DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 401, 488 and 489

[CMS–3255–F]

RIN 0938–AQ33

Medicare and Medicaid Programs: Revisions to Deeming Authority Survey, Certification, and Enforcement Procedures

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

ACTION: Final rule.

SUMMARY: This final rule revises the survey, certification, and enforcement procedures related to CMS oversight of national accrediting organizations (AOs). The revisions implement certain provisions under the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). The revisions 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 statute. The rule also extends some provisions, which are applicable to Medicare-participating providers, to Medicare-participating suppliers subject to certification requirements, and clarifies the definition of ''immediate jeopardy.''

DATES: This final rule is effective on July 21, 2015.

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SUPPLEMENTARY INFORMATION:

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
LSC Life Safety Code
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
SA State Survey Agency
SNF Skilled Nursing Facility
SOM State Operations Manual
The Act Social Security Act
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 specified by the Secretary of the Department of Health and Human Services (HHS). These 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 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 institutional health care providers and suppliers to ascertain compliance with the applicable CoPs, CfCs, conditions of certification, or requirements (as applicable), and certify their findings to us. Based on these state survey agency (SA) 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 ''provider entities'' which include all types of providers and suppliers subject to certification, with the exception of kidney transplant programs and end stage renal dialysis facilities, to demonstrate compliance with Medicare CoPs, requirements, CfCs, or conditions for certification through accreditation by a CMS-approved program of a national accrediting organization (AO). If an AO is recognized by the Secretary as having standards for accreditation that meet or exceed all applicable Medicare CoPs, requirements, CfCs, or conditions for certification, then any provider or supplier accredited by the AO's CMS-approved Medicare accreditation program may be deemed by us to meet the Medicare requirements.

We are responsible for the review, approval and subsequent oversight of national AOs' Medicare accreditation programs, and for ensuring that 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 that 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 §§ 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, in the case of a decision to terminate approval, to affected providers or suppliers.

In addition, 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 paid under the physician fee schedule to a supplier who is accredited by an AO designated by the Secretary. Oversight of these AOs is limited to the requirements at § 414.68, rather than those for accreditation programs based on section 1865 of the Act, codified at 42 CFR part 488, subpart A.

Section 125 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275, enacted on July 15, 2008), entitled ''Revocation of Unique Deeming Authority of The Joint Commission,'' removed prior subsection (a) of section 1865 of the Act and redesignated the remaining subsections. The effect of this removal was to give the Joint

Commission's (TJC) hospital accreditation program the same regulatory status as all other accreditation programs, that is, subject to CMS approval, in accordance with section 1865 of the Act. It also removed from section 1861(e) of the Act, which provides the definition of a hospital for Medicare purposes, references to TJC's hospital accreditation program and replaced them with references to accreditation programs recognized by the Secretary in accordance with section 1865(a) of the Act. Similar revisions were made to section 1875(b) of the Act, which had the effect of expanding the requirement for us to report annually to Congress on the performance of TJC's hospital program to a requirement to report on all accreditation programs approved in accordance with section 1865 of the Act.

Previously, in response to 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, particularly for hospitals, the Secretary instructed CMS to respond appropriately.[1] AOs and their CMS-approved Medicare 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 21 approved accreditation programs offered by nine national AOs. In fiscal year 2013, accredited facilities deemed to meet Medicare standards accounted for over 13,000 Medicare-participating facilities (not including accredited clinical laboratories). With the MIPPA statutory amendments Congress provided us with additional authority to strengthen our oversight.

Part 489 consists of regulations codifying Medicare provider agreement requirements found in section 1866 of the Act. Currently, certain provisions of part 489, such as the regulation governing the effective date of a Medicare agreement at § 489.13, apply to both providers, as well as to supplier types that are subject to certification requirements. However, other provisions pertinent to termination of such Medicare agreements apply only to providers. Part 489 also contains a definition of ''immediate jeopardy'', which applies to all types of certified providers and suppliers, but which employs terminology pertinent only to residential healthcare facilities.

In the April 5, 2013 **Federal Register**, we published the proposed rule ''Medicare and Medicaid Programs: Revisions to Deeming Authority Survey, Certification, and Enforcement Procedures'', and provided for a 60-day public comment period (78 FR 20564). In the May 24, 2013 **Federal Register**, we published a notice extending the deadline for the comment period from June 4, 2013, to July 5, 2013 (78 FR 31472).

II. Provisions of the Proposed Rule and Analysis of and Responses to Public Comments

A. Summary of the Proposed Rule

To conform our regulations to the MIPPA revisions to section 1865 of the Act, we proposed to eliminate the requirements at current § 488.5. That regulation currently addresses hospital accreditation by TJC (previously known as JCAHO) and AOA separately. The regulation also fails to reflect the statutory requirement at section 1865(a)(1) of the Act (as revised by MIPPA) that an AO's Medicare accreditation program meet or exceed all, that is, each, applicable requirement separately.

We also proposed numerous revisions to clarify and reorganize the existing regulations, to eliminate potentially confusing and unnecessary duplication, as well as to strengthen our ongoing oversight processes, consistent with the recommendations of the OIG, and the GAO. All 21 CMS-approved AO Medicare accreditation programs have received extensive reviews in accordance with the application and reapplication processes described at part 488 in recent years. The high volume of comprehensive AO application and reapplication reviews that we conducted has provided us with an abundance of opportunities to apply the existing AO oversight regulations in a variety of circumstances. This experience has helped us to identify areas of our regulations that need revision to more clearly articulate our intentions. Furthermore, 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, we had to require an AO to implement corrective action(s) to ensure comparability with the Medicare requirements. We have also opened deeming reviews outside the normal reapplication process, and issued conditional approvals with a probationary period. We believe it is necessary 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 areas of non-compliance; and ensure continuing compliance and comparability with Medicare requirements.

To ensure that AOs are enforcing Medicare standards adequately, SAs, under the authority of section 1864 of the Act, often perform additional follow-up surveys on CMS' behalf to ensure that AOs are holding provider entities accountable for compliance with Medicare requirements. These Medicare validation surveys are of two types. The first is a comprehensive survey of a representative sample of provider entities' operations. The second is a ''substantial allegation validation survey'', carried out in response to an allegation from an outside party that a specific provider entity is in violation of Medicare CoPs, CfCs, or requirements. The scope of these surveys is limited to the matter that was the subject of the complaint.

Currently, when a ''substantial allegation validation survey'' of an accredited provider or supplier finds substantial non-compliance with one or more of Medicare's conditions or requirements, we have limited flexibility in terms of our next steps. We may either proceed immediately to enforcement action based on that substantial allegation validation survey, or may require the SA to conduct another, full survey which assesses compliance with all of the CoPs or CfCs for that type of provider or supplier. We proposed to expand our flexibility to provide a third option for a SA to conduct another, more comprehensive survey, but not a full survey. This would allow us to make efficient use of survey resources while maintaining an effective enforcement process that is appropriate for each specific case.

We also proposed to expand the scope of the AO oversight regulations at part 488, subpart A to include AOs with CMS-approved Medicare accreditation programs for ADI services. This proposed expansion was part of our initiative to broaden our quality oversight of both the CMS-approved

[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.

AOs, as well as the suppliers of ADI services, which would include future rulemaking to develop and implement more detailed Medicare health and safety standards which the designated AOs must incorporate into their accreditation programs for suppliers of these services.

We proposed to amend part 489 to use more appropriate terminology in the definition of ''immediate jeopardy'' and to extend certain of the provisions governing termination of provider agreements to certified suppliers.

B. Public Comments Received

We received 50 timely pieces of correspondence in response to the April 5, 2013 proposed rule. Most of the comments came from AOs and hospital associations or individual hospitals, with a few comments from practitioner organizations and from groups of patient/resident advocates. This final rule discusses the provisions of the April 5, 2013 proposed rule, summarizes the public comments received on each provision, sets out our response to those comments, and sets forth the provisions of our final rule.

1. General Comments

Many commenters presented brief comments expressing opposition to the proposed rule, but their comments were so vague that we are unable to provide specific responses to them.

Comment: Several commenters stated that the framework for oversight of hospital accreditation established with the creation of Medicare in 1965 was a public-private partnership. One commenter stated that this ''partnership'' presumed that TJC applied higher standards than the Medicare standards, and that SA surveys and certification were never intended to supplant accreditation or become the national benchmark for assessing the quality of care in accredited health care organizations. The commenter stated that the original partnership premise has been replaced by a contractor type of arrangement whereby government sets the terms for AOs at all levels of their processes, standards and functioning, replacing professionally recognized standards as the driver/gold standard. The commenter also stated that there are adverse consequences to the quality of care from CMS' enforcement approach to AO oversight. They stated that: AOs feared to make changes to their programs for fear of being out of step with the State Operations Manual; consistency among AOs was preferred to celebrating their differences that would lead to positive results; excessive CMS focus on too many unimportant issues would result in lost opportunities to work with AOs collaboratively on important quality and safety issues; increased consumption of government and private sector resources on administrative issues brought no value to health care; CMS's methodology was an implicit rejection of AOs' quality improvement since CMS expected accrediting organizations to cite any provider's deviation from a standard, no matter how small or infrequent. The commenter stated that the current scheme caused providers to drop accreditation because of frustration at being held to standards that mimic government standards or because accreditation did not protect them from being surveyed by an SA; that CMS had an inordinate focus on administrative metrics in the performance evaluation of AOs; that there was excess government spending on state investigation of complaints rather than trusting AOs to handle complaints; and that the system resulted in enormous spending by providers to address non-value driven or inappropriate State Operations Manual requirements. The commenter objected to CMS's refusal to allow AOs to provide Life Safety Code (LSC) waivers or equivalencies; to the general atmosphere of distrust between CMS and AOs; and to CMS's disproportionate emphasis on the results of validation surveys, which should be conducted by CMS staff rather than SA surveyors, who, they asserted, were often biased against AOs.

Response: We disagree with the commenter. The statutory framework established in section 1865 of the Act, both before and after the MIPPA amendments, prescribes neither a ''partnership'' nor a ''contractor'' relationship between CMS and AOs. Instead, section 1865 of the Act establishes the criteria for our approval of a national AO's Medicare accreditation program(s), and provides specifically for SAs to conduct validation surveys to validate the oversight by AOs of certified providers and suppliers which they accredit. Section 1875(b) of the Act requires us to report to Congress annually on the operation and administration of AOs, explicitly including the validation surveys specified in section 1865 of the Act. Moreover, the MIPPA amendments of 2008 clearly establish that all accreditation programs, including TJC's hospital accreditation program, are subject to the same CMS oversight. Furthermore, section 1864 of the Act establishes that surveys by SAs are the method by which CMS establishes a provider's or supplier's compliance with the applicable Medicare statutory definition and implementing regulations, with section 1865 of the Act creating a voluntary alternative option for providers or suppliers to substitute accreditation for a state survey in those cases where CMS has approved a national AO's Medicare accreditation program. There is no basis in the statute for the commenter's assertion that SA surveys and certification were never intended to ''supplant'' accreditation. Surveys conducted by SAs on our behalf assess compliance with the applicable Medicare requirements. While an AO's survey may also assess compliance with their own additional, more stringent standards, there cannot be any conflict between the standards of a Medicare accreditation program and those applied by state surveyors, since the express language of section 1865(a)(1) of the Act requires that we find that an AO's program meets or exceeds all applicable Medicare requirements.

Likewise, the commenter's concern that an AO cannot issue waivers to the LSC requirements adopted in various CoPs or CfCs reflects a misunderstanding of our policy. We are not delegating this authority to either the SAs or AOs. The commenter's references to the State Operations Manual (SOM) also appear to be inappropriate, since this manual provides interpretive guidance for the certification regulations at part 488, as well as for the provider-specific CoPs, CfCs, requirements or conditions for certification. If the commenter believes that any particular provider/supplier-specific regulations are in need of revision, there are appropriate avenues outside the AO oversight process for pursuing those changes. In fact, we have published three regulations since 2012 with the express purpose of reducing unnecessary burdens on certified providers and suppliers (''Medicare and Medicaid Programs; Reform of Hospital and Critical Access Hospital Conditions of Participation'' published in the **Federal Register** on May 16, 2012 (77 FR 29034); ''Medicare and Medicaid Program; Regulatory Provisions to Promote Program Efficiency, Transparency and Burden Reduction'' published in the **Federal Register** on May 16, 2012 (77 FR 29002); and ''Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction; Part II'' published in the **Federal Register** on May 12, 2014 (79 FR 27106), and many of the ideas for changes made via those regulations came from AOs, as well as regulated

providers and suppliers. Most importantly, the commenters' objections to the regulatory framework for our oversight of providers or suppliers seem to focus on the current substantive regulatory requirements for those specific providers or suppliers, and they are not suggesting that our proposed revisions created these issues.

We did not propose to change the current regulatory framework to create a ''partnership'' relationship such as the one that the commenters would prefer, nor are we amending our proposal to do so in this final rule, because we believe a ''partnership'' approach would be inconsistent with the statutory requirements, as well as with the recommendations of both GAO and OIG to strengthen our oversight of AOs.

Comment: Some commenters expressed general opposition to the regulation on the basis that it would subject AOs to standards and survey processes that can be out-of-date, ineffective or inappropriate to the delivery of high quality care. Commenters stated that the delivery of sophisticated, rapidly evolving, and technologically intensive services needs to be evaluated using state-of-the art knowledge and standards. Some of these commenters objected to AOs being held to requirements of the SOM, which is not subject to public notice or comment.

Response: We believe the commenters' concerns appear to be with the substantive regulations underlying the SOM, since the manual does not by itself create requirements for Medicare providers and suppliers. The SOM provides interpretive guidance on the requirements established under the provider- and supplier-specific CoPs, requirements, CfCs or conditions for certification, as well as under part 488, governing survey, certification, and accreditation processes in general. These underlying regulations are subject to notice and public comment. Moreover, the provider- and supplier-specific regulations are often written in broad terms that require adherence to generally accepted standards of practice, to enable updates to guidance via the SOM that reflect changes in such standards of practice, without having to go through the more time-consuming process of revising regulations. All SOM revisions are subject to review to ensure that they do not exceed the authority of our regulations, and are guidance, not legal requirements in and of themselves. We occasionally may solicit input from members of the general public before we finalize such guidance. Further, as previously stated, we have over the past 2 years proposed and adopted numerous changes to the CoPs, requirements, CfCs, and conditions for certification to remove outdated and unnecessary requirements, and the SOM is generally revised to reflect these changes. It should be noted that we never object to an AO establishing accreditation requirements that exceed Medicare's requirements; problems arise only when an AO's standards are more permissive than, or in conflict with, the Medicare requirements. Since section 1865 of the Act requires an AO's program to meet or exceed all Medicare requirements, we are obligated either to not approve that program or to require changes to the program as a condition of approval or continued approval. To the extent that the commenters' concerns are with the underlying substantive Medicare requirements that an AO's standards must meet or exceed, it is beyond the scope of this regulation to address those concerns.

Comment: One commenter stated support for the proposed rule, which he found reasonable. The commenter believes the proposed rule provided clarity and direction to AOs on a variety of issues.

Response: We appreciate the commenter's support.

Comment: One commenter stated that a historical anomaly gave a single hospital accreditor statutory recognition and allowed it to avoid many of the requirements imposed on other hospital accreditors that were subject to CMS oversight. As a result, the commenter, a different AO, stated, this made its own hospital accreditation program more rigorous, but also gave it a more burdensome, less flexible appearance. The commenter stated that health care systems with hospitals accredited under both AOs found it difficult to harmonize their processes due to these differences. The commenter stated it had expected that when the statute was changed in 2008 and all AOs came under CMS oversight that this problem would be corrected. However, the commenter stated that this was not the case, and that so-called legacy issues remain 5 years later. For this reason the commenter indicated its reluctance to unconditionally endorse the more demanding oversight requirements embodied in the proposed regulation until CMS demonstrates its willingness and ability to apply its requirements across the board to all AOs.

Response: We are committed to treating all AOs subject to our oversight in the same manner. The commenter is correct that a number of legacy issues came to light that we had not identified during the initial application review process for the AO program affected by the MIPPA amendments, given the complexity of that hospital accreditation program. As legacy issues have been identified we have and will continue to work diligently to assure that all AOs are treated equitably and fairly.

Comment: One commenter called the proposed rule a reflection of CMS's commitment to continuously improve its regulations so that they effective promote accountability, protect public health and safety, and improve operational efficiency. The commenter indicated their understanding of the need for tighter controls and strict application of standards and their appreciation of how this will effectuate the safe and consistent delivery of quality care to patients. The commenter also stated that the challenge is to understand how to preserve the innovative aspects of quality by balancing the necessarily prescriptive characteristics of accreditation with the ability to promote quality using multiple techniques, and expressed his hope that the proposed rule would leave room for some degree of flexibility as AOs continue to navigate this inherent and dynamic tension.

Response: We appreciate the commenter's statements about the regulation. It is our intention to provide AOs the flexibility to innovate within the framework of assuring that the statutory requirements to meet or exceed the Medicare requirements are met.

Comment: A group of commenters expressed concern that the proposed rule left open the possibility that CMS could potentially approve an AO's application for a Medicare-approved accreditation program for Medicare skilled nursing facilities. The commenters noted that section 1865(a) of the Act exempts nursing homes from the categories of providers that are automatically afforded deemed status via Medicare-approved accreditation programs, and sets a higher bar for deeming SNFs because of strong public sentiment that SNF/NF residents should be protected by a publicly accountable federal and state survey and enforcement system. The commenters cite the objections of TJC and the healthcare industry to the proposed rule as evidence why they do not believe we should allow powerful private entities to become entrenched in LTC facility certification. They further state that while the federal/state survey and certification system has not achieved its supporters' expectations, it is still a transparent system whose activities are visible to the public and accountable to beneficiaries, taxpayers and Congress. In the view of these commenters, deemed status promotes secrecy and prohibits

disclosure of information, involves an inherent conflict of interest for AOs, involves an inappropriate consultative, collaborative approach to surveys, lacks accountability to the public, and inappropriately separates the survey process from enforcement, since AOs must refer cases to CMS for enforcement. The commenters indicated their support of our intent to issue regulations to clarify and strengthen our oversight of AOs, but believe that the proposed regulations do not, and probably could not, address what they view are the inherent flaws in the structure, which favors resolution of compliance problems in a non-public process after evaluation by private organizations that maintain a fiduciary relationship with providers. Another group of organizations representing long term care advocacy groups expressed similar concerns, and urged CMS to continue to refuse to permit deemed status for long term care facilities. This group also noted that AOs would be unable to comply with requirements under the Nursing Home Reform Law and the Nursing Home Transparency and Improvement provisions of the Affordable Care Act (Title VI, Subtitle B, sections 6101 through 6121), which among other things, establish a resident's right to examine the results of the most recent survey, and require states to post the survey reports of long term care facilities on the states' Web sites. They also suggest CMS could not maintain Nursing Home Compare without submission of survey report data and categorization of some long term care facilities as special focus facilities. This group also asserted that AOs miss serious problems, noting that research by another commenter on the proposed rule stated that four ''special focus facilities,'' that is, SNFs/NFs whose citation history has led CMS to identify them as having serious, systemic noncompliance issues warranting heightened attention and enforcement action, were currently accredited by an AO, suggesting that there is a serious discrepancy between the standards/survey process used by CMS and those of AOs.

Response: We thank the commenters for their support of our effort to clarify and strengthen our oversight of AOs. The commenters' remarks about the inherent problems they see in permitting a role for private AOs in the Medicare certification process are outside the scope of this proposal, since the statute specifically permits AOs to play such a role. The primary purpose of our proposed revisions to part 488 was to ensure that the regulations are consistent with the statutory provisions at section 1865 of the Act.

The statute distinguishes AO programs for skilled nursing facilities (SNFs) from other accreditation programs for which AOs seek CMS approval in two respects: (1) The statutory timeframe for completing our review of an AO's application for our approval does not apply to accreditation programs for SNFs (section 1865(a)(3)(B) of the Act); and (2) even if we find that an AO's SNF accreditation program meets or exceeds all applicable requirements, we nevertheless have the discretion to not approve that accreditation program. Unlike the situation with kidney transplant and end stage renal dialysis programs, which, in accordance with the provisions at section 1865(a)(1) of the Act, we may not consider for deemed status, the statute does not permit us to refuse to accept for review an AO's application for approval of a Medicare SNF accreditation program. Accordingly, we proposed revisions to the regulations to recognize the technical possibility that at some future date an AO may choose to submit an application for our approval of a Medicare SNF accreditation program.

However, we emphasize that it was not the intent of our proposed revisions to signal any interest on our part in receiving AO applications for approval of a Medicare long term care facility accreditation program. We are on record in an earlier report to Congress as observing:

> ''A fundamental question is the appropriateness of allowing a private entity to perform an important public function. In some sense, Congress has already decided the ''appropriateness'' issue for skilled nursing facilities (SNFs) by granting the Secretary ''discretion'' to grant deemed status provided that accreditation offers a reasonable assurance that Medicare conditions of participation or, for SNFs, requirements, are met. In another sense, probably due to the concerns expressed by deeming's opponents, Congress has circumscribed the ''appropriateness'' issue by exempting SNFs from those accredited provider types for which the Secretary ''must'' accord deemed status if it is found that private accreditation demonstrates compliance with Medicare conditions of participation or requirements. . . . Given that the studies produced overwhelming evidence that the [private AO] surveyors often miss serious deficiencies, in some cases even apparently unjustified deaths, the potential cost savings to deeming would not appear to justify the risk to the health and safety of the vulnerable nursing home population. . . . If future empirical studies produce convincing evidence that LEAP, other accrediting organizations, or a revised JCAHO survey meets all the criteria for comparability with the HCFA survey discussed in this report, then it might be time to revisit the issue of deeming.'' (Executive summary, *HCFA Report to Congress: Study of Private Accreditation (Deeming) of Nursing Homes, Regulatory Incentives and Non-Regulatory Initiatives, and Effectiveness of the Survey and Certification System,* July 1, 1998, accessed on line at *https://archive.org/stream/reporttocongress00unit_11/reporttocongress00unit_11_djvu.txt* 8/6/2014).

There has been no evidence since we issued that report that convinces us that we should reconsider our position. To the contrary, in our recent annual reports to Congress on the performance of AOs with CMS-approved accreditation programs we have continued to identify persistent disparities in identification of significant deficient practices by AOs when compared to SAs through the validation survey program. We continue to work with the AOs through our oversight activities to identify and address the sources of these disparities, but this more recent evidence is consistent with the position that we adopted in 1998.

Further, the commenters raise important issues about the apparent contradictions between section 1865 of the Act's prohibition on disclosure of most accreditation surveys and other statutory provisions that require disclosure of all long term care facility surveys. Should we ever receive an application from an AO seeking our approval of a Medicare SNF accreditation program, these and other similar issues would weigh very heavily in any decision on our part whether to exercise our discretion to disapprove a Medicare SNF accreditation program, regardless of whether the AO's application suggested that its requirements met or exceeded the Medicare SNF requirements.

Upon closer review we also acknowledge that the wording of one proposed provision did not adequately reflect the special statutory status of SNFs at section 1865(a)(3)(B) of the Act. Proposed § 488.5(f)(2) indicated that we would publish a final notice of our decision on an AO's application within 210 calendar days from the date we determined the application to be complete, and proposed § 488.5(f)(2)(ii) would require us to describe, if denying approval, how an organization failed to provide reasonable assurance that its accredited providers or suppliers meet the applicable Medicare requirements. However, section 1865(a)(3)(B) of the Act excepts SNFs from this process. Accordingly, in response to comments, we are revising the proposed provision at § 488.5(e)(2) to indicate that the 210

day period to publish a final notice does not apply when the application is for a SNF accreditation program, and that we may disapprove a SNF accreditation application based either on its failure to provide reasonable assurances to CMS regarding the equivalence of its accreditation program, or based on our decision to exercise our discretion to not approve the AO's application for any other reason, in accordance with section 1865(a)(1)(B) of the Act.

2. Accreditation of Advanced Diagnostic Imaging Suppliers

Comment: One commenter indicated concern for our proposal to include oversight of the accreditors of the technical component of ADI services under part 488. The commenter noted that ADI AOs are currently subject to oversight regulations at § 414.68, which were only adopted in 2010 and which physician suppliers of ADI have been gaining familiarity. The commenter further noted that CMS proposed to retain those regulations in addition to applying the proposed regulations at part 488. The commenter indicated concern that the part 488 requirements, which heretofore only applied to AOs for hospitals and other specified providers and suppliers, would significantly expand the rules applying to ADI accreditation, thus imposing undue burdens on both ADI physician suppliers and their patients. The commenter noted that physician practices are already struggling to keep up with numerous new federal rules and stated they should not be subjected to yet another swath of new requirements and/or increased fees via the accreditation process. The commenter objected to the following proposals: The disclosure of accreditation survey information in connection with a CMS enforcement action; loss of accredited status by physician ADI suppliers if CMS withdraws its approval of the ADI accrediting program without any assurance that the supplier would have enough time to obtain timely accreditation elsewhere, unlike the arrangement under § 414.68; the requirement to notify of an SA that it has submitted an application for accreditation when SAs play no role in oversight of ADI suppliers; requirements for ADI suppliers to submit to validation surveys, permit photocopying of any records and grant immediate access to state survey entities or face termination of their Medicare participation, again when SAs have no role to play. The commenter urged us to carefully consider the inconsistencies between our 2010 rulemaking for ADI accreditation and this proposed rule, and to rescind our proposal in light of the practical difficulties of applying the standards of hospital accreditation to physician office-based suppliers of ADI.

Response: We do not agree that individual elements of increased AO oversight are inappropriate or overly burdensome for suppliers of the technical component of ADI services. We discussed in the proposed rule our initiative to broaden our quality oversight of both the CMS-approved AOs, as well as suppliers of ADI services, indicating we anticipated future rulemaking to develop and implement Medicare health and safety standards for suppliers of ADI services that must be incorporated into all ADI accreditation programs. This initiative is consistent with the GAO's recommendations in its May, 2013 report, ''Establishing Minimum National Standards and an Oversight Framework Would Help Ensure Quality and Safety of Advanced Diagnostic Imaging Services.'' However, we agree with the commenter that it is not appropriate to include ADI AOs and suppliers of the technical component of ADI services in the framework of part 488, which was designed to address issues related to SA surveys and voluntary accreditation of providers and suppliers that are subject to CoPs, CfCs, conditions for certification or long term care requirements to participate in the Medicare or Medicaid programs. Additionally the commenter is correct in noting that we did not propose to rescind § 414.68, so that adoption of our proposed rule would leave ADI AOs subject to two different set of requirements. In light of these considerations, we are removing from this final rule all provisions that would have the effect of subjecting accreditors of suppliers of the technical component of ADI services to the provisions of part 488. At a future date we expect to propose Medicare health and safety standards for suppliers of ADI services that must be incorporated into all ADI accreditation programs, and also to propose revisions to § 414.68 which we believe necessary to strengthen our oversight of ADI accreditors.

In response to comments, we also note that our proposed definition did not clearly exclude physician practices, and it was never our intent to imply that they might be subject to the provisions of parts 488 and 489. Also, the proposed definition incorrectly referred to transplant centers as a type of supplier when in fact they are neither a discrete provider or supplier type, but rather a part of a certified hospital that is subject to additional conditions. The proposed definition also excluded from the definition end stage renal dialysis facilities, which are subject to many of the provisions of part 488, even though they are not eligible by statute to participate in Medicare via deemed status.

We have also had questions about what categories of supplier are subject to accreditation requirements. We believe that to ensure an accurate definition of the suppliers to which part 488 applies, it would be better to enumerate the covered supplier types. Accordingly, in this final rule we are withdrawing our proposed revision to the definition of ''supplier'' at § 488.1 and will continue to rely upon the current definition.

We are also removing the reference to ''1843(e) [sic]—Requirements for Advanced Diagnostic Imaging (ADI) Services'' at § 488.2, Statutory basis.

3. Definitions (§ 488.1)

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

- We proposed 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 received no comments on this proposed revision.
- We proposed 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 received no comments on this proposed revision.
- We proposed expanding the definition of ''certification'' to include the rural health clinic (RHC) conditions for certification; clarifying 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 received no comments on this proposed revision.
- We proposed adding a definition of ''conditions for certification'' to include the terminology for standards that RHCs must meet to participate in the Medicare program. We received no comments on this proposed revision.
- We proposed 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.

Comment: One commenter found the following statement within the definition of ''deemed status'' confusing. The proposed definition reads: ''Deemed status is an alternative to regular surveys by the SA to determine whether or not it continues to meet the Medicare requirements.'' The commenter believes this might be especially confusing for health care organizations that might not be familiar with the deeming ''partnership.'' This commenter suggested instead including a statement in the definition saying that voluntary accreditation by a CMS-approved AO is an alternative to regular surveys by the SA.

Response: We agree with the commenter that the definition could be clearer and are revising it in this final rule to indicate that it means that we have certified a provider or supplier for Medicare participation based on its having been accredited under an approved, applicable Medicare accreditation program, the AO has recommended it for certification based on its accreditation, and we have accepted this recommendation and found that all other participation requirements have been met.

• We proposed revising the definition of ''full review'' to clarify that the regulations at part 488 apply to all providers and suppliers, not just hospitals. We received no comments on this proposed revision.

• We proposed 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. The proposed definition matched the revision we proposed to the definition of ''immediate jeopardy'' at § 489.3. Comments we received are included in our discussion of the part 489 proposed amendments.

• We proposed 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 received no comments on this proposed revision.

• We proposed adding a definition of ''national accreditation organization'' to specify that CMS requires a program for which an AO is seeking initial approval to already be fully implemented and operational nationally.

Comment: We received several comments on this proposal. One commenter proposed that we modify that part of the definition that describes the providers and suppliers accredited by national AOs by replacing the phrase ''healthcare facility'' with ''healthcare organization''. The commenter stated this modification better describes organizations that are ''entities'' which may not be traditional bricks & mortar establishments with a physical building at which services are provided. Several commenters proposed modifying the definition to include a minimum quantitative threshold for accredited facilities to be considered ''national.'' Another commenter stated that CMS should not exceed the existing criteria that an accreditation program includes at least one facility in each of at least five states to be considered national.

Response: We agree that the term ''health care facility'' could be misconstrued to refer only to providers or certified suppliers who provide their services in traditional bricks and mortar settings, rather than to those which provide services in the patient's home, such as home health agencies or hospices. To address this ambiguity, we believe it would be more precise to use the term ''provider entity,'' which is used in section 1865 of the Act, rather than the commenter's suggested term, ''healthcare organization.'' Section 1865(a)(4) of the Act defines a ''provider entity'' as ''a provider of services, supplier, facility, clinic, agency, or laboratory.'' Therefore, we are, in this final rule, revising the definition to replace the term ''health care facility'' with ''provider entity.''

We note that once an AO has a CMS-approved Medicare accreditation program for a specific type of provider or supplier, it must only accredit provider entities consistent with the organization's description as set out in its Medicare provider agreement. For example, a Medicare hospital accreditation program may not award one accreditation to two hospitals that each have a separate Medicare agreement (and thus are two provider entities), nor can it award two accreditations, one for each campus, of a two-campus hospital that participates in Medicare under one Medicare agreement (and thus is one provider entity).

We do not require an AO seeking initial CMS approval of a new Medicare accreditation program to have already accredited at least one provider entity in at least five states, as the commenter suggested, for us to approve it. Not only do we not employ such an inflexible quantitative approach now, we do not agree with the commenters who recommended that we incorporate such an approach in the regulatory definition of a national AO. We require a program seeking initial approval to already be fully implemented, operational, and widely dispersed geographically throughout the country, but we do not establish a minimum or a specific geographic distribution for provider entities that the program must have already accredited. We expect an initial application to demonstrate that the AO is capable of scaling up over time to handle additional facilities. To avoid creating artificial barriers to entry by new AO programs, we believe there should be flexibility for us to review the application submitted by an applicant against these criteria, without our prescribing a more detailed and uniform formula that every applicant must satisfy.

• We proposed 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 received no comments on this proposal.

• We proposed 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 all applicable Medicare conditions or requirements, consistent with language at section 1865(a)(1) of the Act.

Comment: A number of commenters expressed concern with removing the language, ''taken as a whole,'' from the definition of ''reasonable assurance.'' The commenters interpreted the intent of the proposed definition to be a requirement for an exact, one-one correlation of the AO's standards and survey processes with those utilized by SAs in the SOM. Another commenter suggested that we add to the definition the following wording to indicate that requirements which are not identical may achieve the same patient safety goals: ''. . .although AO standards and Medicare requirements need not be identical.'' Still another commenter stated it opposes a requirement for a one-to-one match between AO requirements and the CoPs, and requests we modify the definition to clarify that AO requirements need not be identical to Medicare requirements but would be acceptable if they achieve the same patient safety.

Response: We believe that the language, ''taken as a whole,'' is not consistent with section 1865(a)(1) of the Act, which requires that a national AO demonstrate that its Medicare accreditation program meets or exceeds all, that is, each, of the conditions or

requirements applicable under the Act. The same objection applies to the alternate language proposed by the commenters related to AO standards being acceptable if they achieve the same ''patient safety'' or ''patient safety goals.'' In fact, the CoPs, requirements, CfCs and conditions for certification applicable to the various types of providers and certified suppliers are generally referred to as the Medicare ''health and safety standards'' that we have determined to be necessary for the health, safety and well-being of patients and residents (see, for example, the terminology in section 1861(e)(9) of the Act, related to hospitals). Therefore, we believe that the statutory requirement for AOs to demonstrate that they meet or exceed each of the applicable Medicare requirements is the manner in which AOs demonstrate that their accreditation programs achieve patient safety goals.

Further, when determining if all requirements are met or exceeded in an AO's program, we are required under section 1865(a)(2) of the Act to consider the AO's requirements for accreditation, its survey procedures, its ability to provide adequate resources for conducting required surveys and supplying information for use in enforcement activities, its monitoring procedures for provider entities found out of compliance and its ability to provide us with necessary information for validation. Our primary purpose for proposing to revise part 488 was to align our regulatory requirements with the revised statutory requirements.

We also note that the language, ''taken as a whole,'' in the current definition of ''reasonable assurance'' also contradicts the current § 488.8(a)(1), which requires us, when reviewing an AO's application, to review and evaluate the ''equivalency'' of an AO's accreditation requirements to the comparable Medicare requirements. Likewise, the current regulation at § 488.8(d)(1) requires us to compare the ''equivalency'' of an AO's accreditation requirements to the comparable Medicare requirements when we impose new requirements or change our survey process; when an AO proposes to adopt new requirements or change its survey process; or when our approval of the AO's program has been in effect for the maximum term specified in the final approval notice. In our review of an AO's standards, we have adhered to the requirements at § 488.8, which we believe are consistent with the statutory requirements. Finally, even though an AO must demonstrate that its program meets or exceeds all applicable requirements, it is not our practice to insist that the AO's program exactly replicate the wording or organization of our regulations, or the procedures we establish for SAs. We require AOs to include in their applications a crosswalk in which they identify which of their requirements are comparable to each Medicare requirement. We then evaluate on a case-by-case basis whether accreditation program standards, survey and enforcement processes substantively are equivalent to or exceed the identified comparable Medicare standards, survey and enforcement procedures. We also review the submitted crosswalk to ensure that the AO has identified comparable requirements for every Medicare requirement. After due consideration of the comments, we are adopting in this final rule the definition of ''reasonable assurance'' as proposed.

- We proposed updating the definition of ''SA'' for added clarity and precision. We received no comments on this proposal.
- We proposed revising the definition of ''substantial allegation of non-compliance'' to correct a previous error.

Comment: One commenter suggested, for the definition of ''substantial allegation of noncompliance'', that complaints only be submitted in writing and that they not be permitted to be anonymous, to allow an AO to gather and verify all necessary data and avoid spending resources on an unfounded allegation. Another commenter suggested revising the definition to include the following language: ''could or may *materially* affect the health and safety of patients . . .'' This commenter stated that the language in the current definition is so broad and vague that SAs conduct about 4000 complaint surveys annually in accredited hospitals, but over the past decade only 5 or 6 percent of these surveys have resulted in condition-level deficiency citations.

Response: Part 488 establishes definitions and requirements that are applicable, depending on the context, to actions taken by an SA, AOs or CMS. The term ''substantial allegation of noncompliance'' is used in the current regulations at § 488.7(a) (and in the final rule we are adopting at § 488.9(a)) to describe one circumstance in which we may require an SA to conduct a validation survey of a deemed status provider entity. Validation surveys may be authorized either on a representative sample basis or in response to substantial allegations of noncompliance. We apply the term ''substantial allegation of noncompliance'' to describe the complaints we or SAs receive regarding a deemed status provider entity that are of a serious nature and which, if found to be true, would mean that the provider entity failed to comply with at least one of the Medicare conditions or requirements applicable to it. Such substantial noncompliance may be grounds for terminating the provider entity's Medicare agreement and participation in the Medicare program (with the exception of long-term care facilities, whose standards are enforced under sections 1819(h)(2) and 1919(h)(2) of the Act). Section 1864(c) of the Act authorizes us to use SAs to investigate substantial allegations of noncompliance concerning a deemed status provider entity.

It is our longstanding policy, reflected in the current definition of this term, that we and SAs accept complaints from a variety of sources, including anonymous sources, communicated in any of a wide variety of methods, not just in writing. It has been our experience that complaints can be a very effective means to focus survey activity to identify serious noncompliance by a provider or supplier. The definition for a substantial allegation of noncompliance is used to establish a threshold for us to authorize an SA investigation of a complaint concerning a deemed status provider entity. Thus, we believe the commenter who suggested that all complaints be in writing and that anonymous complaints not be accepted is misunderstanding the context in which this definition is used, given that the commenter's rationale for the suggested changes is that they would make it easier for AOs to gather and validate data related to complaints the AO investigates.

For the suggestion that the word ''materially'' be added to the definition, we do not believe that this would add any more specificity or clarity. We believe that the language about the complaint raising doubts as to a provider's or supplier's compliance with any Medicare CoP, CfC, condition for certification, or other requirement is sufficiently clear. In recent years, we have provided additional guidance and training on the appropriate triage categories for complaints to both our regional offices, and to SAs, which receive most of the complaints. The fact that only 7.4 percent of complaint surveys (based on FY 2012 and FY 2013 data) resulted in citations of condition-level noncompliance does not necessarily mean that the other complaints were not credible allegations that warranted further investigation.

In the course of reviewing the comments on this definition we reviewed not only the current definition

found at § 488.1 but also the statutory basis for a complaint-driven validation survey in section 1864(c) of the Act. Section 1864(c) of the Act permits us to authorize a state to conduct a validation survey of a deemed status provider entity because of a ''substantial allegation of the existence of a significant deficiency or deficiencies which would, if found to be present, adversely affect health and safety of patients.'' We believe that our proposed definition should adhere more closely to this language by using the term ''would'', as does the definition currently found at § 488.1, instead of ''could or may'' and are therefore reverting to the terminology found in the current rule. Further, since a provider entity could include providers that have ''residents'' instead of ''patients'', in the interest of clarity we believe the definition should also refer to ''residents,'' and are therefore revising the definition upon adoption to refer to both residents and patients We are also changing the phrase ''that is,'' when referring to sources of complaints, to ''such as,'' since the brief list that follows the phrase is clearly intended to provide examples and not be an all-inclusive list.

- We proposed 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) and to add a clarification that for the purposes of part 488 the term ''supplier'' does not include suppliers of durable medical equipment and supplies, kidney transplant centers, or end stage renal dialysis facilities. As indicated in our earlier response to comments about the inclusion of suppliers of the technical component of ADI services, we are in this final rule withdrawing our proposal to revise the definition of ''supplier'' and reverting to the current definition, which enumerates the types of certified suppliers covered by part 488. There were no comments on this.
- We proposed 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.

Comment: One commenter objected to our proposal to delete the definition of the term ''validation review period,'' stating that it will be difficult to validate the AO survey if significant time has passed, since the provider may have undergone significant changes in practice, policies, procedures and processes.

Response: We believe the commenter misunderstood the way in which the term ''validation review period'' is used in the current regulations, and thus the effect of our proposal to delete this term. The term ''validation review period'' under the current regulation refers to the 1 year period during which CMS conducts a review of the validation surveys and evaluates the results of the most recent surveys performed by an accrediting organization. After a ''validation review period,'' as set out in the current regulation at § 488.8(d)(2), CMS will conduct a ''validation review'' if an AO has a disparity rate greater than 20 percent; CMS may also conduct a validation review if survey results suggest systemic problems in an AO's accreditation process. As discussed concerning our proposal for revisions at § 488.8, we proposed to replace the concept of a ''validation review'' with the broader concept of a ''performance'' review, making the definition of a ''validation review period'' unnecessary.

However, we believe the commenter is referring, instead, to a maximum length for the time interval between an AO's survey of a provider or supplier and the SA's conduct of a representative sample validation survey of that provider or supplier. We are retaining our current policy, which permits us to use, when calculating the validation survey disparity rate for our annual report required under section 1875 of the Act, only those validation surveys conducted by SAs no more than 60 days after the conclusion of the AO's survey. We note that section 3242 of the SOM articulates the requirement for SAs to adhere to the 60-day timeframe for conducting a representative sample validation survey. After due consideration of these comments, we are, in this final rule, not incorporating a definition of a ''validation review period.''

4. 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 proposed revising § 488.3 to include the statutory citations and/or regulatory references for CAHs, RHCs, hospitals that provide extended care services, hospices, CORFs, CMHCs, OPTs, and ADIs. In addition, we proposed to revise § 488.3(b) to address all providers as well as suppliers of services subject to certification. This proposal would also authorize the Secretary to consult with SAs and other organizations, which would include all AOs and other national standard-setting organizations to develop CoPs.

Comment: Many commenters expressed concerns that the proposed revisions to § 488.3(b) reflect a change in policy that is inconsistent with the requirements under section 1863 of the Act for us to consult with appropriate SAs and national accrediting bodies when determining CoPs. One commenter stated that AOs have rigorous standards development processes and the ability to stay current with standards of medical practice in a way that the CoPs do not. Another commenter indicated that making consultation optional could lead to development of regulations that are not best practices and therefore negatively impact patient care.

Response: Section 1863 of the Act requires us to consult with appropriate SAs and national accrediting bodies when determining CoPs for hospitals, psychiatric hospitals, SNFs, HHAs, CORFs, hospices and ASCs. By contrast, the current language at § 488.3(b)(1) states, the Secretary, after consultation with the JCAHO or AOA, may issue Conditions of Participation for hospitals higher or more precise than those of either those accrediting bodies. This language was related to the now-deleted provision of section 1865 of the Act which concerned hospital accreditation by TJC, rather than to section 1863 of the Act. We note that it has been our longstanding position that the consultation required under section 1863 of the Act is adequately addressed through the public notice and comment process for adopting new or revised CoPs. It was our intent to broaden the option for consultation provided in § 488.3(b) beyond the hospital CoPs, to include the regulations governing all providers, as well as those for suppliers of services subject to certification, not just hospitals. Additionally, we proposed to remove reference to specific AOs found in the current regulatory language, consistent with our policy of referring to national AOs generically throughout the proposed rule to reflect changes made by MIPPA. However, given that § 488.3(b)(1) and (2) include provisions that clearly implement requirements under section 1863 of the Act, we agree with the commenters that § 488.3(b) should also be worded in a manner consistent with this section. We are, therefore revising, § 488.3(b) to state under ''Special conditions'' that there shall be consultation with SAs and national AOs.

5. CMS-Approved National Accreditation Programs for Providers and Suppliers (§ 488.4)

We proposed 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 as follows:

• We proposed at § 488.4(a) to 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 proposed 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, since 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 proposed deleting the reference to ''requirements concerning hospitals accredited by the JCAHO or AOA.''

• We stated in the preamble that we were proposing at § 488.4(b) a new provision, making it explicit that an AO's CMS-approved accreditation program would be approved in its entirety, and that 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.

Comment: Several commenters indicated the provision described at § 488.4(b) in the preamble of the proposed rule did not have any corresponding regulatory text. The regulatory text at § 488.4(b) of the proposed rule indicates ''Reserved.''

Response: The commenters are correct that we proposed to reserve § 488.4(b). The discussion in the preamble was meant to describe the changes we proposed at § 488.4(a)(1).

Comment: Several commenters objected to our statement in the preamble that we were making explicit in proposed § 488.4(a)(1) that an AO's CMS-approved accreditation program is approved in its entirety. Many commenters submitted similar comments stating that reviewing accreditation programs in their entirety represents an overreach of federal authority. The commenters also indicated their belief that if an AO finds that a provider or supplier meets all of its accreditation standards that correspond to Medicare conditions, it should be able to recommend deemed status even if the provider or supplier fails to meet other requirements of the accreditation program which exceed the Medicare requirements. One commenter indicated that this provision would set up a dual standard for non-accredited providers and suppliers, which only have to meet the Medicare conditions, and deemed status providers and suppliers that would have to meet the higher accreditation standards.

Response: Section 1865(a)(1) of the Act refers to ''accreditation of a provider entity'' and authorizes us to accept such accreditation as demonstrating the provider's or supplier's compliance with Medicare conditions or requirements, if we find that the AO's accreditation program meets or exceeds all applicable requirements. If a provider or supplier fails to meet the standards for accreditation, then it does not satisfy the statutory requirement for deemed status. It does not matter which of the accreditation program standards the provider or supplier has failed to satisfy.

We also note that it is a voluntary decision on the part of an AO whether it includes standards that exceed the Medicare requirements in the accreditation program that it submits to us for review when seeking approval as a Medicare accreditation program. We review the program that an AO submits to us, and when we approve a program for purposes of our granting Medicare deemed status to providers or supplier accredited under it, we approve it in its entirety. We do not take any position regarding whether standards exceeding CMS's are necessary or advisable, but likewise, we do not insist that they be removed so that the accreditation program is purely Medicare-specific. We believe the statutory language in section 1865 of the Act, which requires us to find that an accreditation program ''meets or exceeds'' all applicable Medicare standards, indicates an expectation that a program submitted for our review might contain elements that are not required under the Medicare standards.

It would be contrary to the statute if CMS accepted deemed status based on satisfaction of only some of the accreditation requirements in its CMS-approved Medicare accreditation program, because the statute only allows us to recognize those facilities that have received accreditation. If a provider or supplier meets Medicare standards but fails to receive accreditation, it can ask for a state survey instead. Likewise, it would be arbitrary and contrary to our regulations at § 488.8(d)(1)(ii) if an AO modified portions of a CMS-approved Medicare accreditation program subsequent to our approval without informing us. Although the AO may believe that its changes would not affect any accreditation provisions related to Medicare requirements, the determination of whether a revised program continues to meet or exceed Medicare standards is CMS's, rather than the AO's, to make. We have not delegated to the AO itself our responsibility under the statute to ensure that an accreditation program's standards, including any changes to them, continue to meet or exceed Medicare requirements. This is not a new policy on our part, because we believe it is required by our current regulations. We have only proposed to make this policy more explicit in our proposed regulations (at § 488.5(a)(18)) due to the confusion experienced by a few AOs regarding this issue. Our role is to determine if the AO's standards meet or exceed all applicable Medicare requirements. On that basis we determine whether to approve the AO's program for Medicare deeming purposes, and, in the case of an AO's proposal to revise standards within its CMS-approved Medicare accreditation program, whether a program with the proposed revisions would continue to meet or exceed the substantive Medicare facility standards.

