR 660.413(b), (85 FR 75920; November 27, 2020).

In 2021, NMFS determined that SRFC met the criteria in the FMP for being rebuilt and notified the Council (Letter from Barry A. Thom, NMFS West Coast Regional Administrator, to Charles A. Tracy, Pacific Fishery Management Council Executive Director, dated July 23, 2021). As the stock is rebuilt, it is no longer required to be managed under a rebuilding plan and the SRFC rebuilding plan should be removed from regulation to avoid confusion regarding the stock's status. Additionally, removing the SRFC rebuilding plan from regulation will avoid confusion should NMFS make a future determination that the SRFC stock is overfished again, in which case the MSA requires the Council to prepare and implement a rebuilding plan within two years of that determination (50 CFR 600.310(j)(2)(ii)). Leaving the current rebuilding plan in regulation could be confused as being the default rebuilding plan for SRFC, which is the intention of neither the Council nor of NMFS. Therefore, to avoid confusion, it is necessary to remove the existing SRFC rebuilding plan from regulation. Because the rebuilding plan adopted the existing harvest control rule for SRFC described in the Pacific Coast Salmon Fishery Management Plan, removing the rebuilding plan from regulation will not change the management of salmon fisheries that affect SRFC. NMFS determined that a 15-day comment period for the proposed rule was appropriate to allow adequate time for public comment while also allowing for the final rule to be in effect prior to the annual preseason management process for the 2022 ocean salmon fisheries, thereby avoiding confusion about the status of SRFC prior to the fishing season.

In 2013, NMFS implemented a realignment that merged the NWR and SWR to create the WCR. This change was made in order to more effectively manage resources, decision-making, and policy from a holistic West Coast perspective. NMFS is revising the regulations at 50 CFR 660, subpart H, to reflect the 2013 merger of NMFS' NWR and SWR by replacing mentions of NWR and SWR with WCR, and by replacing mention of the Northwest and Southwest Regional Administrators with West Coast Regional Administrator.

Public Comment

No comments were received during the public comment period.

Classification

NMFS is issuing this rule pursuant to section 305(d) of the MSA. The reason for using this regulatory authority is: Pursuant to section 305(d) of the MSA section, this action is necessary to carry out administrative actions, because it will revise outdated regulations.

This final rule has been determined to be not significant for purposes of Executive Order 12866.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration during the proposed rule stage that this action would not have a significant economic impact on a substantial number of small entities. The factual basis for the certification was published in the proposed rule and is not repeated here. No comments were received regarding this certification. As a result, a regulatory flexibility analysis was not required and none was prepared.

This Final rule contains no information collection requirements under the Paperwork Reduction Act of 1995.

List of Subjects in 50 CFR Part 660

Fisheries, Fishing, and Recording and reporting requirements.

Dated: April 25, 2022.

Samuel D. Rauch, III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, NMFS amends 50 CFR part 660 as follows: