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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 488 and 489

[CMS-3255-P]

RIN 0938-AQ33

Medicare and Medicaid Programs; Survey, Certification and Enforcement Procedures

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the survey, certification, and enforcement procedures related to CMS oversight of national accreditation organizations (AOs). These revisions would implement certain provisions under the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). The proposed revisions would also clarify and strengthen our oversight of AOs that apply for, and are granted, recognition and approval of an accreditation program in accordance with the Social Security Act.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on [OFR--insert date 60 days after date of publication in the **Federal Register**].

ADDRESSES: In commenting, please refer to file code CMS-3255-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the instructions under the "More Search Options" tab.

2. By regular mail. You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-3255-P,
P.O. Box 8016,
Baltimore, MD 21244-8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-3255-P,
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-8016.

4. By hand or courier. If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC--

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Room 445-G, Hubert H. Humphrey Building,

200 Independence Avenue, SW.,
Washington, DC 20201

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD--
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the "SUPPLEMENTARY INFORMATION" section.

FOR FURTHER INFORMATION CONTACT: Cindy Melanson, (410) 786-0310; Patricia Chmielewski, (410) 786-6899; or Marilyn Dahl, (410) 786-8665.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential

business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that website to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

Acronyms

ADI – Advanced Diagnostic Imaging Services

AO – Accrediting Organization

ASC – Ambulatory Surgical Center

CAH – Critical Access Hospital

CfC – Condition for coverage

CFR – Code of Federal Regulations

CMHC – Community Mental Health Center

CMS – Center for Medicare & Medicaid Services

CoP – Condition of Participation

CORF – Comprehensive Outpatient Rehabilitation Facility

EMTALA – Emergency Medical Treatment and Labor Act

GAO – Government Accountability Office

HHA – Home Health Agency

HHS – Department of Health and Human Services

MIPPA – Medicare Improvements for Patients and Providers Act of 2008

NF – Nursing Facility

OIG – Office of the Inspector General

OPT – Provider of outpatient physical therapy and speech language pathology services

RHC – Rural Health Clinic

Social Security Act – the Act

SNF – Skilled Nursing Facility

TJC – The Joint Commission

I. Background

To participate in the Medicare program, providers and suppliers of health care services, must be substantially in compliance with specified statutory requirements of the Social Security Act (the Act), as well as any additional regulatory requirements related to the health and safety of patients specified by the Secretary of the Department of Health and Human Services (HHS). These health and safety requirements are generally called conditions of participation (CoPs) for most providers, requirements for skilled nursing facilities (SNFs), conditions for coverage (CfCs) for ambulatory surgical centers (ASCs) and other suppliers, and conditions for certification for rural health clinics (RHCs). A provider or supplier that does not substantially comply with the applicable health and safety requirements risks having its participation in the Medicare program terminated.

In accordance with section 1864 of the Act, state health departments or similar agencies, under an agreement with CMS, survey health care providers and suppliers to ascertain compliance with the applicable CoPs, CfCs, conditions of certification, or requirements, and

certify their findings to us. Based on these state survey agency certifications, we determine whether the provider or supplier qualifies, or continues to qualify, for participation in the Medicare program.

Section 1865(a) of the Act allows health care facilities, except kidney transplant centers, end stage renal dialysis facilities, and suppliers of medical equipment and supplies, to demonstrate compliance with Medicare CoPs, requirements, CfCs, or conditions for certification through accreditation by a CMS-approved program of a national accreditation body. If an accrediting organization (AO) is recognized by the Secretary as having standards for accreditation that meet or exceed Medicare requirements, any provider or supplier accredited by the AO's CMS-approved accreditation program may be deemed by us to meet the Medicare conditions or requirements.

We are responsible for the review, approval and subsequent oversight of national AOs' Medicare accreditation programs, and for ensuring providers or suppliers accredited by the AO meet the quality and patient safety standards required by the Medicare CoPs, requirements, CfCs, and conditions for certification. 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 CMS for a period not to exceed 6 years. The AO must reapply for renewed CMS approval of an accreditation program before the date its approval period expires. This allows providers or suppliers accredited under the program to continue to be deemed to be in compliance with the applicable Medicare CoPs, requirements, CfCs, and conditions for certification. Regulations implementing these provisions are found at 42 CFR 488.1 through 488.9.

In accordance with §488.8(f), if we determine that an AO's accreditation program requirements are no longer comparable to Medicare requirements we may open a deeming

authority review and give the AO up to 180 days to adopt comparable requirements. If at the end of the deeming authority review period, the AO's accreditation program has failed to adopt comparable requirements, we may give the AO conditional approval with a probationary period for up to one year. Within 60 days after the end of any probationary period, we will make a final determination as to whether or not an accreditation program continues to meet the Medicare requirements and will issue an appropriate notice (including reasons for the determination) to the AO and affected providers or suppliers.

Section 1834(e) of the Act requires that, beginning January 1, 2012, Medicare payment may only be made for the technical component of advanced diagnostic imaging (ADI) services for which payment is made under the fee schedule established in section 1848(b) of the Act to a supplier who is accredited by an accrediting organization designated by the Secretary. Currently, oversight of these accrediting organizations is limited to requirements at §414.68, and these accrediting organizations are not subject to the more expansive oversight requirements at 488, subpart A.

II. Provisions of the Proposed Rule

Section 125 of the Medicare Improvement for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110-275, enacted on July 15, 2008) removed legal distinctions between the Joint Commission (TJC) hospital accreditation program and all other accreditation programs approved by CMS in accordance with section 1865 of the Act. In this proposed rule, we are proposing corresponding changes to the regulations in part 488, subpart A, which implement section 1865 of the Act.

The Secretary has endorsed the recommendations of the HHS Office of Inspector General (OIG), and the Government Accountability Office (GAO) to strengthen our oversight and ensure

greater accountability of AOs and instructed CMS to respond appropriately¹. AOs and their CMS-approved accreditation programs significantly impact the health and safety of patients and the quality of care provided in Medicare-participating facilities across the country. We currently have 19 approved accreditation programs offered by seven national AOs. In fiscal year 2011, accredited facilities deemed to meet Medicare standards accounted for over 11,000 Medicare-participating facilities (not including accredited clinical laboratories).

All 19 CMS-approved AO accreditation programs received an extensive review in accordance with the application and reapplication process described at part 488 in recent years. The application and reapplication review process provides us the opportunity to conduct a comprehensive evaluation of an AO's performance and ability to assure that providers or suppliers meet or exceed the applicable Medicare standards. The review process also provides the opportunity to evaluate compliance with the other requirements of subpart A of part 488.

The high volume of comprehensive AO application and reapplication reviews that we have conducted has provided us with an abundance of opportunities to apply the existing AO approval regulations in a variety of circumstances. Throughout each review, we worked closely with the AOs, provided education and extensive feedback, and clarified expectations for the AOs. This experience has helped us to identify areas of our regulations in need of revision to more clearly articulate the requirements for all AOs with a CMS-approved accreditation program, as well as new AOs seeking initial CMS approval.

¹ HCFA's Approval and Oversight of Private Accreditation Organizations (HEHS-99-197R), September 30, 1999. <http://www.gao.gov/products/HEHS-99-197R>

CMS Needs Additional Authority to Adequately Oversee Patient Safety in Hospitals (GAO-04-850) July 20, 2004. <http://www.gao.gov/new.items/d04850.pdf>

Hospital Oversight in Medicare: Accreditation and Deeming Authority. May 6, 2005 http://www.nhpf.org/library/issue-briefs/IB802_Accreditation_05-06-05.pdf

Moffett, M. & Bohara, A. Hospital Quality Oversight by the Joint Commission on Accreditation of Healthcare Organizations. Vol 31, No. 4 (Fall 2005) pp 629-647.

Furthermore, as we have taken actions to exercise more oversight of existing CMS-approved AO programs, we have become aware of the need to clarify, reorganize, and amend our regulations to support a more efficient and effective oversight process. In several situations involving serious and pervasive areas of non-compliance identified in CMS-approved AO accreditation programs, we found it necessary to invoke our oversight authorities under the existing regulations. In each case, we required the AO to implement corrective action(s) to ensure comparability with the Medicare requirements. Actions that we normally take include opening a deeming review outside the normal reapplication process, and issuing a conditional approval with a probationary period. In the course of taking these actions, we identify the need to revise and expand our enforcement tools to strengthen our ability to address serious and pervasive areas of AO non-compliance with the Medicare requirements; ensure that the AO takes the necessary corrective actions to address the area(s) of non-compliance; and ensure continuing compliance and comparability with Medicare requirements.

We propose expanding the scope of the accrediting organizations' oversight regulations at §488, subpart A to include accrediting organizations with CMS-approved accreditation programs for ADI services. The current oversight regulations for accrediting organizations for the technical component of ADI services at §414.68 would remain unchanged. This proposed expansion is part of our initiative to broaden our quality oversight of both the CMS-approved accrediting organizations as well as the suppliers of ADI services. As part of this effort, we anticipate future rule making to develop and implement Medicare health and safety standards for suppliers of these services. Prior to embarking upon this rule making process, we anticipate consulting with key stakeholders to shape the notice of proposed rulemaking. We note that, under section 135 of MIPPA, state survey agencies do not play a role in the oversight of

suppliers of the technical component of ADI services, and we do not have the statutory authority to create such a role.

We propose to clarify that, when a state survey agency substantial allegation validation survey, that is, a complaint survey, of an accredited provider or supplier finds substantial non-compliance with one or more of Medicare's conditions or requirements, we have the flexibility in terms of its next steps. Currently we may either proceed immediately to enforcement action based on that complaint survey, or may instead require the state survey agency to conduct another, full survey which assesses compliance with all of the CoPs or CfCs for that type of provider or supplier. We are proposing not only to retain this flexibility but also to expand it, so that we could require the state survey agency to conduct another, more comprehensive survey, but not a full survey assessing compliance with all the CoPs or CfCs. This clarification supports the ability for us to make efficient use of survey resources while maintaining an effective enforcement process that is appropriate for each specific case.

A. Definitions (§488.1).

Section 488.1 sets forth definitions for terms used in part 488. We are proposing revisions at §488.1 as follows:

- We propose deleting the definition of “accredited provider or supplier.” Use of this language has caused confusion both internally and externally. National AOs offer a variety of accreditation programs. However, not all programs are CMS-approved accreditation programs for the purpose of Medicare participation.

- We propose deleting the language, “AOA stands for the American Osteopathic Association.” The proposed revisions to subpart A would no longer refer to any specific AO. The proposed revisions instead are broader, referencing national AOs generically.

- We propose expanding the definition of “certification” to include the RHC conditions; clarify that each provider or supplier must meet its respective conditions or requirements to be certified; and deleting the language “for SNFs and NFs” to eliminate redundancy.
- We propose revising the definition of “conditions for coverage” for increased clarity and specificity.
- We propose adding a definition of “conditions for certification” to include the terminology for standards that RHCs must meet to participate in the Medicare program.
- We propose adding a definition of “deemed status” to increase clarity and reduce ambiguity when referring to the status of providers and suppliers accredited under a CMS-approved accreditation program and who are participating in Medicare via this accreditation.
- We propose revising the definition of “full review” to clarify that the regulations at part 488 apply to all providers and suppliers, not just hospitals.
- We propose adding a definition of “immediate jeopardy” at §488.1 that would apply generically to all providers and suppliers subject to the certification requirements at part 488.
- We propose deleting the language, “JCAHO stands for the Joint Commission on Accreditation of Healthcare Organizations,” since the proposed revisions to subpart A do not refer to any specific AO.
- We propose adding a definition of “national accreditation organization” to specify that CMS requires a program seeking initial approval to already be fully implemented and operational nationally.
- We propose expanding the definition of “provider of services or provider” to include a clinic, rehabilitation agency or public health agency that furnishes outpatient physical therapy

or speech language pathology services. This proposed change is consistent with the language at section 1861(p)(4) of the Act.

- We propose revising the definition of “reasonable assurance by deleting the language “taken as a whole.” This proposed change would clarify the requirement that an AO’s CMS-approved accreditation program has standards that meet or exceed the applicable Medicare conditions or requirements consistent with language at section 1865(a)(1) of the Act.

- We propose updating the definition of “state survey agency” for added clarity and precision.

- We propose revising the definition of “substantial allegation of non-compliance” to correct a previous error.

- We propose modifying the definition of “supplier” to make it consistent with the definition of supplier as amended by section 901 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-173).

- We propose deleting the definition of “validation review period.” The concept of a fixed review period would not be used in the proposed revisions at §488.8.

B. Statutory Basis (§488.2).

Section 488.2 sets forth the statutory basis for provider and supplier requirements. We propose revising this section by adding pertinent statutory citations and revising the statutory citation at section 1883 of the Act by replacing the title “Requirements for hospitals that provide SNF care” with “Requirements for hospitals that provide extended care services” to be consistent with the statutory language.

C. Conditions of participation; conditions for coverage; conditions for certification; and long-term care requirements (§488.3).

Section 488.3 sets forth the conditions or requirements that a prospective provider or supplier must meet to be approved for participation in or coverage under the Medicare program. We propose revising §488.3 to include the requirements RHCs must meet to participate in Medicare; the statutory citations for CAHs, RHCs, hospitals that provide extended care services, hospices, comprehensive outpatient rehabilitation facilities (CORFs), community mental health centers (CMHCs), providers of outpatient physical therapy and speech language pathology services (OPTs), and advanced diagnostic imaging services (ADIs); and the regulatory references for RHCs, CORFs, CMHCs, CAHs, OPTs, and ADIs. In addition, we propose to revise §488.3(b) to address all providers or suppliers of services subject to certification. This proposal would also authorize the Secretary to consult with state survey agencies and other organizations, which would include all AOs and other national standard-setting organizations to develop Conditions of Participation. We are not proposing any policy changes to this program.

D. CMS-approved national accreditation programs for providers and suppliers (§488.4).

We propose to revise §488.4 as part of our effort to reorganize the application and reapplication process, delete redundancy, and reorganize the accreditation requirements in a more logical sequence. We are proposing revisions at §488.4 as follows:

- Proposed §488.4(a) would replace the requirements currently set out at §488.6(a), with some modifications. The current regulation specifically lists the eligible provider and supplier accreditation programs under which AOs may provide us with reasonable assurance that the AO's requirements are at least as stringent as the Medicare conditions or requirements. We propose eliminating references to specific types of provider and supplier accreditation programs by simply stating that CMS-approved accreditation program for providers and suppliers with the exception of kidney transplant centers, end stage renal dialysis facilities, and suppliers of

medical equipment and supplies may provide reasonable assurance to CMS that it requires providers and suppliers it accredits to meet the requirements that are at least as stringent as the Medicare conditions or requirements. Also, this section addresses national accreditation programs for hospitals other than those offered by TJC and AOA, as well as accreditation programs for other types of providers and suppliers. We propose deleting the reference to “requirements concerning hospitals accredited by the JCAHO or AOA” since the proposed changes are broader and would not specify any particular AO.

- Proposed §488.4(b) would be a new provision, making it explicit that an AO’s CMS-approved accreditation program would be approved in its entirety. Under this provision, an AO would not be permitted to make a recommendation to us for deemed status for a provider or supplier unless that provider or supplier satisfied all of the AO’s requirements for accreditation. This would include both the AO accreditation program standards that may exceed the Medicare standards, as well as those that meet the Medicare standards.

E. Application and reapplication procedures for national accreditation organizations (§488.5).

We propose to revise §488.5 to clarify the requirement that a prospective AO and its accreditation program be national in scope. We also propose moving the regulatory language currently at §488.4 to §488.5 with modifications as part of our effort to reorganize the accreditation requirements in a more logical sequence.

Specifically, we propose the following revisions:

- Proposed §488.5(a) would replace the requirement currently set out at §488.4(a). It would be revised to clarify that these provisions would apply to both initial applications for a new accreditation program, as well as re-approval of an existing CMS-approved accreditation program. The proposed revision further would clarify that each application for approval would

pertain to a single provider/supplier-specific accreditation program.

- Proposed §488.5(a)(1) would replace the requirement currently set out at §488.4(a)(1), concerning the AO's identification in its application of the type of provider or supplier for which it is seeking approval. We propose revising this requirement to clarify that each application for our approval would be separate and distinct from applications for our approval of accreditation programs for other types of providers or suppliers.

- Proposed §488.5(a)(2) would require an AO seeking initial CMS approval of a new accreditation program or renewed approval of an existing program to demonstrate that the program met the definition of a "national accrediting organization." Section 1865 of the Act applies only to programs of national accreditation bodies. Demonstration must be specific to each accrediting program for which new or renewed CMS approval is sought. For example, an AO which has one or more existing CMS-approved programs that seek our initial approval of a new accreditation program must also demonstrate that the new program has been implemented nationally. This proposal implements the "national" requirement in the statute and sets forth a methodology for determining how an AO would meet the "national" qualification in the regulations.

- Proposed §488.5(a)(3) would replace the requirement currently set out at §488.4(a)(2), concerning the requirement that an AO submit a detailed comparison of its standards to Medicare requirements, and clarify the components of an acceptable crosswalk.

- Proposed §488.5(a)(4) would replace the requirement currently set out at §488.4(a)(3), which addresses the requirement that the AO must provide a detailed description of its survey process in its application for our approval of an accreditation program. The language of this provision would remain unchanged.

- Proposed §488.5(a)(4)(i), would replace the requirement currently set out at §488.4(a)(3)(i), concerning the frequency of surveys. The proposed revisions reflect existing CMS policy and would not impose any new requirements on AOs, but would be added to clarify the requirement.
- Proposed §488.5(a)(4)(ii) is a new provision that would ensure surveys conducted by AOs were comparable to the Medicare requirements, and would implement section 1865(a)(2) of the Act.
- Proposed §488.5(a)(4)(iii) would replace the requirement currently set out at §488.4(a)(3)(ii). The language of this requirement would be unchanged and addresses the content and frequency of survey personnel training.
- Proposed §488.5(a)(4)(iv) would replace the requirement currently set out at §488.8(a)(2)(ii), requiring an AO to crosswalk its survey deficiency citations to the comparable Medicare requirements. This proposed provision is being modified for clarity to ensure consistency with existing policy and to ensure that our oversight of the AOs is effective. In addition, we are proposing that the language, “and the ability to investigate and respond appropriately to accredited facilities,” be redesignated to proposed §488.5(a)(7).
- Proposed §488.5(a)(4)(v) would replace the requirement currently set out at §488.4(a)(3)(iii), concerning the survey review and accreditation decision-making process. We would delete language that would be redundant with language being incorporated into the proposed revised regulatory language at §488.5(a)(8).
- Proposed §488.5(a)(4)(vi), currently set out at §488.4(a)(3)(iv), would specify that the AO’s provider or supplier notification procedures meet or exceed those required for state survey agencies. This language represents existing CMS policy and would not impose any new

requirements on AOs, but would be added to clarify the requirement and provide more specific and precise language.

- Proposed §488.5(a)(4)(vii) is a new proposed provision regarding the AOs timeline and procedures for monitoring the facilities found to be out of compliance. This language reflects existing CMS policy and would not impose any new requirements on AOs, but would be added to clarify the requirement and provide more specific and precise language. Further, the proposed provision would be consistent with the requirement at section 1865(a)(2) of the Act.

- Proposed §488.5(a)(4)(viii) would replace the requirement currently set out at §488.8(a)(3), which requires the AO to provide a copy of its most recent accreditation survey for a specified provider or supplier, together with any other information related to the survey that we may require. We propose modifying this provision for consistency and clarity.

- Proposed §488.5(a)(4)(ix) is a new proposed provision regarding AO notification to us when the AO identifies an immediate threat to the health and safety of patients, that is, a situation that constitutes an immediate jeopardy as that term is defined in §489.3. This provision would ensure that we are notified of situations that may put the health and safety of patients receiving care in Medicare-participating facilities at serious risk of harm, and would require us to take immediate action to enforce these provisions.

- Proposed §488.5(a)(5) would replace the requirement currently set out at §488.4(a)(4)(i). The language of this provision is unchanged and addresses the requirement that the AO provide us with detailed information about its surveyors.

- Proposed §488.5(a)(6) would replace the requirement currently set out at §488.4(a)(4)(i). This provision addresses the requirement for the AO to furnish information about the size and composition of its survey teams. The proposed expanded provisions would

recognize that, within a given accreditation program, there can be great variation in the size and complexity of individual health care facilities. We believe that a uniform size and composition for the AO's survey teams would not be appropriate.

- Proposed §488.5(a)(6) is a new proposed provision that would help ensure that an AO maintained an adequate number of trained surveyors to meet the demand for surveys, both initial and re-accreditation surveys. There have been instances where an AO could not maintain the required re-accreditation survey schedule interval for its existing accredited deemed status facilities because it was focusing its resources on meeting the demand of new customers for initial Medicare accreditation surveys. These AOs lacked sufficient personnel resources to handle both existing and new workloads.

- Proposed §488.5(a)(7) would replace the requirement currently set out at §488.4(a)(4)(ii) concerning the AO's education and experience requirements for its surveyors. The proposed revisions would explicitly require documentation of these surveyor requirements.

- Proposed §488.5(a)(8) would replace the requirement currently set out at §488.4(a)(iii) concerning in-service training of AO survey personnel. The language of this provision would be revised to explicitly state that the AO must provide documentation describing the content and frequency of this in-service training.

- Proposed §488.5(a)(9) would replace the requirement currently set out at §488.4(a)(4)(iv) concerning evaluation systems used by the AO to monitor the performance of individual surveyors and survey teams. This provision would be revised to explicitly state that an AO must provide documentation describing these evaluation systems.

- Proposed §488.5(a)(10) would replace the requirement currently set out at §488.4(a)(4)(v), concerning the AO's policies on the involvement of personnel in the survey or

accreditation decision process who have a financial or professional affiliation with the provider or supplier. The provision would be modified to ensure that the AO has policies to avoid such potential conflicts of interest that could undermine the integrity of its accreditation program.

- Proposed §488.5(a)(11) would replace the requirement currently set out at §488.4(a)(5). This provision addresses the requirement that the AO provide information on its data management system in its application. We would reorganize the regulatory text to contain the provisions currently set out at §488.5(a)(6)(i) and §488.5(a)(6)(ii). In proposed §488.5(a)(6), we would retain existing language requiring an AO to submit a description of its data management and analysis system regarding its surveys and accreditation decisions. The description would have to include the submission of the information set out at proposed §488.5(a)(11)(i) and §488.5(a)(11)(ii), which includes provider or supplier and survey information, and accreditation decisions.

- Proposed §488.5(a)(11)(i) would require submission of a detailed description of how the AO uses its data system to assure compliance with the Medicare requirements. This new proposed language would replace existing language, which is being deleted. The existing language proposed for deletion is both too specific and too limiting in elaborating on what information would adequately convey how the AO uses its data management system for compliance purposes. The proposed language would make clear that we are seeking information on how the AO uses its data management systems to meet the various requirements of this subpart.

- Proposed §488.5(a)(11)(ii) would modify the regulatory text currently at §488.4(b)(1), which requires an AO to include in its application a written presentation of its ability to submit information electronically “in ASCII comparable code.” The reference to

ASCII comparable code is outdated and insufficient. The proposed modifications are necessary to ensure that we have the required data to provide effective oversight of an approved accreditation program. We are also proposing to delete §488.8(a)(2)(v), which is a redundant requirement related to electronic data submission in ASCII-comparable code.

- Proposed §488.5(a)(12) would replace the requirement currently set out at §488.4(a)(6). The language of this provision would remain unchanged and addresses the AO's procedures for responding to and investigating complaints.
- Proposed §488.5(a)(13) would replace requirements currently set out at §488.4(a)(7), with modifications. The current provision requires AOs to submit information to us regarding their policies and procedures for withholding, or removing accreditation status for facilities that fail to meet the AOs' standards or requirements. The AO must also report to us any other actions taken by the AO in response to its determination of non-compliance with its standards and requirements. We propose to expand this provision to require submission of the AOs' policies and procedures related to granting accreditation status and assignment of less than full accreditation status. Since the granting of full or less than full accreditation statuses are essential components of an AO's accreditation decision process, it is necessary for us to receive information on the policies and procedures pertaining to these types of decisions as well.
- Proposed §488.5(a)(13)(i) would replace the requirement currently set out at §488.4(a)(8). The current regulation addresses the requirement that AOs provide us a description of all types and categories of accreditation offered under its accreditation program. We would modify this provision by deleting language and terminology specific to one particular AO. Further, the current provision seems to require the AO to submit information on its accreditation programs that fall outside the parameters of its Medicare accreditation programs.

Since we do not approve accreditation programs unrelated to Medicare, we believe that there is no reason to require AOs to submit such information to us, nor for us to have and review this non-relevant information.

- Proposed §488.5(a)(13)(ii) would address the requirement, currently found at §488.4(b)(3)(i), for an AO to agree, as a condition of approval, to notify us of any provider or supplier that has had its accreditation revoked, withdrawn, or revised, or has had any remedial or adverse action taken against it. The current regulation requires the AO to notify us in writing within 30 days of its action. We propose to reduce this timeframe since AOs transmit such information to us electronically. The 30-day timeframe was based on information being sent to us via hard copy mail. Given the instantaneous nature of the electronic notification, as well as our need to learn of such adverse actions as soon as possible to initiate enforcement action as applicable, we believe it would be reasonable to require that the AO provide notice to us within three business days of its having taken the adverse action.

- Proposed §488.5(a)(14) would replace the requirement currently set out at §488.4(a)(9) concerning submission of information on currently accredited facilities as part of the AO's application. This provision would be modified for clarity. Proposed §488.5(a)(15) would create a new requirement for an AO seeking renewed approval for a currently CMS-approved accreditation program. It would require such an AO to demonstrate, as a condition of acceptance of its application for renewal, that it demonstrated growth as evidenced by having accredited at least 50 health care facilities under its CMS-approved accreditation program. We believe that an established AO accreditation program that has not been able to accredit a minimum of 50 health care facilities since receiving initial CMS approval has failed to demonstrate sufficient infrastructure and scale to be sustained over a long period of time.

Although we are willing to be flexible in accepting applications for initial approval from new national accreditation programs that are comparatively small, we believe that an established CMS-approved program that has not been able to accredit at least 50 healthcare facilities during the four-year period since its initial approval would have failed to demonstrate long term national viability. Further, we have limited resources available to conduct the detailed, comprehensive review of the AO's application required under section 1865(a)(2) of the Act. We believe these federal resources are best focused on those larger accreditation programs responsible for oversight of the quality of care provided in hundreds of accredited healthcare facilities, serving millions of patients, rather than on an accreditation program connected with a relatively small number of Medicare beneficiaries.

- Proposed §488.5(a)(16) would replace the requirement currently set out at §488.4(a)(10), which addresses the requirement for AOs to provide us with a list of accreditation surveys scheduled to be performed. We propose to revise this requirement to limit the schedule the AO must provide to surveys expected to be conducted during the six month period following submission of an application for CMS approval. Since we must complete the entire application review and publish a final notice announcing our decision within a 210 day statutory timeframe, it is not useful for a survey schedule to be submitted for a later timeframe. We use this survey schedule to plan our survey observation as part of our review. This requirement applies to both initial and renewal applications and is separate and apart from the requirement at proposed §488.5(a)(11), regarding an approved program, for an AO to submit survey schedules as part of the data it agrees to provide us for our ongoing oversight.

- Proposed §488.5(a)(17) would replace the requirement currently set out at §488.4(b)(2), which requires an AO to provide a resource analysis demonstrating that it has the

resources to support its accreditation program. The proposed modifications would more clearly identify the type of documentation an AO must provide to demonstrate the adequacy of its resources.

- Proposed §488.5(a)(18) is a new provision that would address requirements related to AO written notification and timeframes regarding currently deemed providers or suppliers when the AO elected to terminate its CMS-approved accreditation program voluntarily. This provision would be necessary so that we could give affected state survey agencies and CMS Regional Offices adequate advance notice regarding the providers or suppliers affected by such a termination. In such a case, providers or suppliers would subsequently need to be surveyed and approved by the State survey agency, unless the providers or suppliers sought and received accreditation from another CMS-approved AO.

- Proposed §488.5(a)(19) would replace the requirement currently set out at §488.4(b)(3)(iii). This provision addresses the timeframe for AO notification to us regarding proposed changes in accreditation requirements. We are proposing to modify the regulation by expanding the timeframe to provide adequate time for us to conduct a comprehensive, detailed review of the AO's proposed changes. We are also proposing language clarifying that any proposed changes in a CMS-approved accreditation program may not be implemented by the AO before we approve such changes. This would ensure that the accreditation program continued to meet or exceed the Medicare requirements.

- Proposed §488.5(a)(20) would replace the requirement currently set out at §488.4(b)(3)(iv), concerning AO submission of changes to its standards within 30 days of a change in our requirements. We propose modifying the regulation text by deleting references to specific timeframes. This would provide us the flexibility to consider other factors when

determining an appropriate timeframe for AOs to revise their program and submit the changes to us. These factors may include: the effective date of the applicable final rule, the effective date of our revised interpretive guidance or survey process, and the scope and magnitude of our changes that require corresponding AO changes. AOs would benefit from our having the flexibility to provide them longer timeframes for response, when appropriate. In addition, we propose adding language to ensure the AO program continues to meet or exceed the Medicare requirements, and specify the consequences for an AO's failure to submit timely comparable changes.

- Proposed §488.5(a)(21) would replace the requirement currently set out at §488.4(b)(3)(v), which concerns the requirement for the AO to permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings. We propose modifying the regulation by adding language to clarify the scope of the requirement.
- Proposed §488.5(b) would replace the requirement currently set out at §488.4(c). The language of this provision addresses the requirement that if we determine additional information is necessary to make a determination for approval or denial of an AO's application for deeming authority, the AO will be afforded the opportunity to provide the additional information. We propose deleting the language "deeming authority." This language has been a source of confusion both internally and externally. It has led healthcare facilities and others to think that the AO awards deemed status and participation in Medicare. This proposed change clarifies that we have the authority to grant "deemed status," not the AO.
- Proposed §488.5(c)(1) would replace the requirement currently set out at §488.4(f), which addresses the provision that an AO may withdraw its application at any time before the final notice is published in the **Federal Register**. We propose to modify this provision by

adding language clarifying that only an initial application can be withdrawn.

- Proposed §488.5(c)(2) is a new requirement that addresses situations where an AO wishes to voluntarily terminate its CMS-approved accreditation program. If an AO decides to voluntarily terminate its CMS-approved accreditation program, it must notify us of its decision and provide an effective date of termination. We will publish in the Federal Register a notice that includes the reason for the termination and the effective date. In accordance with the requirements at proposed §488.8(e), the AOs must notify, in writing each of its providers or suppliers of its decision no later than 30 calendar days after the notice is published in the **Federal Register**. Proposed §488.5(d) would replace the requirement currently set out at §488.4(h), which addresses the ability of an AO whose request for approval of an accreditation program has been denied to resubmit its application if certain requirements are met. We would modify this provision by redesignating paragraph (i) to paragraph (e).

- Proposed §488.5(d)(1) through §488.5(d)(3), and §488.5(e) would replace the requirement currently set out at §488.4(h)(1) through §488.4(h)(3)(i). The language of these provisions would be unchanged and addresses the requirements that an AO must meet to resubmit its application for CMS approval of an accreditation program after an initial request has been denied.

- Proposed §488.5(f) is a new proposed provision, titled “Notice and Comment,” that would incorporate the timeframes for review of an AO request for CMS approval of an accreditation program that are set forth in section 1865(b) of the Act. The text currently at §488.5 is being proposed for deletion because section 125 of MIPPA requires us to eliminate the separate provisions for TJC hospital accreditation.

- Proposed §488.5(f)(1) would replace the requirement currently set out at

§488.8(b)(1), concerning publication of a proposed notice announcing our receipt of an AO application in the **Federal Register**. To better capture the purpose of a proposed versus a final notice, this provision would be revised by deleting language describing how the AO's accreditation program provides reasonable assurance that entities accredited by the organization meet the Medicare requirements, and moving it to the provision concerning the final notice at proposed §488.5(f)(2)(i). In addition, language would be added related to the timeframe for public comment consistent with section 1865 of the Act.

- Proposed §488.5(f)(2) would replace the requirement currently set out at §488.8(b)(2), which requires us to publish a final notice announcing our decision to approve or disapprove an AO's accreditation program in the **Federal Register**. In accordance with section 1865(a)(3)(A) of the Act, the final notice must be published no later than 210 days after our receipt of a complete application. The language of the regulations would be streamlined and simplified to more clearly communicate existing requirements.

- Proposed §488.5(f)(2)(i) would replace the requirement currently set out at §488.8(b)(1), §488.8(b)(2), and §488.8(c), which address the contents of the final notice. We propose modifying the current timeframe requirement to be consistent with the provisions of section 1865(a)(3)(A) of the Act. Once a national AO's accreditation program is approved by us and this decision is published in the **Federal Register**, we may approve any provider or supplier that is surveyed or accredited for Medicare participation on or after the effective date of the final Notice (assuming that all other federal requirements have been met).

F. Providers or suppliers that participate in the Medicaid program under a CMS-approved accreditation program (§488.6).

We propose to broaden and revise the standard's title as a conforming change consistent

with section 125 of MIPPA. Proposed regulations at §488.6 would replace the requirement currently set out at §488.5(b), which states that eligibility for Medicaid participation can be established through Medicare deemed status for providers and suppliers that are not required under Medicaid regulations to comply with any requirements other than Medicare participation requirements.

G. Release and use of accreditation surveys (§488.7).

We propose revising this standard's title to be more reflective of the standard's content. Proposed §488.7 would replace the requirement currently set out at §488.6(c)(1), which states that an accredited provider or supplier must authorize its AO to release a copy of its most current accreditation survey, together with any information related to the survey that CMS may require (including corrective action plans) to us and the state survey agency. The proposed revised requirement would be for the deemed provider to authorize release of a copy of its most recent accreditation survey to us. We are also taking this opportunity to clarify that we recognize that, in accordance with the Patient Safety Act and Quality Improvement Act (PSQIA) (Pub. L. 109-41) and implementing regulations at 42 CFR §3.206(b)(8)(i) and (ii), an AO may not further disclose patient safety work product it receives when such work product complies with the requirements for patient safety work product protected under the PSQIA.

Other proposed changes are part of our effort to reorganize and clarify the regulations, as follows:

- Proposed §488.7(a) would replace the requirement currently set out at §488.6(c)(2).

The language of this requirement remains unchanged and addresses the requirement that we may determine that a provider or supplier does not meet the Medicare conditions on the basis of our own analysis of the accreditation survey or any other information related to the survey.

- Proposed §488.7(b) would replace the requirement currently set out at §488.5(c)(3) regarding our authority and discretion to disclose an AO survey and information related to the survey when the accreditation survey is related to an enforcement action taken by CMS. All other disclosures of AO survey information are prohibited under section 1865(b), with the exception of surveys of HHAs. This provision would be revised to clarify requirements for release of survey information.

H. On-going review of accreditation organizations (§488.8).

We propose modifying the title of this standard with language that is more specific and clarifies that our oversight of accreditation programs is continuous. We propose further revisions at §488.8 consistent with our effort to reorganize, streamline and clarify the regulations, as follows:

- Proposed §488.8(a) would replace the requirement currently set out at §488.8(d), which address the continuing federal oversight of equivalency of an AO and removal of deeming authority. The proposed revisions would ensure consistency with section 1875(b) of the Act, which authorizes continuing Secretarial oversight of accreditation organization activities with respect to Medicare participating entities and yearly reports to Congress concerning such activities. The proposed revisions would replace the concept of a “validation” review with the broader concept of an ongoing AO “performance” review. We also propose to remove reference to a “20 percent” rate of disparity at current §488.8(d)(2)(i) as a threshold for triggering a validation review that could result in termination of an AO’s program approval. Our experience over the past few years has demonstrated that, although the rate of disparity between AO and State survey agency surveys of the same facility within a 60 day time period may be one reliable measure of some aspects of AO performance, a single measure used in isolation does not provide

a complete and accurate picture of AO performance. As described in the CMS annual report to Congress, “Review of Medicare’s Program for Oversight of Accreditation Organizations,” we employ a multi-faceted approach that utilizes not only the disparity rate, but a number of other quantitative measures of AO performance, as well as the results of our periodic qualitative reviews of AO standards or of AO renewal applications to develop a comprehensive assessment of an AO’s performance. We believe it is not appropriate to include in the regulation a requirement, based on only one data point, which would trigger an automatic, formal review of an AO’s accreditation program’s continuing approval. Likewise, we believe our ability to open a formal review of an AO program should not be limited by tying such review to one data point. As a result, we propose deleting the specific reference in the regulation to a 20 percent disparity rate triggering a formal validation review. We propose instead to provide at §488.8(a) for an ongoing performance review of approved AO programs, and identify at proposed §488.8(a)(2) the disparity rate as only one of several components that may trigger a performance review. Further, we propose in §488.8(c) to provide for a formal accreditation program review when a performance review reveals evidence of substantial non-compliance. We believe that the proposed revision will enable us to continue to make use of the disparity rate in our ongoing assessment of AO performance, but to also make use of other performance indicators that enable us to reach a more comprehensive assessment of the quality of an AO’s program. This revision would also make clearer that a formal accreditation program review could be opened as the result of a variety of serious compliance concerns.

- Proposed §488.8(a)(1) through §488.8(a)(3) are new proposed provisions which would be added to clarify that we evaluate AO performance by looking at various aspects of their practices.

- Proposed §488.8(b) would revise the requirement currently set out at §488.8(d)(1), which addresses CMS comparability reviews. The proposed revisions would clarify our current practice.

- Proposed §488.8(b)(1) would revise the requirement currently set out at §488.8(d)(1)(i), which address the need for a comparability review when we impose new requirements or change our survey process. We propose adding language which would provide us the flexibility to consider multiple factors when determining an appropriate timeframe for AOs to revise their accreditation program and submit revisions to CMS. These factors may include: the effective date of any final rule which would affect the substantive standards which are applied to various providers and suppliers; the effective date of any revised interpretive guidance or survey process affecting accredited providers or suppliers; and the scope and magnitude of such changes. In addition, the proposed new language would set out the consequences if an AO failed to submit comparable changes in a timely manner. These provisions would parallel proposed revisions at §488.5(a)(12)(ii).

- Proposed §488.8(b)(2) would revise the requirement currently set out at §488.8(d)(1)(ii) concerning circumstances in which an AO proposes to adopt new requirements or changes its survey process. Under the current regulations, an AO must provide written notification to CMS at least 30 days in advance of the effective date of any proposed changes in its accreditation requirements or survey process. We propose expanding the timeframes to allow adequate time for us to conduct a comprehensive, detailed review of the AO's proposed changes. In addition, we propose adding language to clarify that the AO may not implement any changes to its CMS-approved accreditation program prior to receiving CMS approval. The purpose of the proposed new language would be to ensure continuing comparability of the AO's

accreditation program with the Medicare requirements. These changes would parallel comparable changes at proposed §488.5(a)(12)(i).

- Proposed §488.8(c) and §488.8(c)(1) would revise the requirement currently set out at §488.8(e), which states that if a comparability or validation review indicates that an AO is not meeting the Medicare requirements, we will provide written notice to the AO indicating that its accreditation program approval may be in jeopardy and that an accreditation program review is being initiated. We propose revising the standard's title to more accurately reflect the language of the standard that follows and deleting redundant language. We would also add language to broaden the regulation and allow us to consider other aspects of AO performance that may warrant the opening of a review of a CMS-approved accreditation program. For example, if during a validation review, a question arose as to the ability of an AO to conduct re-accreditation surveys in a timely manner, or to provide us with timely and accurate data regarding deemed facilities, we would add this matter to the review. We further propose separating the one standard into two separate standards to more clearly articulate the circumstances that may trigger the opening of a review of a CMS-approved accreditation program and the written notice CMS must provide the AO upon opening such a review.

- Proposed §488.8(c)(1)(i) would relocate the requirement currently set out at §488.8(e)(1), which requires that our notice include a statement of the requirements, instances, rates or patterns of discrepancies that were found in the course of a comparability or validation review, as well as other related documentation associated with the review. We propose deleting language and replacing it with broader language that more clearly describes current practices related to an accreditation program review. The proposed revisions would address the information that we would be required to include in the written notice that we send the AO

indicating that an accreditation program review is being initiated.

- Proposed §488.8 (c)(1)(ii) would revise the requirement currently set out at §488.8(e)(3), which requires that the notice of our comparability or validation review include a description of the process available if the AO wishes an opportunity to explain or justify the findings made during such review. The proposed language would clarify that the AO would not be limited to only one opportunity to offer factual information and documentation. Instead, such opportunities would be available throughout the accreditation program review process.

- Proposed §488.8(c)(1)(iii) would revise the requirement currently set out at §488.8(e)(4), which describes the possible enforcement actions that we may take based on findings from a validation review. We propose deleting the language, “from the validation review,” and replacing it with the conforming language, “based on the findings of the accreditation program review.”

- Proposed §488.8(c)(1)(iv) would revise the requirement currently set out at §488.8(f)(2). The current provision states that if CMS determines, following the accreditation program review, that the AO failed to adopt requirements comparable to CMS’s, or to submit new requirements in a timely manner, the AO may be given conditional CMS approval of its accreditation program with a probationary period of up to 180 days to adopt comparable requirements. To clarify the existing requirements, we propose revising this provision to include the actions an AO would have to take to address the identified deficiencies, including a timeline for implementation not to exceed 180 calendar days from the date of issuance of the electronic version of the CMS letter, indicating that an accreditation program review is being initiated.

- Proposed §488.8(c)(2) would revise the requirement currently set out at §488.8(f)(1). The current provision requires CMS to conduct a review of an AO’s accreditation program if the

comparability or validation reviews produce findings that an AO has failed to adopt requirements comparable to Medicare. The language of this provision would be modified for increased clarity by utilizing current terminology.

- Proposed §488.8(c)(3) would replace the requirement currently set out at §488.8(f)(2). The current provision provides us authority to grant conditional approval of deeming authority with a probationary period of up to 180 days to adopt comparable requirements when the AO has failed to adopt requirements comparable to CMS's, or has failed to submit new requirements in a timely manner during a deeming review. We propose expanding the language to clarify that the probationary period of up to 180 calendar days would apply only when an AO has not adopted the necessary comparable changes to its existing CMS-approved accreditation program by the end of the 180-calendar-day accreditation program review. It further would clarify that an accreditation program review probationary period could not extend beyond the AO's term of approval. Finally, it would clarify the differences between an accreditation program review and renewal application review related to a probationary period, versus a conditional approval with a probationary period.

- Proposed §488.8(c)(3)(i) would revise the requirement currently set out at §488.8(f)(4), which states that within 60 days after the end of any probationary period, we will make a final determination as to whether or not an accreditation program continues to meet the Medicare requirements and will issue an appropriate notice to the AO and affected providers or suppliers. We propose clarifying this provision by deleting the language, "make a final determination" and replacing it with, "issue a written determination." We further propose deleting the language, "criteria described at paragraph (a)(1) of this section," and replacing it with, "requirements of this subpart."

- Proposed §488.8(c)(3)(ii) would revise the requirement currently set out at §488.8(f)(5) concerning the requirement that if the AO has not made improvements acceptable to us by the end of the probationary period, we will remove its approval effective 30 days from the date that it provides written notice to the AO. We propose modifying this provision by expanding the timeframe to account for the process required in order to publish a notice in the **Federal Register**.

- Proposed §488.8(c)(3)(iii) would revise the requirement currently set out at §488.8(f)(7), which instructs us to publish a notice in the **Federal Register** when necessary, withdrawing its approval of an AO's accreditation program, including a justification for its decision. We propose clarifying this provision by specifying the timeframe for publication of this notice.

- Proposed §488.8(d) would revise the requirement currently set out at §488.8(g), which state that when we determine that continued approval of an AO's accreditation program poses an immediate jeopardy to the patients of the entities accredited by that organization, or such continued approval otherwise constitutes a significant hazard to the public health, we may immediately withdraw approval of that AO's accreditation program. We propose clarifying this provision by deleting the language, "deeming authority" and replacing it with the conforming change, "CMS-approved accreditation program."

- Proposed §488.8(e) is a new provision that would address an AO's responsibility to notify its providers or suppliers in the event that CMS withdraws approval of its accreditation program or the AO voluntarily terminates its program. This new, proposed provision would be necessary to ensure that providers or suppliers affected by an AO's loss of CMS approval for an accreditation program would be informed that they were no longer deemed to meet the Medicare

requirements. Notification would afford affected providers or suppliers an opportunity to seek accreditation through another CMS-approved AO accreditation program, or participate in Medicare under the state survey agency's jurisdiction.

- Proposed §488.8(f) would revise the requirement currently set out at §488.8(h), which provides an AO that is not satisfied with CMS's determination to withdraw approval of its accreditation program the opportunity to request a reconsideration of that determination in accordance with subpart D of this part. We propose clarifying this provision by deleting the language, "deeming authority" and replacing it with the conforming change, "CMS-approved accreditation program."

- Proposed §488.8(g) would revise the requirement currently set out at §488.8(f)(8). The current requirement states that after we remove approval of an AO's accreditation program, an affected provider's or supplier's deemed status continues in effect for 60 days after removal of approval. It further states that we may extend the period for an additional 60 days if it determines that the provider or supplier submitted an application within the 60 day timeframe to another approved AO or to us so that compliance with Medicare conditions can be determined. We propose revising this provision by expanding the timeframe for continued deemed status of an affected provider or supplier if certain criteria are met, and the provider or supplier provides notice to the state survey agency to avoid duplication of services by the state survey agency and the AO.

- Proposed §488.8(h) would replace the requirement currently set out at §488.8(f)(9), which states that a provider's or supplier's failure to comply with the timeframes set forth will jeopardize its participation in the Medicare program and, where applicable, the Medicaid program. The language of this proposed provision would remain unchanged.

- Proposed §488.8(i) would revise the requirement currently set out at §488.9. This provision addresses the onsite observation of an AO's operations. We propose modifying this provision and adding language that provides greater specificity and clarity. In addition, we propose expanding the provision to give us greater flexibility in the timing of onsite visits to improve our oversight of approved AO accreditation programs.

I. Validation surveys (§488.9).

We propose revising the title of this section because proposed §488.9 sets out the language currently at §488.7 that addresses validation surveys. The regulatory language would remain unchanged with the exception of: deleting language related to a plan of correction that no longer reflects current state survey agency practice; and deleting language regarding compliance with the Life Safety Code that would be duplicative of proposed language at §488.12(a)(2). In addition, we are proposing minor changes to conform this section to the rest of the proposed rule.

J. State survey agency review: Statutory provisions (§488.10).

We propose to revise §488.10 to implement section 125 of MIPPA (revising section 1865(a) of the Act) to clarify that our proposed regulations apply to several types of providers and suppliers, not just hospitals. The regulation currently at §488.10(c) addresses the authority of the Secretary to enter into agreements with state survey agencies for the purpose of conducting validation surveys. It further states, "Section 1865(d) provides that an accredited hospital which is found after a validation survey to have significant deficiencies related to the health and safety of patients will no longer be deemed to meet the conditions of participation." We propose revising this provision by separating it into two separate provisions, §488.10(c) and §488.10(d). We propose modifying this provision by updating the regulatory citation to implement changes associated with section 125 of MIPPA. We further propose modifying this

provision by adding broader language to make it clear that the regulations would apply to all national AOs with CMS-approved accreditation programs, and all provider or supplier types.

K. State survey agency functions (§488.11).

We propose to revise §488.11(b) by deleting the word, “accredited,” and replacing it with “deemed” as a conforming change for increased clarity. We also propose deleting the citation, “§488.7,” and replacing it with “§488.9.” This change would be consistent with the proposed reorganization of the requirements.

L. Effect of survey agency certification (§488.12).

Section 488.12 addresses provider or supplier certification recommendations made by the state survey agency to CMS. Section 488.12(a)(2) addresses whether an accredited hospital is deemed to meet the Medicare CoPs or is subject to a full review by the state survey agency. We propose modifying this provision by inserting broader language to make it clear that the revised regulations not only pertain to hospitals exclusively, but to all deemed providers and suppliers. We further propose modifying this provision for clarity and conforming changes.

M. Loss of accredited status (§488.13).

Section 488.13 is a new proposed section entitled, “Loss of Accreditation.” We believe that this proposed section is necessary to address the consequences of a provider’s or supplier’s loss of accreditation, either voluntary or involuntary, from an AO’s CMS-approved accreditation program. Voluntary loss of accreditation occurs when a provider or supplier chooses to withdraw from a CMS-approved accreditation program. Involuntary loss of accreditation occurs when an AO terminates a provider’s or supplier’s accreditation due to non-compliance with the AO’s CMS-approved accreditation program requirements, or the provider’s or supplier’s non-payment of AO fees. The proposed additions address the timing of a state survey agency survey

in such circumstances.

N. Providers or suppliers, other than SNFs and NFs, with deficiencies (§488.28).

We propose to revise §488.28(a) to state that in immediate jeopardy situations involving providers or suppliers other than nursing homes or SNFs, the Secretary may require a shorter timeframe for a provider or supplier to come into compliance. This is consistent with our longstanding enforcement policy regarding immediate jeopardy situations with respect to provider types other than long term care facilities. We believe it would be beneficial to make this practice explicit in this proposed rule.

O. Statutory basis (§489.1).

We propose to revise §489.1(b), which addresses the scope of part 489. This proposed revision would expand the scope of these provisions to indicate that suppliers are subject to certification, as well as providers. Currently §489.1(b) indicates that the regulations at §489.13, governing the effective date of the provider agreement or supplier approval, are applicable not only to providers but also to suppliers that require certification in accordance with §488.3 and §488.12 to participate in Medicare. Various supplier-specific rules in this chapter that require certification also establish requirements related to termination of the supplier's participation agreement with the Medicare program. However, only some of these rules provide for termination of the agreement where the supplier places restrictions on the persons it will accept for treatment and fails to either exempt Medicare beneficiaries or apply the restrictions in the same way for Medicare beneficiaries as all other persons seeking care in the supplier facility. We believe that this non-discrimination provision should also apply as a basis for termination of all Medicare-certified suppliers.

Likewise, neither the certified supplier-specific rules governing termination of their

agreements, nor the current termination of provider agreement rules at §489.53 provide for termination of the supplier agreement where the certified supplier denies immediate access to state surveyors or other authorized entities or refuses to allow photocopying of its records. Currently, the only enforcement remedy in the face of such denial or refusal by a certified supplier would be exclusion of the certified supplier from Medicare by the OIG pursuant to 42 CFR §1001.1301(a). It would be quicker and more efficient for us to handle such a denial or refusal of access to the certified supplier facility or photocopying of its records in the same manner as is currently used for providers, that is, CMS termination of the Medicare agreement.

Accordingly, we propose amending §489.1(b) to expand the enumeration of provisions of part 489 that apply to certain suppliers, as well as providers. Because these provisions would apply only to those types of suppliers that require certification and not to all suppliers, we are including language in the proposed revised §489.1(b) describing which types of suppliers would be affected, using the same language currently found at §489.13. This language would indicate that the affected types of suppliers participate in Medicare based on surveys conducted by the state survey agency or CMS surveyors, or on the basis of accreditation by CMS-approved AO.

We propose redesignating the current language in §489.1(b), which makes the effective date rules at §489.13 applicable to suppliers as well as providers, as new paragraph §489.1(b)(1). Further, we propose adding a new paragraph at §489.1(b)(2) indicating that the termination provisions at §489.53(a), §489.53(a)(2), and §489.53(a)(13) and proposed new §489.53(a)(18) (discussed below) would apply to suppliers as well as providers.

P. Definitions (§489.3).

The regulations at §489.3 define the term “immediate jeopardy” as a situation in which the provider's non-compliance with one or more requirements of participation has caused, or is

likely to cause, serious injury, harm, impairment, or death to a resident. This definition is identical to the one at §488.301, which, in that context, applies only to long term care facilities, that is, nursing facilities (NFs) and SNFs. However, the regulation at §489.53(d) addresses exceptions permitted for the required notice of termination which we must provide to the provider or supplier. This regulation permits exceptions in the case of immediate jeopardy situations in hospitals that have violated the Emergency Medical Treatment and Labor Act (EMTALA) requirements at §489.24(a) through (e), as well as to immediate jeopardy situations in SNFs. We propose to revise the definition of immediate jeopardy at §489.3 to clarify that it has the meaning found in proposed new §488.1, which applies to all types of providers and suppliers subject to certification.

Q. Termination by CMS (§489.53).

We propose to revise §489.53(a), which addresses the basis for us to terminate a Medicare provider agreement. We propose deleting the language “with any provider” from the heading for this provision since we are proposing that several of the termination provisions apply to suppliers, as well as providers. We propose retaining language stating that we may terminate the agreement with any provider if we find that any of the failings enumerated in §489.53(a) is attributable to that provider. We further propose adding language indicating that we may, in addition to applying the various provisions in this chapter governing the termination of agreements with suppliers, terminate agreements with those suppliers that fail to comply with the requirements set out in §489.53(a)(13) and proposed new §489.53(a)(18).

We propose adding language in §489.53(a)(2) to indicate that when a provider or supplier places restrictions on the persons accepted for treatment services without either exempting Medicare beneficiaries from such restrictions, or applying the restrictions to Medicare

beneficiaries in the same manner as to all other persons seeking care, this may be grounds for termination of the Medicare agreement. The current language at §489.53(a)(2) applies only to providers.

We propose adding language at §489.53(a)(13) to indicate that failure by a provider or supplier to permit photocopying of any records or other information by, or on behalf of us, as necessary, to determine or verify compliance with participation requirements, may be grounds for terminating the Medicare agreement. The current language at §489.53(a)(13) applies only to providers.

Further, we propose adding a new §489.53(a)(18) to state explicitly that denial of immediate access to a state survey agency or other authorized entity for the purpose of determining, in accordance with §488.3, whether the provider or supplier meets the applicable requirements, conditions of participation, conditions for coverage, or conditions for certification, may be grounds for termination of the provider agreement or supplier approval. Consistent with the definition at 42 CFR §1001.1301(a)(2), we interpret “failure to grant immediate access” to mean the failure to grant access at the time of a reasonable request or to provide a compelling reason why access may not be granted.

Finally, we propose a technical correction to §489.53(d)(2)(i). Section 489.53(d) governs the timeframe for provision of a minimum 15-day advance notice of termination of a provider agreement by us to the affected provider, while subsection (d)(2) governs exceptions to the general timeframe in situations involving immediate jeopardy. The first exception, at §489.53(d)(2)(i), applies to hospitals that have been determined by us to have an EMTALA violation which poses an immediate jeopardy. In these cases, we are required to give the hospital a preliminary notice of termination in 23 days if the hospital does not correct its identified

deficiencies or refute the finding, and a final notice of termination at least 2, but not more than 4, days before the effective date of termination. We are proposing clarifying that this exception to the timing notice provision applies to a hospital that has been found to be in violation of any of the EMTALA requirements found at §489.24, paragraphs (a) through (f). The current regulation refers to hospitals with emergency departments found in violation of §489.24, paragraphs (a) through (e). This proposed clarification would not change current EMTALA citation or enforcement practices.

R. Table of Current Location and Proposed Location of Regulations Text.

Table 1 identifies the current location, as well as the proposed location of the regulations text associated with this proposed rule.

TABLE 1: Current Location and Proposed Location of Regulations Text

Current Location	Proposed Location
§488.3(b)(1)	§488.3(b)
§488.4(b)	§488.5(a)
§§488.4(b)(3) and 488.4(b)(3)(i)	§488.5(a)(8)(ii)
§488.4(b)(3)(vii)	§488.5(a)(4)(ix)
§488.4(b)(3)(viii)	§488.5(a)(12)(ii)
§488.4(d)	§488.9.
§488.4(e)	§488.5(f)(1)
§488.6(a)	§488.4(a)
§488.4	§488.5
§488.4(a)	§488.5(a)
§488.4(a)(1)	§488.5(a)(1)
§488.4(a)(2)	§488.5(a)(3)
§488.4(a)(3)	§488.5(a)(4)
§488.4(a)(3)(i)	§488.5(a)(4)(i)
§488.(a)(3)(ii)	§488.5(a)(4)(iii)
§488.8(a)(2)(ii)	§488.5(a)(4)(iv)
§488.4(a)(3)(iii)	§488.5(a)(4)(v)
§488.4(a)(3)(iv)	§488.5(a)(4)(vi)
§488.8(a)(3)	§488.5(a)(4)(viii)
§488.4(a)(4)(i)	§488.5(a)(5)
§488.4(a)(4)(i)	§488.5(a)(6)
§488.4(a)(4)(ii)	§488.5(a)(7)

§488.4(a)(4)(iii)	§488.5(a)(8)
§488.4(a)(4)(iv)	§488.5(a)(9)
§488.4(a)(4)(v)	§488.5(a)(10)
§488.4(a)(5)	§488.5(a)(11)
§488.4(b)(1)	§488.5(a)(11)(ii)
§488.4(a)(6)	§488.5(a)(12)
§488.4(a)(7)	§488.5(a)(13)
§488.4(a)(8)	§488.5(a)(13)(i)
§488.4(b)(3)(i)	§488.5(a)(13)(ii)
§488.4(a)(9)	§488.5(a)(14)
§488.4(a)(10)	§488.5(a)(16)
§488.4(b)(2)	§488.5(a)(17)
§488.4(b)(3)(iii)	§488.5(a)(19)
§488.4(b)(3)(iv)	§488.5(a)(20)
§488.4(b)(3)(v)	§488.5(a)(21)
§488.4(c)	§488.5(b)
§488.4(f)	§488.5(c)
§488.4(h)	§488.5(d)
§488.4(h)(1)-§488.4(h)(3)(i)	§488.5(d)(1)-§488.5(d)(3), §488.5(e)
§488.8(b)(1)	§488.5(f)(1)
§488.8(b)(2)	§488.5(f)(2)
§488.8(b)(1), §488.8(b)(2), §488.8(c)	§488.5(f)(2)(i)
§488.5(b)	§488.6
§488.6(c)(1)	§488.7
§488.6(c)(2)	§488.7(a)
§488.5(c)(3)	§488.7(b)
§488.8(d)	§488.8(a)
§488.8(d)(1)	§488.8(b)
§488.8(d)(1)(i)	§488.8(b)(1)
§488.8(d)(1)(ii)	§488.8(b)(2)
§488.8(e)	§488.8(c)-§488.8(c)(1)
§488.8(e)(1)	§488.8(c)(1)(i)
§488.8(e)(3)	§488.8(c)(1)(ii)
§488.8(e)(4)	§488.8(c)(1)(iii)
§488.8(f)(2)	§488.8(c)(1)(iv)
§488.8(f)(1)	§488.8(c)(2)
§488.8(f)(2)	§488.8(c)(3)
§488.8(f)(4)	§488.8(c)(3)(i)
§488.8(f)(5)	§488.8(c)(3)(ii)
§488.8(f)(7)	§488.8(c)(3)(iii)
§488.8(h)	§488.8(d)
§488.8(g)	§488.8(e)
§488.8(f)(8)	§488.8(f)
§488.8(f)(9)	§488.8(f)(1)
§488.9	§488.8(g)
§488.7	§488.9

§488.10(d)

§488.10(b)

III. Collection of Information Requirements

While this rule does contain information collection requirements, we believe they are exempt under 5 CFR §1320.3(c)(4). The requirements would affect less than 10 entities in a 12-month period. The requirements in the document have been in existence since September 2008. Since implementation, there have only been a total of seven entities that meet the criteria necessary to become accrediting organizations, with the seventh having just been added as recently as September 2008. Should the number of eligible entities approach or exceed 10, we will prepare an information collection request for OMB approval. As required by the Paperwork Reduction Act of 1995, we will announce the information collection request via the required **Federal Register** notices and allow the public ample time to review the request and submit comments.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the "DATES" section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Statement (or Analysis)

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 Social Security 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.

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 \$7.0 million to \$35.5 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 proposed rule will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis 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 603 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 proposed 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 2013, that threshold level is currently approximately \$141 million. This proposed rule has no consequential effect on state, local, or tribal governments or on the private sector.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects42 CFR Part 488

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

42 CFR Part 489

Health facilities, Medicare, Reporting and recordkeeping requirements.

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

PART 488--SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

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

Authority: Secs. 1102, and 1871 of the Social Security Act, unless otherwise noted (42 U.S.C 1302 and 1395(hh)); Section 6111 of the Patient Protection and Affordable Care Act (Pub. L. 111-148).

2. Section 488.1 is amended by--

A. Revising the definitions of “Certification,” “Full review,” “Provider of services or provider,” “Reasonable assurance,” “State survey agency,” “Substantial allegation of non-compliance,” and “Supplier.”

B. Removing the definitions of “Accredited provider or supplier,” “AOA,” “JCAHO,” and “Validation review period.”

C. Adding the definitions of “Conditions for certification,” “Deemed status,” “Immediate jeopardy,” and “National accrediting organization.”

The revisions and additions read as follows:

§488.1 Definitions.

* * * * *

Certification means a determination made by the state survey agency that providers and suppliers are in compliance with the applicable conditions of participation, conditions for coverage, conditions for certification, or requirements.

* * * * *

Conditions for certification means the health and safety standards RHCs must meet to participate in the Medicare program.

Deemed status is awarded by CMS when a provider or supplier has voluntarily applied for, and received, accreditation from a CMS-approved national accrediting organization; been recommended by the national accrediting organization for Medicare participation; has met all other requirements for participation in the Medicare program as determined by CMS; and, is participating in the Medicare program on the basis of CMS's acceptance of the accrediting organization's recommendation. Deemed status is an alternative to regular surveys by the state survey agency to determine whether or not it continues to meet the Medicare requirements.

Full review means a survey of a provider or supplier for compliance with all of the Medicare conditions or requirements applicable to that provider or supplier type.

Immediate jeopardy means a situation in which the provider's or supplier's non-compliance with one or more Medicare requirements, conditions of participation, conditions for coverage or certification has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident or patient.

* * * * *

National accrediting organization means an organization that accredits health care facilities under a specific program and whose accredited healthcare facilities under each program are widely located geographically across the United States.

Provider of services or provider refers to a hospital, critical access hospital, skilled nursing facility, nursing facility, home health agency, hospice, comprehensive outpatient

rehabilitation facility, or a clinic, rehabilitation agency or public health agency that furnishes outpatient physical therapy or speech pathology services.

* * * * *

Reasonable assurance means that an accrediting organization has demonstrated to CMS's satisfaction that its accreditation program requirements meet or exceed the Medicare program requirements.

* * * * *

State survey agency refers to the state health agency or other appropriate state or local agency CMS uses to perform survey and review functions provided for in sections 1864, 1819(g), and 1919(g) of the Act.

Substantial allegation of non-compliance means a complaint from any of a variety of sources (that is, patient, relative, or third party), including complaints submitted in person, by telephone, through written correspondence, or in newspaper or magazine articles, that, if substantiated, could or may affect the health and safety of patients or raise doubts as to a provider's or supplier's compliance with any Medicare condition of participation, condition for coverage, condition for certification, or other requirements.

Supplier means unless the context otherwise requires, a physician or other practitioner, a facility, or other entity (other than a provider of services) that furnishes items or services. For the purposes of this part, the term does not include suppliers of durable medical equipment and supplies, kidney transplant centers, or end stage renal dialysis facilities.

3. Section 488.2 is amended by--

A. Adding the following statutory provisions in numerical order.

B. Revising the description of section 1883 of the Social Security Act.

The additions and revisions read as follows:

§488.2 Statutory basis.

* * * * *

1138(b)-Requirements for organ procurement organizations and organ procurement agencies.

* * * * *

1820-Requirements for CAHs.

1832(a)(2)(C)-Requirements for Organizations that provide outpatient physical therapy and speech language pathology services.

1832(a)(2)(F)-Requirements for ASCs.

1832(a)(2)(J)-Requirements for partial hospitalization for CMHCs.

1843(e)-Requirements for Advanced Diagnostic Imaging (ADI) services.

1861(e)-Requirements for hospitals.

* * * * *

1861(p)(4)-Requirements for rehabilitation agencies.

* * * * *

1861(aa)-Requirements for RHCs and FQHCs.

1861(cc)(2)-Requirements for CORFs.

1861(dd)-Requirements for hospices.

1861(ff)(3)(A)-Requirements for CMHCs.

* * * * *

1863-Consultation with state agencies, accrediting bodies, and other organizations to develop conditions of participation, conditions for coverage, conditions for certification, and requirements for providers or suppliers.

* * * * *

1875(b)-Requirements for performance review of CMS-approved accreditation programs.

1881-Requirements for ESRDs.

1883-Requirements for hospitals that furnish extended care services.

* * * * *

4. Section 488.3 is revised to read as follows:

§488.3 Conditions of participation, conditions for coverage, conditions for certification and long term care requirements.

(a) Basic rules. To be approved for participation in, or coverage under, the Medicare program, a prospective provider or supplier must meet the following:

(1) Meet the applicable statutory definitions in section 1138(b), 1819, 1820, 1832(a)(2)(C), 1832(a)(2)(F), 1832(a)(2)(J), 1834(e), 1861, 1881, 1883, 1891, 1913 or 1919 of the Act.

(2) Be in compliance with the applicable conditions, certification requirements, or long term care requirements prescribed in part 405 subparts U or X, part 410 subpart E, §410.33, §414.68, part 416, part 418 subpart C, parts 482 through 485, part 491 subpart A, or part 494 of this chapter.

(b) Special conditions – The Secretary may consult with state agencies and other organizations to develop conditions of participation, conditions for coverage, conditions for certification, and long term care requirements.

(1) The Secretary may, at a state's request, approve health and safety requirements for providers or suppliers in the state that exceed Medicare program requirements.

(2) If a state or political subdivision imposes requirements on institutions (that exceed the Medicare program requirements) as a condition for the purchase of health services under a state Medicaid plan approved under title XIX of the Act, (or if Guam, Puerto Rico, or the Virgin Islands does so under a state plan for Old Age Assistance under title I of the Act, or for Aid to the Aged, Blind, and Disabled under the original title XVI of the Act), the Secretary imposes similar requirements as a condition for payment under Medicare in that state or political subdivision.

5. Section 488.4 is revised to read as follows:

§488.4 General rules for a CMS-approved accreditation programs for providers and suppliers.

(a) A national accrediting organization can apply to CMS for approval to accredit providers and suppliers (except for kidney transplant centers, ESRD facilities, and suppliers of medical equipment and supplies) as meeting or exceeding the Medicare conditions or requirements. The following requirements apply when a national accrediting organization approved by CMS provides reasonable assurance to CMS that it requires providers or suppliers (except for kidney transplant centers, ESRD facilities, and suppliers of medical equipment and supplies) it accredits to meet requirements that meet or exceed the Medicare conditions or

requirements:

(1) When a provider or supplier demonstrates full compliance with all of the accreditation program requirements of the national accrediting organization's CMS-approved accreditation program, the national accrediting organization may recommend to CMS to grant deemed status to the provider or supplier.

(2) CMS may deem the provider or supplier to be in compliance with the applicable Medicare conditions or requirements. The provider or supplier is subject to validation surveys under §488.9.

(b) [Reserved]

6. Section 488.5 is revised to read as follows:

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

(a) Information submitted with application. A national accrediting organization applying to CMS for approval or re-approval of an accreditation program under §488.4 must furnish CMS with all of the following information and materials to demonstrate that the program provides reasonable assurance that the entities accredited under the program meet or exceed the applicable Medicare conditions or requirements. This information must include the following:

(1) Documentation that demonstrates the organization meets the definition of a "national accrediting organization" under §488.1 as it relates to the accreditation program.

(2) The type of provider or supplier accreditation program for which the organization is requesting approval or re-approval.

(3) A detailed crosswalk (in table format) that identifies, for each of the applicable Medicare conditions or requirements, the exact language of the organization's comparable

accreditation requirements and standards.

(4) A detailed description of the organization's survey process to confirm that a provider or supplier meets or exceeds the Medicare program requirements. This description must include all of the following information:

(i) Frequency of surveys performed and agreement by the organization to re-survey every accredited provider or supplier, through unannounced surveys, no later than 36 months after the previous accreditation survey, including an explanation of how the accrediting organization will maintain the schedule it proposes. If there is a statutorily-mandated survey interval of less than 36 months, the organization must indicate how it will adhere to the statutory schedule.

(ii) Documentation demonstrating the comparability of the organization's survey process and surveyor guidance to those required for state survey agencies conducting federal Medicare surveys for the same provider or supplier type, as specified in the CMS State Operations Manual (Pub. No. 100-07).

(iii) Copies of the organization's survey forms, guidelines, and instructions to surveyors.

(iv) Documentation demonstrating that the organization's survey reports identify, for each finding of non-compliance with accreditation standards, the comparable Medicare conditions of participation, conditions for coverage, conditions for certification, or requirements.

(v) Description of the organization's accreditation survey review process.

(vi) Description of the organization's procedures and timelines for notifying surveyed facilities of non-compliance with the accreditation program's standards.

(vii) Description of the organization's procedures and timelines for monitoring the provider's or supplier's correction of identified non-compliance with the accreditation program's standards.

(viii) A statement acknowledging that, as a condition for CMS approval of a national accrediting organization's accreditation program, the organization agrees to provide CMS with a copy of the most recent accreditation survey for a specified provider or supplier, together with any other information related to the survey as CMS may require (including corrective action plans).

(ix) A statement acknowledging that the accrediting organization will provide timely notification to CMS when an accreditation survey or complaint investigation identifies an immediate jeopardy as that term is defined at §489.3 of this chapter. Using the format specified by CMS, the accrediting organization must notify CMS within 1 business day from the date the accrediting organization identifies the immediate jeopardy.

(5) The criteria for determining the size and composition of the organization's survey teams for the type of provider or supplier to be accredited, including variations in team size and composition for individual provider or supplier surveys.

(6) The overall adequacy of the number of the organization's surveyors, including how the organization will increase the size of the survey staff to match growth in the number of accredited facilities while maintaining re-accreditation intervals for existing accredited facilities.

(7) A description of the education and experience requirements surveyors must meet.

(8) A description of the content and frequency of the organization's in-service training it provides to survey personnel.

(9) A description of the organization's evaluation systems used to monitor the performance of individual surveyors and survey teams.

(10) The organization's policies and procedures for avoiding potential conflicts of interest by precluding individuals who are professionally or financially affiliated with a provider or supplier from participating in the survey or accreditation decision process with respect to that provider or supplier.

(11) A description of the organization's data management and analysis system with respect to its surveys and accreditation decisions, including all of the following:

(i) A detailed description of how the organization uses its data to assure the compliance of its accreditation program with the Medicare program requirements.

(ii) A statement acknowledging that the organization agrees to submit timely, accurate, and complete data to support CMS's evaluation of the accrediting organization's performance. The organization must submit to CMS the data according to the instructions and timeframes CMS specifies. Data submissions include, but are not limited to, accredited provider or supplier demographic information, survey schedules, survey findings, and notices of accreditation decisions.

(12) The organization's procedures for responding to, and investigating, complaints against accredited facilities, including policies and procedures regarding coordination of these activities with appropriate licensing bodies and ombudsmen programs.

(13) The organization's accreditation status decision-making process, including its policies and procedures for granting, withholding, or removing accreditation status for facilities that fail to meet the accrediting organization's standards or requirements, assignment of less than

full accreditation status or other actions taken by the organization in response to non-compliance with its standards and requirements. The organization must furnish the following:

(i) A description of all types and categories of accreditation decisions associated with the program for which approval is sought, including the duration of each.

(ii) A statement acknowledging that the organization agrees to notify CMS (in a manner CMS specifies) of any provider or supplier-specific accreditation decisions, including but not limited to the following: accreditation revoked, withdrawn, or revised; or has had any remedial or adverse action taken against it, within 3 business days from the date the organization takes an action.

(14) A list of all facilities currently accredited by the organization under the program for which CMS approval is sought, including the type and category of accreditation currently held by each provider or supplier, and the expiration date of each provider's or supplier's current accreditation.

(15) CMS considers applications for re-approval of a national accrediting organizations accreditation program if the accrediting organization demonstrates it has accredited at least 50 providers or suppliers under its current CMS-approved accreditation program.

(16) A schedule of all accreditation surveys expected to be conducted by the organization during the 6-month period following submission of the application.

(17) The 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.

(18) A statement that it will provide written notification to all providers or suppliers accredited under a CMS-approved accreditation program at least 90 calendar days in advance of the effective date of a decision by the organization to voluntarily terminate its CMS-approved accreditation program.

(19) A statement that it will provide written notification to CMS at least 60 calendar days in advance of the effective date of any proposed changes in the organization's CMS-approved accreditation program requirements, including an agreement not to implement the changes before receiving CMS's approval.

(20) A statement that, in response to a notice from CMS 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. The organization must comply with the following requirements:

(i) The proposed changes must be submitted within 30 calendar days or by the date specified in the CMS notice, whichever is later.

(ii) The organization may not implement the proposed changes before receiving CMS's approval.

(21) A statement acknowledging that, as a condition for CMS's approval of an accreditation program, the organization will agree to require its surveyors to serve as witnesses in a legal proceeding if CMS takes an adverse action against a provider or supplier on the basis of the organization's accreditation survey findings.

(b) Additional information needed. If CMS determines that additional information is necessary to make a determination for approval or denial of the organization's initial application or re-application for CMS's approval of an accreditation program, CMS will notify the organization and afford it an opportunity to provide the additional information.

(c)(1) Withdrawing an application. An accrediting organization may withdraw its initial application for CMS's approval of its accreditation program at any time before CMS publishes the final notice described in paragraph (f)(2) of this section.

(2) Voluntary termination of a CMS-approved accreditation program. An accrediting organization may voluntarily terminate its CMS-approved accreditation program at any time. The AO must notify CMS of its decision to voluntarily terminate its approved accreditation program and provide an effective date of termination. CMS will publish in the **Federal Register** a notice that includes the reasons for the termination and the effective date. In accordance with the requirements at §488.8(e), the AOs must notify, in writing each of its providers or suppliers of its decision.

(d) Requesting reconsideration of a disapproval. If an accrediting organization has requested, in accordance with subpart D of this part, a reconsideration of CMS's determination that its request for approval of an accreditation program is denied, it may not submit an initial application for approval of an accreditation program for another type of provider or supplier until the hearing officer's final decision is rendered.

(e) Re-submitting a request. Except as provided in paragraph (d) of this section, an organization whose request for CMS's approval or re-approval of an accreditation program has been denied may resubmit its application if the organization completes all of the following:

(1) Revises its accreditation program to address the issues related to the denial of its previous request.

(2) Demonstrates that it can provide reasonable assurance that its accredited facilities meet the applicable Medicare program requirements.

(3) Resubmits the application in its entirety.

(f) Public notice and comment. CMS publishes a notice in the **Federal Register** when the following conditions are met:

(1) Proposed notice. When CMS receives a complete application from a national accrediting organization seeking CMS's approval of an accreditation program, it publishes a proposed notice. The proposed notice identifies the organization and the type of providers or suppliers to be covered by the accreditation program and provides 30 calendar days for the public to submit comments to CMS.

(2) Final notice. When CMS decides to approve or disapprove a national accrediting organization's application, it publishes a final notice within 210 calendar days from the date CMS determines the accrediting organization's application was complete. The final notice specifies the basis for the CMS decision.

(i) Approval or re-approval. If CMS approves or re-approves the accrediting organization's accreditation program, the final notice describes how the accreditation program provides reasonable assurance that the providers or suppliers accredited by the organization under that program meet the applicable Medicare requirements. The final notice specifies the effective date and term of the approval (which may not be later than the publication date of the notice and which will not exceed 6 years).

(ii) Disapproval. If CMS does not approve the accrediting organization's accreditation program, the final notice describes how the organization fails to provide reasonable assurance that the providers or suppliers accredited by the organization under that program meet the applicable Medicare requirements. The final notice specifies the effective date of the decision.

7. Section 488.6 is revised to read as follows:

§488.6 Providers or suppliers that participate in the Medicaid program under a CMS-approved accreditation program.

A provider or supplier that has been granted "deemed status" by CMS by virtue of its accreditation from a CMS-approved accreditation program is eligible to participate in the Medicaid program.

§488.9 [Removed]

8. Section 488.9 is removed.

§488.7 [Redesignated as §488.9]

9. Section 488.7 is redesignated as new §488.9.

10. New section 488.7 is added to read as follows:

§488.7 Release and use of accreditation surveys.

A Medicare participating provider or supplier deemed to meet program requirements in accordance with §488.4 must authorize its accrediting organization to release to CMS a copy of its most current accreditation survey and any information related to the survey that CMS may require (including, but not limited to, corrective action plans).

(a) CMS may determine that a provider or supplier does not meet the applicable Medicare conditions or requirements on the basis of its own investigation of the accreditation survey or any other information related to the survey.

(b) With the exception of home health agency surveys, general disclosure of an accrediting organization's survey information is prohibited under section 1865(b) of the Act. CMS may publically disclose an accreditation survey and information related to the survey, upon written request, to the extent that the accreditation survey and survey information are related to an enforcement action taken by CMS.

11. Section 488.8 is revised to read as follows:

§488.8 Ongoing review of accrediting organizations.

(a) Performance review. In accordance with section 1875(b) of the Act, CMS evaluates the performance of each CMS-approved accreditation program on an ongoing basis. This review includes, but is not limited to the following:

(1) Review of the organization's survey activity.

(2) Analysis of the results of the validation surveys under §488.9(a)(1), including the rate of disparity between certifications of the accrediting organization and certifications of the state survey agency.

(3) Review of the organization's continued fulfillment of the requirements in §488.5(a).

(b) Comparability review. CMS assesses the equivalency of an accrediting organization's CMS-approved program requirements to the comparable CMS requirements if the following conditions exist:

(1) CMS imposes new requirements or changes its survey process.

(i) CMS provides timely notice of the changes to the affected accrediting organization.

(ii) CMS specifies a timeframe, not less than 30 calendar days, for the accrediting organization to submit its proposed equivalent changes, including an implementation timeframe, for CMS review and approval.

(iii) After approval of the proposed changes, CMS determines whether the changes were implemented within the approved timeframe.

(iv) If an organization fails to submit timely comparable changes, CMS may open an accreditation program review in accordance with paragraph (c) of this section.

(2) An accrediting organization proposes to adopt new requirements or to change its survey process.

(i) An accrediting organization must provide written notice to CMS at least 60 calendar days before the proposed effective date of any proposed changes in its accreditation requirements or survey process.

(ii) The accrediting organization must not implement any changes before receiving CMS's approval.