In our view, this does not create a double standard with deemed status providers and suppliers having to satisfy higher standards to participate in Medicare. We note that the decision on the part of a provider or supplier to seek to demonstrate compliance with Medicare requirements through accreditation rather than survey by an SA is voluntary. We welcome the decision by many providers and suppliers to seek accreditation under programs that have requirements that exceed the Medicare standards, but this does not change the statutory requirement that they must be

accredited to be recommended for deemed status.

In view of the changes we made to the definition of ''supplier,'' as discussed above, we are making conforming changes in this final rule to § 488.4(a), indicating that we will not accept applications for approval of accreditation programs for kidney transplant centers within hospitals or for end stage renal dialysis facilities. We are also making a technical correction to replace potentially ambiguous language stating that AOs apply for our approval to accredit providers or suppliers with more precise language indicating that they apply for our approval of their accreditation programs.

6. Application and Reapplication Procedures for National Accreditation Organizations (§ 488.5).

We proposed to revise § 488.5 to clarify the requirement that an AO seeking our approval of a Medicare accreditation program be national in scope. We also proposed 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 proposed the following revisions:

- We proposed at § 488.5(a) to replace the requirement currently set out at § 488.4(a) concerning the application and reapplication procedures for an AO seeking our initial or continued approval of a Medicare accreditation program. We further proposed revising the current language to clarify that all of these provisions would apply to both initial applications for new accreditation programs, as well as reapprovals of existing CMS-approved accreditation programs, and to clarify that each application for approval would pertain to a single provider/supplier-specific accreditation program. We received no comments on the above proposed changes and are adopting them as proposed in this final rule.
- We proposed at § 488.5(a)(1) to require an AO seeking either our initial approval of a new Medicare accreditation program or renewed approval of an existing program to demonstrate for that program that the organization meets the definition of a ''national AO.'' Section 1865 of the Act applies only to programs of national accreditation bodies. We stated in our proposal that this demonstration must be specific to each accrediting program for which new or renewed CMS approval is sought. We indicated as an example that an AO which has one or more existing CMS-approved programs and which seeks our initial approval of a new accreditation program must demonstrate that the new program has been implemented nationally. Several commenters addressed this provision in terms of the definition of a ''national AO'' and we addressed their comments in our discussion of § 488.1 above. We are adopting this provision in this final rule without change.
- We proposed at § 488.5(a)(1) to require an AO seeking either our initial approval of a new Medicare accreditation program or renewed approval of an existing program to demonstrate for that program that the organization meets the definition of a ''national AO.'' Section 1865 of the Act applies only to programs of national accreditation bodies. We stated in our proposal that this demonstration must be specific to each accrediting program for which new or renewed CMS approval is sought. We indicated as an example that an AO which has one or more existing CMS-approved programs and which seeks our initial approval of a new accreditation program must demonstrate that the new program has been implemented nationally. Several commenters addressed this provision in terms of the definition of a ''national AO'' and we addressed their comments in our discussion of § 488.1 above. We are adopting this provision in this final rule without change.
- We proposed at § 488.5(a)(2) to replace the requirement currently set out at § 488.4(a)(1), concerning the AO's identification of the types of provider or supplier for which it is seeking approval. We indicated that this revision would clarify that each application for our approval must be specific to a particular type of provider or supplier and would be separate and distinct from applications for our approval of accreditation programs for other types of providers or suppliers. We received no comments on this proposed revision and are adopting it in this final rule as proposed.
- We proposed at § 488.5(a)(3) to 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 set out the components of an acceptable crosswalk. We received no comments on this proposed revision and are adopting it in this final rule as proposed.
- We proposed at § 488.5(a)(4) to replace the requirement currently set out at § 488.4(a)(3), which addresses the requirement that the AO must provide us a detailed description of its survey process in its application for our approval of an accreditation program. We proposed to leave the language of this provision unchanged. We received no comments on this proposed provision and are adopting it in this final rule as proposed.
- We proposed at § 488.5(a)(4)(i) to replace the requirement currently set out at § 488.4(a)(3)(i), concerning the frequency of surveys. We stated that the proposed revisions reflect existing policy requiring re-survey of an accredited provider or supplier no later than 36 months after the previous accreditation survey, and thus would not impose any new requirements. We indicated that we were proposing the revision to clarify the existing requirements.

Comment: A commenter proposed expanding the definition of ''survey'' to include a ''desk review'' for suppliers of advanced diagnostic imaging.

Response: Since we are rescinding our proposal to apply the provisions of part 488 to accreditors of suppliers of the technical component of advanced diagnostic imaging services, it is not necessary to address in this final rule issues that are specific to such accreditation. For deemed status providers and suppliers, as defined in this final rule, a reaccreditation survey assessing compliance with all accreditation program standards must be conducted via an on-site survey.

Comment: One commenter indicated that the current AO performance measure used by CMS to assess if triennial surveys are timely requires that, for ASCs surveyed for first-time participation in an AO's Medicare accreditation program, the start date [for accreditation] is the date an acceptable plan of correction has been received, and therefore the end date of the accreditation term and deemed status term is no later than 36 months after that date. The commenter notes the proposal would change the requirement to 36 months from the initial survey date. The commenter suggested this would result in an inconsistency with the current performance measures and will lead to unnecessary changes in the current AO reporting structure.

Response: We proposed a maximum interval of 36 months from the ''previous accreditation survey,'' which could encompass more than the last date the AO was on-site as part of its reaccreditation survey. The commenter may be confusing the special requirements that apply to accreditation surveys of initial applicants for Medicare participation for determining a participation effective date with the way in which we calculate the timeframe for when a triennial survey is due. However, in response to this

comment, we believe it would more accurately reflect our current practice and reduce confusion to use the phrase ''prior accreditation effective date'' and are making this revision in this final rule.

Comment: One commenter proposed that we require that a minimum percentage of surveys commence during off-business hours, to further reduce the predictability of surveys.

Response: We do not impose such an obligation on SAs, except in the case of long term care facilities, and we see no compelling reasons why we should do so for AOs for non-long term care provider or supplier types. While it might be possible to conduct a survey outside typical ''business hours'' in health care facilities that provide care on a 24 hours per day/7 days per week basis, such surveys in ambulatory care settings would generally eliminate the possibility of surveyors being able to observe how care is actually provided by the facility. Even in the case of other types of acute care facilities operating on a 24/7 basis, there would be fewer opportunities to observe the wide range of health care services furnished than during daytime hours. If an AO has received a credible allegation of serious deficiencies that occur only during specific time periods, then it would be logical to conduct a survey during such periods, but we are not aware of such complaints specific to off-hours operations. We are making no changes in response to this comment.

- We proposed at § 488.5(a)(4)(ii) a new provision to ensure surveys conducted by AOs were comparable to the Medicare requirements, consistent with section 1865(a)(2) of the Act. Specifically, we proposed that an AO be required to demonstrate the comparability of its survey process and guidance to the process and guidance that we require for SAs conducting a Federal survey for the same provider or supplier type; the operative guidance for each provider and supplier type is specified in our Publication 100–07, the SOM.

Comment: One commenter representing health care services consumers indicated its support for requiring comparability of the survey process, to ensure surveys meet Medicare requirements. By contrast, a number of other commenters representing hospitals or AOs expressed their opposition to this proposal. Several of these commenters said that the SOM is outdated, and often includes language and practices that do not reflect the best practice in quality and safety standards. A number of these commenters also noted that the SOM represents subregulatory guidance and is not open for public comment and review, with one commenter expressing concern about the precedent set by holding private entities to sub-regulatory guidance they had no voice in creating. The commenter further expressed concerns that the proposed provision would require AOs to have comparably-sized survey teams and survey duration, which would greatly increase the cost of an accreditation survey. This commenter suggested that SAs typically maintain much larger survey teams and conduct longer surveys to meet the requirements set out in the SOM, and urged us to remove this requirement and continue to place the authority with AOs to use state-of-the-art survey processes to evaluate compliance with Federal requirements. Another commenter suggested we follow the best practices established by AOs and not hold the latter to the SOM, instead letting them survey at greater detail and test innovative approaches. This commenter urged us to clarify that the term ''demonstrating comparability'' does not mean identical standards and survey processes related to the SOM. This commenter also expressed concerns that requiring comparably sized survey teams and survey duration would increase costs. Another commenter expressed similar cost-based concerns, and also was concerned about an adverse impact on current AO survey processes, such as tracer methodology, complaint surveys, frequency, and costs. Another commenter suggested that we establish a comment process for the SOM prior to final publication and a process for distributing the responses to the AOs. One commenter requested that we make it clear that we do not require one-to-one comparability between the SOM and AO procedures.

Response: The SOM is a complex document that provides guidance for a number of different Medicare regulations. The commenters' references to what they view as outdated quality and safety standards seem to be referring to those parts of the SOM that provide our official policy interpreting the various provider/supplier-specific CoPs, CfCs, conditions for certification or requirements. Thus, this aspect of the objection to the proposed provision at § 488.5(a)(4)(ii) concerning comparability of survey processes appears to be misplaced. We also note for the record that the SOM does not establish but instead implements existing regulatory requirements, and thus is subregulatory guidance that is not subject to the requirements for public notice and comment. Nevertheless, we often confer informally with AOs and other members of the general public when we revise our interpretive guidance for the applicable conditions, and have found their input to be invaluable in helping us develop and update such guidance.

We also have noted that it is not uncommon for objections to be raised about ''the SOM'' which are really objections to the underlying regulatory requirements found in the various conditions or requirements. We take such concerns seriously and have made a number of regulatory changes to various providers and suppliers in recent years, to revise outdated regulations and remove unduly burdensome requirements that do not contribute to increased patient or resident quality and safety. However, we emphasize that an AO does not have the authority to modify in its Medicare accreditation program Medicare requirements that it disagrees with, nor is the AO application review process the appropriate venue for an AO to air, or us to resolve, its complaints about substantive provider/supplier-specific Medicare conditions of participation, conditions for coverage, conditions for certification, or long term care requirements. The purpose of the application review is to determine whether the applicant's accreditation program meets or exceeds existing Medicare standards.

For the commenters' objections to survey process issues, such as survey team composition, survey frequency and duration, how complaints are handled, etc., we note that Section 1865(a)(1) of the Act requires us to make a finding that the AO's accreditation program meets or exceeds all applicable Medicare conditions or requirements, and section 1865(a)(2) of the Act requires us, when making this finding, to consider a national AOs ''survey procedures'' and ''. . . its ability to provide adequate resources for conducting required surveys and supplying information for use in enforcement activities, its monitoring procedures for provider entities found out of compliance with the conditions or requirements. . . .'' The longstanding requirements under the existing regulations at § 488.4(a)(3) implemented this statutory provision by requiring AOs to provide us with detailed information on their survey processes, including their forms, guidelines and instructions to surveyors, frequency of their surveys, the size and composition of their survey teams, the qualifications of their surveys, the way in which they train their surveyors, etc. Moreover, the existing regulations at § 488.8(a)(2)(ii)

require us, when reviewing an application, to determine ''the comparability of survey procedures to those of SAs, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.'' It has been our practice to assess comparability by reviewing the information in the AO's application in light of the SOM survey process requirements for SAs, which implement survey process requirements found in parts 488 and 489 of our regulations governing certification and provider agreements. Our proposal was only intended to make the role of the SOM in articulating and implementing the regulatory requirements for survey process more explicit. We believe commenters' concerns about our imposing survey processes that inhibit use of best, most efficient survey practices that are efficient are unfounded. In fact, it has been our practice to allow both SAs and AOs flexibility in determining the size and composition of their survey teams and the duration of their surveys, and considerable variation exists among both SAs and AOs in this regard. We not only have no objection to an AO's use of a tracer methodology, but we also have developed tools for state surveyors to employ tracers as one component of their surveys. We note, further, that many of the commenters represent hospital organizations that are accredited by TJC, whose hospital program was not subject to the comparability requirements of section 1865 of the Act prior to July 15, 2010. This may account for their erroneous perception that our proposal represented a significant departure from current requirements and practices. Nevertheless, in consideration of the above comments, we are revising this provision upon adoption to require an AO to provide documentation demonstrating the comparability of its survey process and surveyor guidance to those required for SAs conducting federal surveys for the same provider or supplier type, in accordance with the applicable regulations. We are removing the explicit reference in this provision to the SOM as unnecessary, but this will not change our practice of assessing comparability in light of the SOM survey process requirements for SAs, which implement survey process requirements found in parts 488 and 489 of our regulations governing certification and provider agreements.

Comment: One commenter expressed concern this provision would conflict with recent legislation in its State recognizing national AO accreditation in place of a State hospital licensure survey, recognizing that an AO can be more nimble in updating its accreditation standards than the State can in updating its licensure standards. The commenter stated the provisions of this rule would be a step back by forcing AOs to rely on outdated provisions that are part of the SOM.

Response: We do not establish state licensure requirements. We believe this comment also is referring primarily to provider/supplier-specific conditions or requirements rather than to survey process requirements. However, for both accreditation standards and survey processes, we are compelled by section 1865 of the Act to determine whether an AO's requirements meet or exceed all applicable Medicare requirements. It is not within our authority to consider the impact our determinations may have directly or indirectly on a state's licensure requirements.

- We proposed at § 488.5(a)(4)(iii) to redesignate the requirement currently set out at § 488.4(a)(3)(ii). This provision requires an accreditation organization to provide us with information on the content and frequency of survey personnel training. We proposed to leave unchanged the current language of this requirement. We received no comments on this proposed provision and are adopting it in this final rule as proposed.
- We proposed at § 488.5(a)(4)(iv), consistent with the requirement currently set out at § 488.4(a)(3), to require an AO to provide us a copy of its most recent survey report and any other survey-related information we require. We proposed to require documentation that the AO's survey reports identify for each accreditation deficiency cited the applicable Medicare requirement. We received no comments on this proposed provision and are adopting it in this final rule as proposed.
- We proposed at § 488.5(a)(4)(v) to replace the requirement currently set out at § 488.4(a)(3)(iii), concerning the survey review and accreditation decision-making process. We proposed to delete language that would be redundant with language being incorporated into the proposed revised regulatory language at § 488.5(a)(8). We received no comments on this provision and are adopting it in this final rule as proposed.
- We proposed at § 488.5(a)(4)(vi) to replace the requirement currently at § 488.4(a)(3)(iv) and to revise the existing language to specify that the AO must provide us a description of its provider or supplier notification procedures as well as its timelines for notifying surveyed facilities of noncompliance with accreditation program standards. We received no comments on this provision and are adopting it in this final rule as proposed.
- We proposed at § 488.5(a)(4)(vii) a provision similar to the current requirement at § 488.4(a)(3)(iv), regarding providing us information on the AO's procedures for monitoring the facilities found to be out of compliance. In our proposal, we added a requirement to provide information on timelines for monitoring corrections, and revised the provision to clarify the requirement and provide more specific and precise language. We indicated that the proposal was consistent with our longstanding practice and thus imposed no new burdens.

Comment: One commenter expressed support for this provision, saying it would allow CMS to better monitor an AO and its actions.

Response: We thank the commenter for their support. We are adopting this provision without change in this final rule.

- We proposed at § 488.5(a)(4)(viii) to replace the requirement currently set out at § 488.8(a)(3), which requires the AO to provide us 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 proposed modifying the language of this provision for consistency and clarity.

Comment: One commenter requested clarification whether the proposed requirement would change the current process for providing survey information to CMS. Several commenters responded to this provision expressing concerns about disclosing survey and survey-related information to CMS. One commenter indicated that the proposed provision would provide CMS with broad authority to collect information related to a survey, including patient safety work product (PSWP) protected under the Federal Patient Safety and Quality Improvement Act (PSQIA). The commenter suggested CMS add clarifying language acknowledging that it may not be feasible for the AO to provide some information obtained from an accredited entity during a survey. The commenter also requested that we add the language ''when specifically requested by CMS'' since it does not believe routine submission of information to CMS is needed. Another commenter expressed concern that certain information protected from disclosure by federal standards would lose its protected

status if shared, and requested we add clarification that information required would only be related to the deemed status accreditation survey. By contrast, other commenters stated that CMS cannot monitor the work of AOs without seeing their most recent surveys for a provider and indicated the proposed provision would improve CMS's ability to obtain this information. The commenters suggested that failure of an AO to furnish us with copy of an accreditation survey be grounds for withdrawing deeming authority for that organization.

Response: Consistent with the existing requirement at § 488.8(a)(3) we have, since 2009, required AOs to routinely submit information to us electronically, including survey information extracted from their survey reports. Since 2013, we have asked for these submissions to be made to us monthly. We have also required that AOs routinely submit to us, for initial surveys only, a copy of the actual survey report. In addition to this routine electronic submission of data from every survey report and survey reports for initial surveys, we also request, from time to time, a copy of the actual survey report, as well as additional supporting information, such as plans of correction for reaccreditation or complaint investigation surveys. The proposed revision to the regulation was not intended to alter current practice. Section 1865(b) of the Act prohibits us from disclosing accreditation surveys, except for home health surveys, but permits us to disclose surveys to the extent that they related to an enforcement action we take. With the exception of denials of certification to applicants for initial enrollment in the Medicare program, we generally use our enforcement discretion to not take enforcement action based solely on an accreditation survey. For example, if an AO notifies us that it has terminated accreditation due to a provider's or supplier's inability to demonstrate compliance, we instruct the SA to survey that provider or supplier as soon as possible, and use the results of the SA's survey to make enforcement decisions. Accordingly, with the exception of home health agency surveys, generally most accreditation surveys may not be disclosed by us to any third parties.

For an AO not being permitted to disclose to CMS patient safety work product protected under the Patient Safety and Quality Improvement Act (PSQIA) (Public Law 109–41), we do not believe that the PSQIA was intended to inhibit our legitimate AO approval, validation and other oversight activities under part 488. Additionally, providers/suppliers cannot unilaterally declare the factual information used in developing a ''patient safety work product'' (PSWP) to be itself non-disclosable. Indeed, the Department's final rule implementing PSQIA, ''Patient Safety and Quality Improvement; Final Rule'' states explicitly that ''nothing in the final rule or the statute relieves a provider from his or her obligation to disclose information from such original records or other information that is not patient safety work product to comply with state reporting or other laws.'' (73 FR 70732, 70786, November 21, 2008.) An AO's survey report must include the factual evidence that supports the citations the AO makes for violations of its accreditation standards. Accordingly, we find it unlikely that AO survey reports or other material we might request would contain PSWP. We agree that the PSQIA does not permit an AO to re-disclose to us PSWP disclosed to the AO by a ''provider,'' as that term is defined in the PSQIA and its implementation regulation, and which encompasses both providers and suppliers that are certified for Medicare participation on the basis of their accreditation by the AO. We expect that accrediting organizations, in carrying out their surveys and appropriately documenting their findings, will generate survey reports that do not contain PSWP, and thus may be provided to us, as required under section 1865 of the Act.

For the commenter's suggestion that we add language, ''when specifically requested by CMS,'' we believe that our proposal could more effectively differentiate between the routine electronic submission we require of information extracted from each survey report from copies of the survey report, as well as other information related to the survey report which we request routinely in the case of surveys of initial applicants for Medicare participation, from case-specific circumstances where we request additional information. Accordingly, in this final rule we are revising this provision to state that an AO agrees, as a condition of CMS approval of its accreditation program, to provide us with information extracted from each accreditation survey as part of its data submissions required under § 488.5(a)(11)(ii) and, upon request from us, a copy of the most recent AO survey tougher we any other information related to the survey that we may require.

- We proposed at § 488.5(a)(4)(ix) to replace the requirement currently found at § 488.4(b)(3)(vii), requiring an AO to notify us when it 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 at § 489.3. We proposed to revise the timeframe for notifying us from the current requirement of ten days to within one business day from the date the immediate jeopardy is identified. We indicated this proposed 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 which would require us to take immediate action to enforce the Medicare requirements applicable to these facilities.

Comment: One commenter noted a contradiction between our proposed requirement and the requirement for AOs accrediting suppliers of the technical component of advanced diagnostic imaging services at § 414.68(g)(14)(vi), which requires notification to CMS of an immediate jeopardy within 2 business days.

Response: We agree that there was a conflict between our proposal and § 414.68(g)(14)(vi). However, since we have removed all reference to accreditation of suppliers of the technical component of ADI services from part 488 in this final rule, there is no longer a conflict. AOs that accredit such suppliers continue to be subject to the requirement at § 414.68(g)(14)(vi). We expect to propose changes to § 414.68 in future rulemaking, to strengthen our oversight of AOs that accredit suppliers of the technical component of ADI services, making such oversight more consistent with part 488.

Comment: Several commenters found the proposed shortening of the timeframe from 10 days to 1 business day problematic. One commenter suggested 2 days as an alternative. Another commenter said a one-day notification is feasible, but may result in omission of important information or details pertaining to the case, which could lead CMS to make uninformed decisions or conclusions. This commenter also suggested that CMS Regional Offices be held to the same requirement and should notify the pertinent AO when the SA or Regional Office declares an immediate jeopardy situation. Another commenter also suggested that its experience with follow-up requests from us for more detailed information calls into question the utility of requiring faster, but less detailed notification. On the other hand, another commenter applauded us for reducing the notification time, but believed that 1 business day was too

long, given the possibility of greater harm to patients occurring. This group suggested we revise our proposal to require immediate notification.

Response: We believe that once an immediate jeopardy has been determined by an AO to be present, regardless of whether or not the AO survey team also finds that the immediate jeopardy was removed while the team was on site, there is sufficient information within one business day for AOs to provide notification to CMS. As previously indicated, we generally exercise our enforcement discretion to require an SA survey before taking official enforcement action against a provider or supplier, and to arrange a timely state survey to determine whether there continues to be either an immediate jeopardy or even lower-level but substantial noncompliance requiring our enforcement action, we need prompt notice from an AO. We also note that since the original provision was adopted, email has generally replaced hard-copy mail as the primary means of communication between AOs and ourselves, and thus an extended 10-day time frame is no longer necessary. We do recognize that we frequently ask an AO to provide us with more detail about an immediate jeopardy after its initial notice to us before we authorize a state survey, and thus we believe it would be appropriate to extend the notification timeframe to 2 business days. For the comment calling for us to shorten the timeframe to immediate notification, we believe that this affords the AO too little time to complete its internal notification and decision-making processes. Since we expect that the AO will be taking appropriate action to require prompt correction of any immediate jeopardy situation, we believe that a small delay does not increase the risk of harm. Accordingly, we are revising the proposed provision in this final rule to require notice to us about an immediate jeopardy situation within two business days. This policy is consistent with the policy we have adopted for the technical component of advanced diagnostic imaging services.

- We proposed at § 488.5(a)(5) to replace the requirement currently set out at § 488.4(a)(4)(i), which requires AO applicants to provide us information on the size and composition of their survey teams for each type of accredited provider or supplier. We proposed to add to the existing provision language requiring the AO to furnish us information on its criteria for determining survey team size and composition, including variations for individual provider or supplier surveys. We stated that, within a given accreditation program there can be great variation in the size and complexity of individual health care facilities, and that we believe a uniform size and composition for the AO's survey teams would not be appropriate.
- We also proposed at § 488.5(a)(6) a new provision that would help ensure that an AO maintains an adequate number of trained surveyors to meet the demand for surveys, both initial and re-accreditation surveys. We reported that 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 limited 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.

Comment: Several commenters objected to both of these proposed provisions, expressing concerns they would prescribe the size and composition of survey teams, thereby increasing the costs to facilities, which could cause more facilities to seek Medicare participation through SAs and thereby increase costs to the government. One commenter stated that CMS should evaluate AOs on the basis of their performance and not dictate processes used by the AOs. The commenter also stated its formula for determining survey team size is proprietary, and that increasing the survey team size will increase costs to providers/suppliers and the government. Another commenter said it would oppose this provision if CMS intends to prescribe a specific ratio of surveyors to accredited facilities, saying AOs vary greatly in their business operations and therefore may also vary in the number of facilities that can be supported by surveyors. This commenter suggested it should be sufficient for each AO to provider its rationale.

Response: Section 1865(a)(2) of the Act requires us, when determining whether an AO meets or exceeds all applicable Medicare requirements, to consider, among other things, an AO's ''ability to provide adequate resources for conducting the required surveys . . .''. Under the existing requirement at § 488.4(a)(4)(i), AOs are already required to furnish us information about the size and composition of their survey teams. In our proposed revisions, we refined these requirements to obtain information that would better enable us to assess an AO's ability to provide adequate resources, recognizing that variations in the size and complexity of facilities necessarily impact an AO's survey process, and that growth in an AO's accreditation program may require an adjustment in the overall number of surveyors the AO utilizes to accomplish its surveys. For example, the resources required to evaluate compliance in a 50-bed rural hospital are considerably different than those required to accomplish the same evaluation in a 600-bed urban academic medical center. Likewise, the overall survey resources required by an accreditation program which is increasing the number of facilities it accredits will be different than those required by an AO whose program is relatively static in size. Accordingly, the final rule will require AOs to give us information on how they adjust survey teams and composition to account for facility differences, and how they adjust the overall size of their survey staff to account for growth in their accreditation program and still fulfill their survey obligations. This information will enable us to evaluate more effectively the AO's ability to provide adequate resources, as required by the statute. The final rule does not mandate specific survey team sizes or composition which AOs must use, and thus we do not agree with those commenters who stated that it would increase costs to the facilities surveyed by AOs. We do not intend to impose a specific ratio of surveyors to accredited facilities on AOs by policy. However, we will review the information and rationale provided us by an AO in its application; if the rationale is not supported by the information in the provider's application or by performance data we have collected, in the case of a renewal application, we reserve the right to withhold our approval until the AO either provides us a more convincing rationale or revises its approach to assuring adequate survey resources.

For the comment about focusing on AO performance rather than dictating internal AO processes, we note that it was through our ongoing evaluation of AO performance that we identified problems with several AOs, such as failure to identify serious noncompliance with the LSC requirements, or inability to perform timely reaccreditation surveys, which may be related to the survey resources the AO makes available to accomplish its required survey work. Therefore, we believe it is incumbent upon us to obtain more information from AO applicants for new or renewed approval about the way in which they assure adequate survey resources. We are making no changes in this final rule in

response to these comments and are adopting § 488.5(a)(5) and (6) as proposed.

• We proposed at § 488.5(a)(7) to replace the requirement currently set out at § 488.4(a)(4)(ii) concerning furnishing us with information on the AO's education and experience requirements for its surveyors.

Comment: We received one comment asking for clarification of the difference between ''surveyors'' and ''AO staff'' and also recommending that surveyors for ADI have experience in diagnostic imaging.

Response: We consider ''surveyors'' to include all individuals who conduct on-site surveys, or inspections, of providers and suppliers seeking new or continued deemed status. Surveyors typically also have additional off-site responsibilities established by the AO. We believe the commenter's question relates to some of the unique circumstances pertaining to accreditation of suppliers of the technical component of ADI services. Given our decision to remove all reference to ADI services and their accreditation from part 488 in this final rule, we believe that it is not necessary to address the commenter's recommendation for ADI surveyor qualifications. We are not making any changes in response to this comment and are adopting this provision in this final rule as proposed.

• We proposed at § 488.5(a)(8) to replace the requirement currently set out at § 488.4(a)(4)(iii), which requires an AO applicant to provide us information concerning the content and frequency of in-service training of AO survey personnel. We received no comments on this proposed revision and are adopting it without change in this final rule.

• We proposed at § 488.5(a)(9) to replace the requirement currently set out at § 488.4(a)(4)(iv), which requires an AO applicant to provide us information concerning evaluation systems it uses to monitor the performance of individual surveyors and survey teams.

Comment: One commenter expressed its opposition to the proposal since it believes it implies that the AO's surveyor evaluation system would require prior approval, which would restrict the AO's flexibility in adjusting evaluation processes to emerging trends and impair the evaluation of quality assurance processes.

Response: This requirement is unchanged from the existing requirement at § 488.4(a)(4)(iv), and thus we proposed no change from our current practice. We do not micromanage the process by which AOs review their surveyors' performance, but we must evaluate whether an AO has a credible process for evaluating on an ongoing basis the performance of its surveyors and survey teams. We are making no changes in response to this comment and are adopting the provision in this final rule as proposed.

• We proposed § 488.5(a)(10*)* to replace the requirement currently set out at § 488.4(a)(4)(v), which requires an AO to provide us detailed information its policies and procedures concerning the involvement of personnel in the survey or accreditation decision process who may have a financial or professional affiliation with the provider or supplier. We proposed to modify the provision to state more clearly that we expect an AO to have policies and procedures to avoid potential conflicts of interest by precluding the participation of individuals who have a professional or financial affiliation with a provider or supplier from participating in the survey or accreditation decision.

Comment: Some commenters proposed adding a minimum timeframe of 2 years after termination of a surveyor's affiliation with a provider or supplier during which the surveyor would be precluded from participating in a survey or accreditation decision for that provider or supplier. The commenters also proposed we require an AO to have different personnel on a survey team from that which previously surveyed the provider or supplier.

Response: The commenters are focusing on prior affiliations and seems to presume that an AO's surveyors are full-time staff. Our proposal was focused on avoiding conflicts of interest where AO staff has current affiliations with providers or suppliers, since it is our understanding that few AOs employ full-time surveyors, but instead rely upon contracted surveyors who often have ongoing relationships with some providers and suppliers. However, we agree that it could also create the appearance of a conflict of interest for an individual to participate in a survey of a provider or supplier with which he or she was previously affiliated and that such appearance should also be avoided as much as possible. Nevertheless, we do not specifically mandate in regulation or policy that SAs preclude newly-hired staff from engaging in surveys or decisions affecting a prior employer for a specified period of time. In section 4008 of the SOM we establish a policy for conflicts of interest of SA employees engaged in federal survey and certification work, indicating that such conflicts may arise when public employees utilize their position for private gain or to secure unfair advantages for outside associates. We specifically state that it is not possible to list all situations that could be construed as potential conflicts of interest, but do provide some examples of potential conflicts, including having various relationships with a health care facility in the employing state. We also indicate in section 4008B of the SOM that state codes provide judicial or administrative remedies for abuses of influence and that employee actions would be handled in accordance with the applicable State procedures. Thus we do not prescribe uniform limitations or prohibitions that all states must incorporate. AOs might not be as likely as states to have conflict of interest policies absent our requirement that they do so, but this does not necessarily mean that we should specify in regulation the detailed content of such policies. We also believe that a 2-year ban on a surveyor's participation is excessive and might unduly limit an AO's (or state's) ability to use its staff resources effectively. Within CMS, for example, a newly-hired employee is precluded from participating in matters concerning a prior employer for one year. In summary, while we believe it is prudent for both AOs and states to avoid conflicts of interest involving previous as well as current affiliations, we believe we should not in this regulation specify in detail how to avoid such conflicts.

We also do not require SAs to use different personnel for successive surveys of a provider or supplier; in fact, we believe it is more likely that SAs would have the same personnel conducting successive surveys than would AOs, given the national scope of an AO's operations. We also see no particular value to such a requirement; one might argue that familiarity of a surveyor with a facility might enhance their ability to identify deficient practices. In fact, some AOs have suggested that SAs tend to be more successful in identifying LSC deficiencies in providers or suppliers precisely because they have long-standing familiarity with the physical plants of facilities in their states.

Comment: Commenters stated that the ''business-client relationship'' that exists between AOs and the facilities they survey creates an inherent conflict of interest and expressed concern that this provision does not address this more generic type of conflict of interest.