(c) CMS-approved accreditation program review. If a comparability or performance review reveals evidence of substantial non-compliance of an accrediting organization's CMS-approved accreditation program with the requirements of this subpart, CMS may initiate an accreditation program review.

(1) If an accreditation program review is initiated, CMS provides written notice to the organization indicating that its CMS-approved accreditation program approval may be in jeopardy and that an accreditation program review is being initiated. The notice provides all of

the following information:

(i) A statement of the instances, rates or patterns of non-compliance identified, as well as other related information, if applicable.

(ii) A description of the process to be followed during the review, including a description of the opportunities for the accrediting organization to offer factual information related to CMS's findings.

(iii) A description of the possible actions that may be imposed by CMS based on the findings of the accreditation program review.

(iv) The actions the accrediting organization must take to address the identified deficiencies including a timeline for implementation not to exceed 180 calendar days after receipt of the notice that CMS is initiating an accreditation program review.

(2) CMS reviews the accrediting organization's plan of correction for acceptability.

(3) If CMS determines as a result of the accreditation program review or a review of an application for renewal of an existing CMS-approved accreditation program that the accrediting organization has failed to meet any of the requirements of this subpart, CMS may place the accrediting organization's CMS-approved accreditation program on probation for a period up to 180 calendar days to implement corrective actions, not to exceed the accrediting organization's current term of approval. In the case of a renewal application where CMS has placed the accreditation program on probation, CMS indicates that any approval of the application is conditional while the program is placed on probation.

(i) Within 60 calendar days after the end of any probationary period, CMS issues a written determination to the accrediting organization as to whether or not a CMS-approved

accreditation program continues to meet the requirements of this subpart, including the reasons for the determination.

(ii) If CMS has determined that the accrediting organization does not meet the requirements, CMS withdraws approval of the CMS-approved accreditation program. The notice of determination provided to the accrediting organization includes notice of the removal of approval, reason for the removal, including the effective date determined in accordance with paragraph (c)(3)(iii) of this section.

(iii) CMS publishes in the **Federal Register** a notice of its decision to withdraw approval of a CMS-approved accreditation program, including the reasons for the withdrawal, effective 60 calendar days from the date of publication of the notice.

(d) Immediate jeopardy. If at any time CMS determines that the continued approval of a CMS-approved accreditation program of any accrediting organization poses an immediate jeopardy to the patients of the entities accredited under that program, or the continued approval otherwise constitutes a significant hazard to the public health, CMS may immediately withdraw the approval of a CMS-approved accreditation program of that accrediting organization and publishes a notice of the removal, including the reasons for it, in the **Federal Register**.

(e) Notification of providers or suppliers. An accrediting organization whose CMS approval of its accreditation program has been withdrawn or the organization voluntarily terminates its program must notify, in writing, each of its providers or suppliers of withdrawal of deemed status no later than 30 calendar days after the notices is published in the **Federal Register**.

(f) Request for reconsideration. Any accrediting organization dissatisfied with a

determination to withdraw CMS approval of its accreditation program may request a reconsideration of that determination in accordance with subpart D of this part.

(g) Continuation of deemed status. After 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**. The provider or supplier must provide written notice to the state survey agency that it has submitted an application for accreditation with deemed status with another CMS-approved accrediting organization within this same 60-calendar day timeframe. Failure to comply with the timeframe requirements specified in this section will place the provider or supplier under the state survey agency's authority for continued participation in Medicare and on-going monitoring.

(h) Onsite observations of accrediting organization operations. As part of the application review process, the ongoing review process, or the continuing oversight of an accrediting organization's performance, CMS may conduct at any time an onsite inspection of the accrediting organization's operations and offices to verify the organization's representations and to assess the organization's compliance with its own policies and procedures. The onsite inspection may include, but is not limited to, the review of documents, auditing meetings concerning the accreditation process, observation of surveys, the evaluation of survey results or the accreditation decision-making process, and interviews with the organization's staff.

12. Newly designated §488.9 is revised to read as follows:

§488.9 Validation surveys.

(a) Basis for survey. CMS may require a survey of an accredited provider or supplier to validate the accrediting organization's CMS-approved accreditation process. These surveys are conducted on a representative sample basis, or in response to substantial allegations of non-compliance.

(1) For a representative sample, the survey may be comprehensive and address all Medicare conditions or requirements, or it may be focused on a specific condition(s) as determined by CMS.

(2) For a substantial allegation, the state survey agency surveys for any condition(s) or requirement(s) that CMS determines is related to the allegations.

(b) Selection for survey. (1) A provider or supplier selected for a validation survey must cooperate with the state survey agency that performs the validation survey.

(2) If a provider or supplier selected for a validation survey fails to cooperate with the state survey agency, it will no longer be deemed to meet the Medicare conditions or requirements, but will be subject to a review by the state survey agency in accordance with §488.10(a), and may be subject to termination of its provider agreement under §489.53 of this chapter.

(c) Consequences of a finding of non-compliance. (1) If a CMS validation survey results in a finding that the provider or supplier is out of compliance with one or more Medicare conditions or requirements, the provider or supplier will no longer be deemed to meet the Medicare conditions or requirements and will be subject to ongoing review by the state survey agency in accordance with §488.10(a) until the provider or supplier demonstrates compliance.

(2) CMS may take actions with respect to the deficiencies identified in the state validation survey in accordance with §488.24, or may first direct the state survey agency to conduct another survey of the provider's or supplier's compliance with specified Medicare conditions or requirements before taking the enforcement actions provided for at §488.24.

(3) If CMS determines that a provider or supplier is not in compliance with applicable Medicare conditions or requirements, the provider or supplier may be subject to termination of the provider or supplier agreement under §489.53 of this chapter or of the supplier agreement in accordance with the applicable supplier conditions and any other applicable intermediate sanctions and remedies.

(d) Re-instating deemed status. An accredited provider or supplier will be deemed to meet the applicable Medicare conditions or requirements in accordance with this section if all of the following requirements are met:

(1) It withdraws any prior refusal to authorize its accrediting organization to release a copy of the provider's or supplier's current accreditation survey.

(2) It withdraws any prior refusal to allow a validation survey, if applicable.

(3) CMS finds that the provider or supplier meets all applicable Medicare conditions of participation, conditions for coverage, conditions of certification, or requirements.

(e) Impact of adverse actions. The existence of any performance review, comparability review, deemed status review, probationary period, or any other action by CMS, does not affect or limit conducting any validation survey.

13. Section 488.10 is amended by revising paragraphs (b) through (d) to read as follows:

§488.10 State survey agency review: Statutory provisions.

* * * * *

(b) Section 1865(a) of the Act provides that if an institution is accredited by a national accrediting organization recognized by the Secretary, it may be deemed to have met the applicable conditions or requirements.

(c) Section 1864(c) of the Act authorizes the Secretary to enter into agreements with state survey agencies for the purpose of conducting validation surveys in institutions accredited by an accreditation program recognized by the Secretary.

(d) Section 1865(c) provides that an accredited institution that is found after a validation survey to have significant deficiencies related to health and safety of patients will no longer meet the applicable conditions or requirements.

14. Section 488.11 is amended by revising paragraph (b) to read as follows:

§488.11 State survey agency functions.

* * * * *

(b) Conduct validation surveys of deemed facilities as provided in §488.9.

* * * * *

15. Section 488.12 is amended by revising paragraph (a)(2) to read as follows:

§488.12 Effect of survey agency certification.

* * * * *

(a) * * *

(2) A provider or supplier accredited under a CMS-approved accreditation program remains deemed to meet the Medicare conditions or requirements, or will be placed under the

jurisdiction of the state survey agency and subject to further enforcement actions in accordance with the provisions at §488.9.

* * * * *

16. Section 488.13 is added to read as follows:

§488.13 Loss of accreditation.

If an accrediting organization notifies CMS that it is terminating a provider or supplier due to non-compliance with its CMS-approved accreditation requirements, the state survey agency will conduct a full review in a timely manner.

17. Section 488.28 is amended by revising paragraph (a) to read as follows:

§488.28 Providers or suppliers, other than SNFs and NFs, with deficiencies.

(a) If a provider or supplier is found to be deficient in one or more of the standards in the conditions of participation, conditions for coverage, or conditions for certification or requirements, it may participate in, or be covered under, the Medicare program only if the provider or supplier has submitted an acceptable plan of correction for achieving compliance within a reasonable period of time acceptable to the Secretary. In the case of an immediate jeopardy situation, the Secretary may require a shorter time period for achieving compliance.

* * * * *

PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

18. The authority citation for part 489 is revised to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh)).

19. Section 489.1 is amended by revising paragraph (b) to read as follows:

§489.1 Statutory basis.

* * * * *

(b) Although section 1866 of the Act speaks only to providers and provider agreements, the following rules in this part also apply to the approval of supplier entities that, for participation in Medicare, are subject to a determination by CMS on the basis of a survey conducted by the state survey agency or CMS surveyors; or, in lieu of a state survey agency or CMS-conducted survey, accreditation by an accrediting organization whose program has CMS approval in accordance with §488.4 at the time of the accreditation survey and accreditation decision, in accordance with the following:

(1) The effective date rules specified in §489.13.

(2) The requirements specified in §489.53(a)(2), (13), and (18), related to termination by CMS of participation in Medicare.

* * * * *

20. Section 489.3 is amended by revising the definition of “Immediate jeopardy” to read as follows:

§489.3 Definitions.

* * * * *

Immediate jeopardy means a situation in which the provider’s or supplier’s non-compliance with one or more requirements, conditions of participation, conditions for coverage, or certification has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident or patient.

* * * * *

21. Section 489.53 is amended by—

- A. Revising paragraphs (a) introductory text, (a)(2), (a)(13).
- B. Adding reserved paragraph (a)(17).
- C. Adding paragraph (a)(18).
- D. Revising paragraph (d)(2)(i) introductory text.

The additions and revisions read as follows:

§489.53 Termination by CMS.

(a) Basis for termination of agreement. CMS may terminate the agreement with any provider if CMS finds that any of the following failings is attributable to that provider, and may, in addition to the applicable requirements in this chapter governing the termination of agreements with suppliers, terminate the agreement with any supplier to which the failings in paragraphs (a)(2), (a)(13), and (a)(18) of this section are attributable:

* * * * *

(2) The provider or supplier places restrictions on the persons it will accept for treatment and it fails either to exempt Medicare beneficiaries from those restrictions or to apply them to Medicare beneficiaries the same as to all other persons seeking care.

* * * * *

(13) The provider or supplier refuses to permit photocopying of any records or other information by, or on behalf of, CMS, as necessary to determine or verify compliance with participation requirements.

* * * * *

(17) [Reserved]

(18) The provider or supplier fails to grant immediate access upon a reasonable request to a state survey agency or other authorized entity for the purpose of determining, in accordance with §488.3, whether the provider or supplier meets the applicable requirements, conditions of participation, conditions for coverage or conditions for certification.

* * * * *

(d) * * *

(2) * * *

(i) Hospitals. If CMS finds that a hospital is in violation of §489.24 (a) through (f), and CMS determines that the violation poses immediate jeopardy to the health or safety of individuals who present themselves to the hospital for emergency services, CMS—

* * * * *

CMS-3255-P

Authority: (Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare--Hospital Insurance; and Program No. 93.774, Medicare--Supplementary Medical Insurance Program)

Dated: November 15, 2012.

Marilyn Tavenner,
Acting Administrator,
Centers for Medicare & Medicaid Services.

Approved: March 13, 2013

Kathleen Sebelius,
Secretary.

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