Response: Section 1865 of the Act specifically allows for us to certify providers or suppliers as meeting the applicable conditions or requirements on the basis of accreditation of

providers or suppliers by private AOs. Thus, under the law the business-client relationship is not prohibited in those cases where we have reviewed the AO's Medicare accreditation program and found that it meets or exceeds all applicable requirements. We also note that we exercise continuing oversight over AOs, including making the determination whether or not to accept an AO's recommendation of a provider or supplier for deemed status.

Comment: Several commenters proposed that we also preclude surveyors from participating in a survey or accreditation decision when they have a financial or professional affiliation with a competitor of the provider or supplier being surveyed.

Response: We believe there is merit to the commenters' concerns, particularly given that few AOs employ full-time surveyors but instead rely upon contracted surveyors who often have ongoing relationships with some providers and suppliers. We expect AOs to be careful to avoid the appearance of conflicts of interest that could compromise confidence in the objectivity of their survey findings or accreditation decisions. At the same time, we are reluctant to attempt to specify in regulation a definition or methodology for determining which providers or suppliers are ''competitors'' of a provider or supplier being surveyed, since there are many varying factors that could influence whether there is a competitive relationship among providers and suppliers and to what extent that would deleteriously impact surveyors' objectivity.

In light of the various commenters' concerns about potential conflicts of interest scenarios that go beyond the situation of a surveyor being involved in a survey or accreditation decision of a facility with which he or she has a current professional or financial affiliation, as well as our intent to not micro-manage the way in which either states or AOs avoid conflicts of interest, we are in this final rule revising this provision to state more generically that an AO must provide us its policies and procedures for avoiding conflicts of interest, including the appearance of conflicts of interest.

- We proposed at § 488.5(a)(11) to replace the requirement currently set out at § 488.4(a)(5), which addresses the requirement that the AO provide information on its data management system in its application. We proposed at § 488.5(a)(11) to retain the existing language at § 488.4(a)(5). In addition, we proposed a new provision at § 488.5(a)(11)(i) to require submission of a detailed description of how the AO uses its data system to assure compliance of its accreditation program with the Medicare requirements.
- We also proposed at § 488.4(a)(11)(ii) requirements replacing those at current § 488.4(a)(9), which requires the AO to furnish us a list of all currently accredited facilities including type of accreditation and expiration date, and at § 488.8(a)(2)(v), requiring us to determine the AO's ability to provide us electronic data in ACSII comparable code and reports necessary for effective validation and assessment of the AO's survey process. We indicated the regulatory text currently at § 488.8(a)(2)(v) which requires an AO to include in its application a written presentation of its ability to submit information electronically ''in ASCII comparable code,'' is outdated and insufficient. We stated that the proposed modifications are necessary to ensure that we have the required data to provide effective oversight of an approved accreditation program.

Comment: One commenter indicated its support for these provisions, while another indicated it appreciated that this provision would require AOs to devote more resources to articulating their plans for data use.

Response: We thank the commenters for their support.

Comment: One commenter proposed we add language indicating CMS will be judicious and prudent with its requests for data, acknowledging that each demand for data is resource intensive and can be costly.

Response: We agree that we should not require AOs to submit data that are not necessary for us to support our evaluation of an AO's performance, and that we should be mindful of the need to avoid undue burdens on AOs. However, we do not agree that the regulations need further revisions to reflect this principle, since it already clearly links the data to be submitted to our evaluation of an AO's performance. Upon adoption we are, however, making non-substantive stylistic edits and changing the order of the last two sentences of this provision.

- We proposed at § 488.5(a)(12) to replace the requirement currently set out at § 488.4(a)(6), which requires an AO to provide us information on its procedures for responding to and investigating complaints, including coordination with appropriate licensing bodies and ombudsmen programs.

Comment: One commenter proposed we mandate that AO procedures for investigating complaints, include timeframes for resolution and a process to communicate the results to the complainant. The commenter also proposed that complaint resolution timeframes be consistent with those utilized by SAs and the complaint procedures be made publicly available upon request.

Response: We require in this provision that AOs seeking CMS-approval of their accreditation program provide us information on their processes for responding to, and investigating complaints, including grievances, against accredited facilities. We compare their policies and procedures to those we require for SAs during the application process and determine whether all applicable Medicare requirements are met or exceeded.

Comment: One commenter asked us to identify ombudsmen programs for advanced diagnostic imaging.

Response: We are not aware of ADI ombudsmen programs, and since we have rescinded our proposal to apply part 488 to accreditors of suppliers of the technical component of ADI services, the question is largely moot. However, we are taking this opportunity to note that we believe the language of the regulation makes it clear that we expect AOs to coordinate with licensing bodies and ombudsman programs in their investigation of complaints when it is appropriate to do so. For example, if in the course of an investigation an AO identifies a matter that appears to warrant separate investigation and action by the state authority responsible for licensing health care professionals, we would expect the AO to make an appropriate referral. Likewise, if there is an ombudsman program for the type of provider or supplier the AO accredits, we would also expect it to make appropriate referrals to such ombudsman programs. To make our intent clearer we are revising this provision in this final rule to require referrals, when applicable, to appropriate licensing bodies and ombudsman programs.

- We proposed at § 488.5(a)(13) to replace requirements currently set out at § 488.4(a)(7) and (a)(8), with modifications. The current provision at § 488.4(a)(8) require AOs to provide us a description of all types and categories of accreditation offered, including duration, etc. We proposed to modify this provision by deleting language and terminology specific to one particular AO. Furthermore, 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 indicated that we believed that there was no reason to require AOs to submit such information to us, nor for us to have and review this non-relevant information.

The current provision at § 488.4(a)(7) requires an AO to submit information to us regarding its policies and procedures for withholding, or removing accreditation status or taking any other actions related to noncompliance with its standards. Since the granting of full or less than full accreditation status is an essential component of an AO's accreditation decision process, we stated it is necessary for us to receive information on the policies and procedures pertaining to these types of decisions.

We also proposed to include within § 488.5(a)(13), with modification, the requirement currently set out at § 488.4(b)(3)(i), which requires an AO to commit to notifying us of any facility that has had its accreditation revoked, withdrawn, or revised or that has had any other remedial or adverse action taken against its accreditation within 30 days of such action. We proposed to change the notification period to within three business days of the date of action. We proposed 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 in a timely manner so that, when applicable, we may initiate enforcement action, we indicated 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.

Comment: We received no comments on proposed § 488.5(a)(13) and § 488.5(a)(13)(i). Several commenters made comments related to the proposal at § 488.5(a)(13)(ii) to require notice to us within 3 business days of any adverse action. Most of these commenters indicated that this proposal would not allow sufficient time for AOs to process appeals of its decisions by its accredited providers and suppliers and suggested that notice not be required until after appeals are completed and final decisions made. One commenter suggested that we clarify our use of the term ''withdrawal.'' This commenter indicated that if the term refers to involuntary withdrawal from accreditation, then the timeframe is appropriate. If the term includes a voluntary withdrawal from accreditation, then the timeframe is not appropriate, since the AO takes a number of steps, including attempting to change the organization's mind about remaining accredited. In this case the commenter proposed we set different reporting timeframes for involuntary versus voluntary withdrawals of accreditation. One commenter noted that ADI AOs currently provide only weekly reports to CMS and said CMS would need to increase the frequency of data transmissions for them to comply. By contrast another commenter suggested that the notification deadline be one day, noting that 3 business days could be a total of 5 days, and that this delays CMS action against these agencies, leaving home health patients in situations where their health and safety might be seriously jeopardized.

Response: By ''withdrawal'' we mean a voluntary decision on the part of the accredited provider or supplier to end its participation in the accreditation program. This is in contrast to an AO's revocation of accreditation, which we view as including both an action taken when an AO concludes that a provider or supplier is substantially noncompliant with accreditation standards and has not corrected its deficient practices within the timeframe specified by the AO, as well as an action taken by an AO to revoke a provider's or supplier's accreditation due to the provider's or supplier's nonpayment of accreditation fees. By ''revised'' we mean a change in a provider's or supplier's accreditation status, based on the formal accreditation status categories the AO employs. We intended this latter term to include both adverse changes that fall short of revocation, as well as positive changes reflecting a provider's or supplier's improved compliance. Reflecting upon the commenters' comments, we believe that our additional language ''any remedial or adverse action taken against it'' is vague and potentially duplicative, and thus should be removed. Our intent was for AOs to notify us when they have taken a final action concerning a change in the accreditation status of a deemed status provider or supplier. If an action is not final until after an appeals process, then notice would not be required until three business days after that process has concluded and a final AO determination has been made. If a voluntary withdrawal from accreditation is not effected until an AO completes a number of steps to try to reverse the provider's or supplier's decision, and the AO continues to accredit the provider/supplier during this process, then notice would not be required until 3 business days after the effective date that the AO ultimately processes the provider's or supplier's voluntary withdrawal. In this latter case we would expect that the AO's timeframe for pursuing a revised decision from its customer would not be unreasonably long, so as to call into question whether the provider/supplier continued to meet the AO's accreditation standards. For example, we anticipate that a provider/supplier might notify an AO of its intent to withdraw shortly before its next payment is due, which might also be shortly before its current 3-year accreditation expires. We believe it is important to have these providers/suppliers recertified via another survey, either by another AO the provider or supplier has concurrently chosen or, in the alternative, by an SA in a timely manner. In the case of an HHA, we must ensure that the statutorily-mandated maximum survey interval of no more than 36 months is maintained, and that SAs are afforded as much advance notice of their need to conduct a survey as possible.

We do not believe that it would be reasonable to shorten this timeframe further, to 1 day. We note that the separate requirement at § 488.4(a)(4)(ix) for AOs to notify us of any immediate jeopardy they identify should permit us to take prompt action when the health and safety of patients are threatened.

For ADI AOs, this comment was one of the many that made us conclude that this type of accreditation could not reasonably be accommodated within the framework of part 488 and that we needed to remove ADI accreditation from this final rule. We have already established a weekly data submission schedule for ADI AOs to identify all suppliers of the technical components of ADI services that they accredit as of that week, to ensure that their Medicare claims can be appropriately and timely paid. We need to explore further with ADI AOs how best to incorporate into future rulemaking modifications of this process that include notice to us of the nature of the accreditation decisions underlying the week-to-week changes.

In light of these clarifications, we are revising the provision to clarify that notice is required for any decision to revoke, withdraw, or revise the accreditation status of a specific deemed status provider or supplier within 3 business days' of the effective date the AO takes action.

- We proposed at § 488.5(a)(14) to 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. We proposed to modify the current language for clarity. We received

no comments on this proposal and are adopting it without change in this final rule.

• We proposed at § 488.5(a)(15) to create a new requirement for an AO seeking renewed approval for a current CMS-approved Medicare accreditation program. We proposed that the AO seeking renewed approval must demonstrate, as a condition of our acceptance of its application for renewal, that it demonstrated growth from its initial approval, as evidenced by there being at the time of its renewal application at least 50 health care facilities with deemed status based on the AO's CMS-approved Medicare accreditation program. We stated that we believe that an established AO accreditation program that has not been able to accredit a minimum of 50 health care facilities under its Medicare accreditation program since receiving initial CMS approval has failed to demonstrate sufficient infrastructure and scale to be sustained over time. Although we indicated we were willing to be flexible in accepting applications for initial approval from new national accreditation programs that were comparatively small, we stated we believe that an established CMS-approved Medicare accreditation program that was not able to accredit at least 50 healthcare facilities during the period since its initial approval would have failed to demonstrate long-term national viability. Further, we indicated that we have limited resources available to conduct the detailed, comprehensive review of an AO's application required under section 1865(a)(2) of the Act. We indicated we believe these limited 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 providers or suppliers.

Comment: One commenter suggested that if an AO is truly national in scope, then it should be accrediting significantly more than 50 facilities. This commenter also suggested the final rule should make clear the time interval for reaching the threshold. By contrast, all of the other commenters on this provision opposed this proposal. One commenter found the number to be both too large and arbitrary. Several commenters suggested that we consider all of an AO's approved programs when assessing its infrastructure and sustainability, rather than each individual Medicare accreditation program in isolation. They indicated that an AO with a small program could rely upon the infrastructure and capabilities of larger, similar types of programs. Another commenter noted that the pool of potential facility applicants for some accreditation programs might be limited, giving as an example psychiatric hospitals. One commenter noted that the provision could present a barrier for an AO to maintain approval of a program that focuses on rural areas or markets with fewer resources to support their health care facilities. Another indicated that introduction of a minimum number of facilities an AO must accredit would create a significant barrier for entry for AOs seeking to gain or retain deeming authority and is on its face anti-competitive. This commenter pointed out that, since accreditation is typically for 3 years, the opportunity to convert a facility from one AO to another is infrequent, so that it can take years for an AO to grow. The commenter also noted that sometimes health care systems seek a single AO for all of their facilities, making it vital for an AO to provide comprehensive services, even if one of their programs does not meet an arbitrary number that CMS has set. Another commenter indicated that requiring an AO to achieve a minimum of 50 accredited facilities during its initial approval period for an accreditation program is acceptable, but that thereafter the AO should be considered to have met the criteria even if its program falls below 50 facilities. This commenter mentioned that some facilities may flock to an AO to obtain initial deemed status only to drop accreditation in favor of the state agency when it is time for them to be recertified. The commenter indicated this might be an unlikely scenario, but could not be ruled out, given the economic realities for some providers, and AOs should not be disqualified due to temporary fluctuations.

Response: We do not agree that our proposal would have created a significant barrier to entry for AO's seeking our initial approval. Our proposal would have established a minimum of 50 accredited facilities for each Medicare accreditation program for which an AO was seeking renewed approval. AOs seeking their first approval from us would not have been subject to this provision. When we approve an initial applicant, we typically provide a four-year approval and expect to see the AO's program grow during that first 4 years, to be sustainable over the longer term. Since accreditation programs typically provide a three-year accreditation, a program with fewer than 50 facilities might be conducting 16 or fewer surveys per year, making it difficult to ensure surveyor teams maintain their skill levels in conducting surveys for that type of provider or supplier.

On the other hand, we recognize the merit of those commenters who pointed out that the market for a particular program might be more limited, as is the case with psychiatric hospitals or for programs focused on rural areas. We also agree that smaller AOs seeking to compete with larger AOs have a legitimate interest in providing ''one-stop shopping'' for health care systems seeking deemed status for all the various types of providers and suppliers in their system. Finally, we acknowledge that the overall surveyor and administrative infrastructure of an AO that has several CMS-approved Medicare accreditation programs should be considered when assessing a given program's long-term sustainability. This does not entirely mitigate our concern about surveyors having more limited experience in understanding and applying the accreditation standards and survey methods for a small individual program. However, we agree that through the application review process for a renewal application we should be able to determine whether, all things considered, a program lacks adequate infrastructure and/or capabilities to warrant our renewed approval. Therefore we are not adopting the proposed provision at § 488.5(a)(15) in this final rule. We are renumbering all of the subsequent provisions of § 488.5(a) accordingly.

• We proposed at § 488.5(a)(16) to 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 proposed to revise this requirement to state that the AO would need to provide us only its survey schedule for the 6-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, we indicated that it would not be useful for a survey schedule to be submitted for a longer timeframe. We stated that we use this survey schedule to plan our survey observation as part of our review of the AO's application. We indicated that this requirement would apply to both initial and renewal applications and would be distinct from the requirement proposed at § 488.5(a)(11) that an AO to submit survey schedules on a regular basis as

part of the data it agrees to provide us for our ongoing oversight.

Comment: We received one comment suggesting that we include the phrase ''deemed status'' in front of ''accreditation'' in the phrase ''all accreditation surveys.''

Response: For an accreditation program for which an AO is seeking our initial approval, addition of the suggested phrase would not be appropriate, since none of the facilities accredited by the AO under that not-yet-approved program would have deemed status based on that accreditation program. Even for a renewal application, an AO might include a survey scheduled for a provider or supplier that does not have deemed status, either because it is seeking initial enrollment and certification in the Medicare program, or because it is already enrolled as a non-accredited provider or supplier, or with deemed status based on another AO's program. However, upon adoption as § 488.5(a)(15), we are revising this provision to make clear our intent that an AO applicant provide us a survey schedule only for surveys for the accreditation program under our review.

• We proposed at § 488.5(a)(17) to 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. We stated that our proposed modifications of the current language would more clearly identify the type of documentation an AO must provide to demonstrate the adequacy of its resources. We received no comments on our proposal, and other than renumbering this provision to be § 488.5(a)(16), we are adopting this provision in this final rule as proposed.

• We proposed at § 488.5(a)(18) a new provision that would address requirements related to AO providing written notification at least 90 days in advance to its currently deemed providers or suppliers when the AO elected to terminate its CMS-approved accreditation program voluntarily. We stated that the affected providers or suppliers would subsequently need to be surveyed by SAs, unless they sought and received accreditation from another CMS-approved Medicare accreditation program.

Comment: One commenter indicated that an AO should be required to provide written notice to all patients or assure that the providers they accredit provide patients written notice, saying that patients have a right to know of any change in oversight of the provider.

Response: We believe that it is both unnecessary and unduly burdensome to require written notification of each patient when there is a change in their provider's oversight, whether from one AO to another, or from an AO to SA supervision, or from SA supervision to an AO, regardless of whether the change is due to decisions in individual cases on the part of the provider/supplier or AO, or if it is due to a voluntary or involuntary termination of an AO accreditation program's approval for Medicare deemed status. We believe that for patients and residents of Medicare-participating providers and suppliers, the specific nature of the oversight of their participation in Medicare is not pertinent, since our approval of an AO's accreditation program indicates that it meets or exceeds all Medicare requirements. By contrast, we do believe it is important for patients to know whether a provider's participation in Medicare has been terminated, whether voluntarily or involuntarily. However, even in this case we do not require individual patient notifications. Particularly for acute care providers and suppliers that have rapid turnover in patients from day to day, an individual notice requirement would be impractical. In the case of a voluntary termination of a provider, we require at § 489.52(c) that the provider must provide notice to the public through a local newspaper at least 15 days before the voluntary termination is effective; and in the case of an involuntary termination of a provider, in accordance with the provisions at § 489.53(d)(5), we similarly provide notice to the public.

Comment: One commenter noted a contradiction between this provision and the one we proposed at § 488.8(e), which would require an AO to give written notice to its accredited providers and suppliers in the event either of a voluntary or involuntary termination of its CMS-approved accreditation program no later than 30 days after publication of the termination notice in the **Federal Register**. The commenter noted that the timeframes may be compatible, but questioned why there needed to be two different provisions. The commenter also urged that hospitals be provided as much notice as possible, at least 90 days, and to simplify the notice requirement so that providers know what to expect.

Response: We agree that the interaction between proposed § 488.5(a)(18) and proposed § 488.8(e) is confusing. We are, therefore, revising this provision to distinguish between notice requirements for voluntary and involuntary terminations and to make explicit that notice of a voluntary termination must be given to us as well. In the revised provision in this final rule an AO would agree to provide written notice to us and its accredited providers or suppliers at least 90 calendar days in advance of the effective date of its voluntary termination of its CMS-approved accreditation program, and in the case of an involuntary termination action by us, to give notice to its accredited providers or suppliers as required by § 488.8(e). We are also requiring the AO to include in its notice the implications for the deemed status of its accredited providers or suppliers, in accordance with § 488.8(g)(2). We are also making conforming changes at § 488.8(e) to remove all reference to voluntary termination of a CMS-approved Medicare accreditation program by an AO.

• We proposed at § 488.5(a)(19) to replace the requirements currently set out at § 488.4(b)(3)(iii), which addresses the timeframe for AO notification to us regarding proposed changes in accreditation requirements. We indicated that we proposed to modify the current requirement by lengthening the advance notice period from 30 to 60 days, to provide adequate time for us to conduct a comprehensive, detailed review of the AO's proposed changes. We also proposed language clarifying that any proposed changes in a CMS-approved accreditation program could not be implemented by the AO before we approved such changes. We stated that this policy would ensure that the accreditation program continued to meet or exceed the Medicare requirements.

Comment: Numerous commenters expressed concerns with or opposition to our proposed changes. Some of the commenters made objections similar to those they raised about our proposal at § 488.4(a)(1), concerning our approval of a program in its entirety. Various commenters suggested that an AO only be required to submit to us only those proposed standard changes related directly to the CoP; or be required to submit only ''proposed material changes''; other commenters expressed concerns that this provision would give us authority over ''non-deeming aspects'' of an accreditation program's standards; or that this requirement would be ''contrary to the very essence of the originally-intended deeming relationship.''

One commenter referenced our preamble statement, with regard to proposed § 488.5(a)(13)(i), that we were revising the current language to clarify that there would be no requirement for an AO to submit information on its

accreditation programs that fell outside the parameters of its Medicare accreditation programs, and indicated that it agreed it would be inappropriate to require an AO to submit changes to their programs that were unrelated to Medicare deeming status. The commenter suggested we amend our proposal to require advance submission only of ''Medicare-related standards.'' Another commenter indicated its support for the previous commenter's proposal.

Several commenters indicated that not allowing an AO to adopt revised standards prior to our approval would slow down implementation of changes needed to meet an ever-changing health care environment and advances in the oversight of quality and safety.

One commenter indicated that 60 days was a reasonable amount of time for an AO to prepare and CMS to review proposed changes, but expressed concern about the uncertainty created for the AO if it was prohibited from implementing its proposed changes until we gave our approval. This commenter indicated there could be potentially damaging and costly implementation effects if CMS did not give its approval in a timely fashion and noted that there was nothing in the proposed rule to hold us accountable for rendering timely decisions. The commenter suggested that we revise the proposal to state that unless we affirmatively rejected an AO's proposed changes within 60 days, the changes would be deemed approved and would take effect. The commenter also proposed as an alternative that we eliminate the 60 day advance notice requirement and replace it with a requirement that an AO submit proposed changes prior to implementation and not implement the changes until 30 days after receiving approval from CMS. The commenter stated that this would give CMS an open-ended review period, prevent implementation prior to approval, and not interfere with AOs' plans to roll-out a change. Another commenter requested that we establish a timeframe by which CMS would have to give its response to a proposed change.

Response: We find many of the comments surprising, since we do not believe our proposal differs substantively, beyond the change from 30 to 60 days, from the requirements under the current regulations, which are found at § 488.4(b)(3)(iii) and § 488.8(d)(1)(ii). Taken together, these provisions oblige an AO to submit its proposed changes to us 30 days in advance and oblige us to conduct a comparability review of the proposed changes to determine the equivalency of the AO's proposed revised requirements to the Medicare requirements. As we stated in our response to comments on proposed § 488.4(a)(1), it would be arbitrary and contrary to the statute if, under the theory that its changes would not affect any accreditation provisions related to Medicare requirements, an AO modified portions of a CMS-approved Medicare accreditation program without providing us prior notice and our determination of whether the revised program continued to meet or exceed the Medicare standards, and could continue to be approved. We may not delegate to an AO our responsibility under the statute to determine whether an accreditation program, including any changes to it, meets or exceeds all Medicare requirements. This is not new policy on our part, because we believe it is required by the statute and our current regulations. We proposed to make this policy more explicit in our proposed regulations due to confusion a few AOs have had around this issue.

The commenter who noted our preamble statement in reference to our proposal at § 488.5(a)(13)(i) misunderstood our statement, or misapplied it in the context of proposed § 488.5(a)(19). We are aware that some AOs offer multiple types of accreditation programs, and that CMS-approved Medicare accreditation programs may be a subset of their overall accreditation program offerings. Our preamble statement related to proposed § 488.5(a)(13)(i) was intended to clarify that we do not require an AO to submit information to us on any accreditation program it offers which is not a Medicare accreditation program for which it is seeking our initial or renewed approval. Our statement was not intended to imply that an AO does not have to submit proposed changes within its CMS-approved Medicare accreditation program, and the express language of our proposal at § 488.5(a)(19) makes clear that, in fact, we expect all proposed changes to a CMS-approved Medicare accreditation program to be submitted to us in advance.

We find merit in those comments that expressed concern about undue delays if our reviews are not timely. We believe that we should be accountable to AOs just as we expect them to be accountable to us. We also agree that the language of both the current and proposed regulations, by specifying a notice requirement tied to the effective date of an AO's proposed changes, can be a source of confusion. Accordingly, in this final rule we are revising this provision to: change the number to § 488.4(a)(18), reflecting the prior revision; remove reference to the effective date of the changes; and indicate that the AO agrees to not implement the changes before receiving CMS approval, unless 60 calendar days after submission of the proposal has passed and CMS has not responded. We are also making conforming changes to § 488.8(b)(1)(iv) to state that an AO may implement a change in its standards without jeopardizing its Medicare accreditation program if we do not notify the AO within 60 calendar days after receipt of their proposed revisions of the results of our comparability review, including whether or not the AO's Medicare accreditation program, as revised, would continue to have CMS approval.

- We proposed at § 488.5(a)(20) to 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 proposed modifying the regulation text by deleting references to specific timeframes. We indicated this would provide us the flexibility to consider other factors when determining an appropriate timeframe for AOs to revise their program and submit their conforming changes to us. We stated 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. We further stated that AOs would benefit from our having the flexibility to provide them longer timeframes for response, when appropriate. In addition, we proposed 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.

Comment: One commenter requested clarification on how CMS will communicate these changes, asking if they would be published in the **Federal Register** as notices of proposed and final rules.

Response: Our reference to changes to the ''applicable Medicare conditions or requirements'' refers both to changes in our regulations governing the various types of providers or suppliers, including applicable changes in our regulations at parts 488 and 489, as well as substantial revisions to our official interpretation of applicable regulatory requirements. All regulation changes are accomplished through **Federal Register** notices of proposed rulemaking and notice of adoption of a final rule. All changes to our official interpretation of

applicable regulatory requirements are distributed to SAs via Survey and Certification Policy memoranda, which are also distributed to affected AOs and are published online. These changes are then subsequently incorporated into our online SOM, Publication 100–07. Our proposal called for an AO to submit its proposed conforming changes to us within 30 calendar days or by the date specified in the CMS notice to the AO, whichever is later. We recognize, however, that the proposed regulatory language, by using the term ''notice,'' appears to have led some commenters to believe we were referring to **Federal Register** notices. To avoid future confusion we will revise the regulatory text to state: ''in response to a written notice from CMS to the organization of a change. The proposed changes must be submitted within 30 calendar days of the date of the written CMS notice to the organization, or by the date specified in the notice, whichever is later.''

Comment: Several commenters requested that the provision be modified to include a mechanism for AOs to request additional time in implementing changes to their programs in response to CMS-initiated changes. These commenters also proposed that we include a timeframe to complete our review of the AO's changes, with one commenter suggesting 30 days.

Response: We agree and are modifying our proposal in this final rule to indicate we will give due consideration to an AO's request for extension submitted prior to the deadline. We also are revising the final rule to indicate that the AO agrees not to implement its proposed changes without our prior written notice of continued program approval, except as provided for at § 488.8(b)(1)(iv). That provision will state that an accreditation program's proposed changes in its standards will be deemed approved unless we provide the AO with a written notice of the results of our review no later than 60 days after receipt of the proposed changes.

Comment: One commenter opposed our requiring AOs to obtain CMS approval prior to implementing any changes to a CMS-approved program, indicating this would cause delays in implementation and limit flexibility.

Response: Section 1865 of the Act requires us to determine whether an AO's Medicare accreditation program meets or exceeds all applicable Medicare requirements. When those requirements change, it is necessary for us to determine whether the AO's program continues to meet or exceed the applicable Medicare requirements. We believe it would be even more time-consuming and disruptive if an AO were to implement changes that we subsequently determined no longer met Medicare standards. The AO would be faced, in this case, with then having to make and implement further program changes or else undergo a deeming review that could result in our terminating our approval of its program as a Medicare accreditation program. Accordingly we believe it is prudent for all parties if the AO agrees in its application to not implement changes that have neither been found nor deemed to warrant our continued program approval.

In this final, rule we are adopting this provision revised to reflect the numbering change referenced above, to make clearer that the purpose of our review is to determine whether the proposed revised accreditation program meets the standards for our continued approval, to make explicit that we will give due consideration to timely requests for an extension of the deadline for submitting proposed revisions to us; and to cross-reference § 488.8(b)(1)(iv), that permits a revised program to be deemed to have our continued approval if we do not issue a written determination within 60 days of receipt of notification.

- We proposed at § 488.5(a)(21) to modify the requirement currently set out at § 488.4(b)(3)(v), which requires the AO to permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings. We proposed modifying the regulation by adding language to clarify the scope of the requirement.

Comment: Two commenters expressed concerns with our proposal to change the current requirement for an AO to ''permit'' its surveyors to act as witnesses to a requirement for its surveyors to serve as witnesses. One indicated a surveyor should be able to refuse to be a witness. The other indicated that this provision would force an employer to condition an employee's hire on compelled speech, which could impact an individual's First Amendment rights. This commenter suggested the current provision could be strengthened without impacting an individual's rights, and proposed we used language such as ''make surveyors available'' or have CMS serve an AO with an administrative subpoena if a surveyor is reluctant to serve as a witness.

Response: Although section 1865(b) of the Act clearly authorizes us to take enforcement action on the basis of a survey conducted by an AO with an approved Medicare accreditation program, in practice we generally exercise our enforcement discretion to take enforcement action based on SA surveys conducted for us. That is why we typically require an SA survey, when an AO reports an adverse accreditation action on its part, or when it reports finding an immediate jeopardy situation. However, one standard exception to this practice concerns AO surveys of prospective providers or suppliers seeking initial certification to participate in Medicare. Since we have for a number of years, in an effort to make efficient use of federal resources, established initial surveys for prospective providers and suppliers that have an accreditation option as the lowest work priority for SAs, we usually make initial certification decisions involving applicants who seek deemed status after reviewing AO survey reports. These initial certification decisions include denials of certification and determination of the effective date of the Medicare provider agreement or supplier approval, and both of these types of decisions may be appealed by the applicant at the administrative level. Generally such appeals actions do not require an AO's surveyors to appear as a witness, but we cannot exclude this as a possibility. Thus we proposed that an AO require its surveyors to be available to serve as a witness. Therefore, we are revising this provision to require an AO to permit surveyors to serve as witnesses, and to cooperate with CMS to make surveyors available when needed as witnesses. We are also renumbering this provision, consistent with our revisions above.

- We proposed at § 488.5(b) to revise the requirement currently set out at § 488.4(c), which provides that if we need additional information to make a determination for approval or denial of an AO's application for deeming authority, the AO will be notified and afforded the opportunity to provide such information. We stated that we proposed deleting the language, ''deeming authority,'' which has been a source of confusion both internally and externally. It has led healthcare facilities and others to mistakenly believe that the AO awards deemed status and participation in Medicare. We stated that this proposed removal clarifies that only CMS has the authority to grant ''deemed status,'' not the AO. We received no comments on this proposal and are adopting it in this final rule without change.

We proposed at § 488.5(c)(1) to 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 also proposed a new requirement at § 488.5(c)(2) to address situations where an AO wishes to voluntarily terminate its CMS-approved Medicare accreditation program. We stated that in such case, the AO must notify us of its decision and provide an effective date of termination. We proposed that we would publish in the **Federal Register** a notice that includes the reason for the termination and the effective date. We stated that, in accordance with the requirements we proposed at § 488.8(e), the AOs would have to notify, in writing, each of its providers or suppliers of its decision no later than 30 calendar days after the notice was published in the **Federal Register**. We received no public comments on these proposed revisions, but are making conforming changes to reflect the changes we are making in response to public comments to § 488.4(a)(17) and § 488.8(e), to remove any reference to publishing a notice in the **Federal Register**.

- We proposed at § 488.5(d) and § 488.5(e) to replace the requirements currently set out at § 488.4(h), which addresses requests for reconsideration, as well as those occasions when we permit an AO whose request for approval of an accreditation program has been denied to resubmit its application, including certain requirements to be met. Specifically, we proposed at § 488.5(d) that if an AO has requested, in accordance with part 488 subpart D, a reconsideration of a disapproval, it may not submit an initial application for an accreditation program for another type of provider or supplier until the hearing officer's final decision has been rendered. We proposed at § 488.5(e) to allow an AO to resubmit its application for an accreditation program after our initial denial if the AO revises its program to address the issues related to the previous denial, demonstrates that it can provide reasonable assurance that its accredited facilities meet the applicable Medicare program requirements, and resubmits the application in its entirety.

Comment: We received no comments on our proposed § 488.5(e), but did receive a comment on proposed § 488.5(d) which requested that we remove it as contrary to the principle set out in the rest of the rule that each accreditation program is independent of other programs of an AO. The commenter stated that reconsideration of a denial should not be tied to an AO's ability to submit an initial application for a different program.

Response: We agree with the commenter that an AO's ability to request a reconsideration of a denial should not be conditioned upon precluding that AO's submission of an initial application for a different program. As we indicated in the preamble to the proposed rule, it was not our intent to change the current regulatory requirement, but we agree that the language in the proposed § 488.5(e) does not accurately reflect our expressed intent. We are therefore revising these provisions in this final rule by deleting a separate paragraph (d) and renumbering and revising paragraph (e) to allow resubmission of an application for a program previously denied by us if the AO has revised the program to address the issues related to the denial, demonstrates reasonable assurance and resubmits the application in its entirety. We are also taking this opportunity to make a technical correction to change the terminology ''demonstrates reasonable assurance that its facilities meet the applicable Medicare program requirements'' to ''demonstrates reasonable assurance.'' The definition of ''reasonable assurance'' at § 488.1 in this final rule already requires meeting the applicable Medicare program requirements, so the deleted language was superfluous. Consistent with the current requirement, we are also indicating that an AO that has requested reconsideration of our denial may not resubmit an application for that type of provider or supplier accreditation until the reconsideration is administratively final.

- We proposed at § 488.5(f) a new proposed provision, entitled ''Public 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. Specifically, we proposed at § 488.5(f)(1) to 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, we indicated that we proposed to revise the language or current provision by deleting reference to describing how the AO's accreditation program provides reasonable assurance that entities accredited by the organization meet the Medicare requirements, since this language is more appropriate for the provision concerning the final notice. In addition, we proposed to add language related to the timeframe for public comment, consistent with section 1865(a)(3)(A) of the Act. Further, we proposed at § 488.5(f)(2) to 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. We stated that our proposed revision would streamline and simplify the language of the regulations, to more clearly communicate existing requirements. Finally, we proposed at § 488.5(f)(2)(i) to replace the requirements 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 stated that once a national AO's accreditation program is approved by us and this decision is published in the **Federal Register**, we could approve any provider or supplier that is surveyed for Medicare participation on or after the effective date of the final notice (assuming that all other federal requirements have been met).

Comment: Two commenters responded to this provision by indicating the public cannot evaluate and comment on an applicant if it does not have the information in the application. One commenter requested that we publish in the final rule information on how to obtain a copy of an AO's application, while the other requested that the application be posted on the internet during the public comment period.

Response: The information about an AO's application which the Secretary is required to disclose to the public in accordance with section 1865(a)(3)(A) of the Act is the identity of the AO making the request, and the nature of the request. We appreciate the commenters' interest in having more information to enable them to make comments to us. However, AOs regard the detailed information about their programs to be proprietary information which is exempted from disclosure under the Freedom of Information Act (5 U.S.C. 552(b)(4)) and HHS regulations (see, for example, 45 CFR 5.65), and thus we do not provide copies of the applications when requested to do so, nor would we be able to post these applications on our Web site.

As discussed in our response to comments about the application of section 1865 of the Act to long term care facilities, we are making a technical correction to reflect the fact that the 210 day timeframe does not apply in the case of an application for a Medicare SNF accreditation program. We are also

making a technical correction to § 488.5(e)(2)(i) and (ii), which discuss final notice provisions when we approve, re-approve or disapprove an accreditation program. We are removing superfluous language that is already incorporated into the definition of ''reasonable assurance.'' We are also renumbering this paragraph as § 488.5(e), as a resulting of our consolidation of proposed paragraphs (d) and (e) discussed above.

7. Providers or Suppliers That Participate in the Medicaid Program Under a CMS-Approved Accreditation Program (§ 488.6)

• We proposed to broaden and revise the standard's title. We stated that the proposed regulations at § 488.6 would replace the requirement currently set out at § 488.5(b) (78 FR 20570). As with the previous version of this provision in both § 488.5(b) and § 488.6(b), eligibility for Medicaid participation may be established through Medicare deemed status for those providers and suppliers that are not required under Medicaid regulations to comply with any requirements other than Medicare participation requirements. Additional Medicaid eligibility requirements and state plan requirements, as applicable, would continue to apply. We received no comments on our proposal and are adopting it in this final rule. We have made one clarifying revision so that it more closely reflects the existing policy set out at § 488.5(b) and § 488.6(b).

8. Release and Use of Accreditation Surveys (§ 488.7)

• We proposed revising this standard's title to be more reflective of the standard's content. We proposed at § 488.7 to 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 SA. We indicated that under the proposed revision the deemed status provider or supplier would be required to authorize release of a copy of its most recent accreditation survey only to us.

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

• We proposed at § 488.7(a) to replace the requirement currently set out at § 488.6(c)(2), which indicates 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. We indicated that the language of this requirement would remain unchanged, although we note that we made two technical revisions, that is, referring to ''conditions and requirements'' so that the provision would unambiguously apply to any type of provider or supplier accreditation program.

• We proposed at § 488.7(b) to 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) of the Act, with the exception of surveys of HHAs. We proposed to revise this provision to clarify its requirements.

We also stated that we were taking the opportunity to clarify in the preamble 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.

Comment: A number of commenters indicated their opposition to the disclosure of accreditation surveys and related information. One commenter proposed that CMS provide any corrective action plan when releasing information about enforcement action.

Response: Section 1865(b) of the Act prohibits our disclosure of any accreditation surveys conducted by AOs, with the exception of surveys conducted of HHAs. In the case of HHAs, routine disclosure is expressly permitted under the Act. However, for accreditation surveys of any type of provider or supplier, section 1865(b) of the Act also provides that we may disclose an accreditation survey and related information to the extent that such survey and information relate to an enforcement action we have taken. In such cases our policy is to disclose the information upon receipt of a written request. If we have received related corrective action plans developed by the provider/supplier, we would include those in the disclosure.

Comment: One comment from a group of organizations indicated that, given the large amount of public funding nursing homes receive, consumers have a right to know about quality of care in a nursing home. They also questioned how Nursing Home Compare could be maintained without AO survey results, stating that deemed status would undermine Nursing Home Compare. This group also recommended that we change the language of the regulation to say we ''must,'' upon written request, disclose surveys and information related to an enforcement action.

Response: Section 1865(b) of the Act says that we ''may'' disclose an accreditation survey and other information related to an enforcement action we take, but does not require us to do so. The policy we proposed at § 488.7(b) reflects the statute and continues the policy that our regulations have reflected at least since 1993, when the provision at § 488.5(c)(3) was last amended. We do not believe it would be prudent for CMS to restrict the discretion permitted to us under the statute. Accordingly, we are not revising this final rule to state that we must make such a disclosure.

With regard to public disclosure requirements related to surveys of nursing homes and the potential impact on Nursing Home Compare of not disclosing accreditation surveys, we believe these are among the many issues we would need to consider should we ever receive an application from an AO seeking our approval of a Medicare long-term care accreditation program.

Comment: A number of commenters, mostly representing hospitals, expressed concern with the provision indicating that we may determine on the basis of our own investigation of the accreditation survey that a provider or supplier does not meet the applicable Medicare conditions or requirements. One commenter stated that, given the framework of the AO deeming structure and its checks and balances, CMS should not be second-guessing the decisions of the AOs. The commenter recommended instead that if CMS has concerns about a particular survey it should engage the AO in a conversation about those concerns. Several commenters found it unclear why CMS would keep this redundant requirement rather than trust the AOs to which CMS has delegated authority, and called for us to remove the provision. Another commenter indicated that it is not clear from the regulatory language what an ''investigation'' of the accreditation survey would entail and whether CMS could issue a compliance decision to the accredited facility, regardless of whether any federal requirements were found to have not been met in a validation survey. The commenter indicated this lack of clarity about the requirements of the CMS ''investigation'' of an AO's survey posed a significant risk to hospitals for action by CMS and urged

clarification of the parameters of the ''investigation'' and articulation of the potential adverse actions to be taken against healthcare providers as a result of the review. Along similar lines, another commenter objected to this provision, saying the regulation would not require CMS to conduct a site visit prior to rendering a decision, and was vague and ambiguous regarding what other information could be used in the investigation, raising the possibility of inconsistent decisions that could be adverse to the provider. The commenter also objected to there being no guidance on how far back CMS could look when taking into account ''other information'' and asked whether it could be 2 years or even 5 years. Another commenter also asked for clarification of the phrase ''investigation of the accreditation survey,'' inquiring if CMS would make a decision about compliance with the Medicare requirements based only on an accreditation survey, especially those that had no condition-level findings.

Response: This provision is a long-standing regulatory component of part 488. Section 1865(c) of the Act provides that if we find a provider entity has significant deficiencies, that entity shall not be deemed to meet the conditions or requirements. Neither approval of an AO's accreditation program nor a section 1864 agreement with an SA are delegations of authority to either AOs or SAs to make Medicare participation determinations. We state explicitly at § 488.12 that SA ''certifications'' of a provider's or supplier's compliance or noncompliance are recommendations to CMS, and that CMS makes the determination on the basis of these recommendations on whether a provider or supplier is eligible for Medicare participation. Likewise the current, longstanding provision at § 488.6(c)(2) states that we may determine that the provider or supplier does not meet the Medicare conditions based on our own investigation of the accreditation survey or related information. All AOs with current approved Medicare accreditation programs have been informed on more than one occasion that they must explicitly characterize their written notice to us concerning their positive accreditation decision for a specific facility as a ''recommendation'' for deemed status. Moreover, a recent decision of the Appellate Division of the Departmental Appeals Board (DAB) agreed with our reading of the statute that we are not compelled to accept an AO's recommendation of deemed status for a specific facility *(Wesley Medical Center, LLC, d/b/a/Galichia Heart Hospital, Dk. No. A–14–44, DAB Decision No. 2580 (June 30, 2014))*

As we stated in our response to comments concerning proposed § 488.5(a)(21), typically we rely upon AO recommendations concerning deemed status, and therefore review an AO's survey report, when the AO recommends deemed status for a prospective provider or supplier seeking initial participation in the Medicare program. Generally, we have no prior survey or other information on such applicants, so that the issue of how far back we may look at prior information is moot. Limited exceptions may occur, such as when the applicant was previously enrolled in Medicare and involuntarily terminated for failure to comply with Medicare requirements. In accordance with § 489.57(a), we are required in such cases to find that the reason for termination of the prior Medicare agreement has been removed and there is reasonable assurance it will not recur. Another exception would occur when an applicant for whom we recently denied participation based on either a state or AO survey is recommended for deemed status. In such cases we would review the AO's survey report in light of the survey findings on which we based our denial. Even if we were to begin relying directly upon AO surveys to take adverse enforcement action against current providers or suppliers, it is important to note that, in the case of non-long term care providers and suppliers, we take enforcement action based only on current noncompliance, so that the issue of a look-back timeframe would continue to be moot.

To illuminate what we mean by an ''investigation,'' we provide the following examples of situations when, after our review, we have rejected an AO's deemed status recommendation and have denied a prospective provider's or supplier's application for certification and Medicare participation. We emphasize that this is not an exhaustive list and that other circumstances could arise that require our investigation. We have had instances where our review of an AO's survey report indicates that it conducted a focused survey instead of a full accreditation survey in the case of a facility with a new owner who has rejected assignment of the prior owner's Medicare agreement. Our regulations and policy clearly indicate that, when a new owner rejects assignment, that prior Medicare agreement with the seller is voluntarily terminated and the new owner has the same status as any other new applicant for Medicare participation, and must undergo a survey to evaluate compliance with all Medicare or, in the case of an applicant seeking deemed status, accreditation requirements.

We have also had instances where an AO's survey report for a prospective provider or supplier indicated that deficiencies were identified that the AO did not find rose to substantial noncompliance with a Medicare condition. In these cases, the AO recommended deemed status after the facility agreed to an acceptable plan of correction. However, our review of the AO's survey report concluded that the AO's own description of one or more of the identified deficiencies clearly indicated substantial noncompliance, and that the AO should have advised us of this rather than awarding accreditation. In such circumstances, we would have denied the certification. In accordance with § 489.13(c) the effective date of a positive accreditation decision may not be earlier than the date on which the applicant is found to meet all applicable conditions. Further, section 2005A4 of the SOM states that an AO must notify us of substantial noncompliance, so that we can issue a denial of certification. The provision also allows the AO to continue to work with the applicant for up to 6 months after our initial denial of certification, before we issue a final notice of denial to the Medicare Administrative Contractor, which in turn would deny enrollment. When we believe an AO's own survey report does not support its recommendation of deemed status, we often reach out to the AO to discuss the situation, but still do not certify an applicant with substantial noncompliance.

Occasionally we obtain information that raises compliance issues not addressed by the AO's survey. For example, for hospitals or CAHs enrolling in Medicare, we collect extensive descriptive data via the Hospital/CAH Medicare Database Worksheet, Exhibit 286 in the SOM. This worksheet is not completed by the provider or AO, but is instead completed either by the SA, when it conducts a full survey, or by our regional office, usually by telephone call to the applicant, in the case of a deemed status hospital or CAH applicant for certification. There have been a few occasions when the applicant's responses raise significant questions about the manner in which it operates, and we have then followed up with the AO for more information. In rare instances where the AO's responses fail to clarify the situation, before issuing a denial of certification we have used an on-site survey by a state or federal

survey team to gather additional information to enable us to render an appropriate certification decision. After consideration of the public comments we are adopting proposed § 488.7 in this final rule without change.

9. On-Going Review of Accreditation Organizations (§ 488.8)

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

• We proposed at § 488.8(a) to replace the requirement currently set out at § 488.8(d), which addresses the continuing federal oversight of equivalency of an AO's approved accreditation program. We stated that the proposed revisions would ensure consistency with section 1875(b) of the Act, which requires our continuing oversight of the accreditation process of AOs approved in accordance with section 1865 of the Act and yearly reports to Congress concerning the operation of AO programs. The proposed revisions would replace the concept of a ''validation'' review with the broader concept of an ongoing AO ''performance'' review. We also proposed to remove reference at current § 488.8(d)(2)(i) to a ''20 percent'' validation survey rate of disparity as a threshold for triggering a review that could result in our termination of an AO's program approval. We stated that our experience over the past few years has demonstrated that, although the rate of disparity between AO and SA representative sample validation 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. We indicated that, 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 representative sample validation survey disparity rate, but also 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 indicated that we believe it is not appropriate to include in the regulation a requirement, based on only one calculation, 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 proposed deleting the specific reference in the regulation to a 20 percent disparity rate triggering a formal validation review. We proposed instead to provide at § 488.8(a) for an ongoing performance review of approved AO programs, and we identified at proposed § 488.8(a)(2) the representative sample validation survey disparity rate as only one of several components that may trigger a performance review. Further, we proposed in § 488.8(c) to provide for a formal accreditation program review when a performance review revealed evidence of substantial non-compliance. We stated that we believed that the proposed revision would enable us to continue to make use of the disparity rate in our ongoing assessment of AO performance, but also to make use of other performance indicators. Additional indicators would enable us to reach a more comprehensive assessment of the quality of an AO's program. We indicated that 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. We also proposed at § 488.8(a)(1) through § 488.8(a)(3) to clarify that we would evaluate AOs' performance by looking at various aspects of their practices.

Comment: One commenter expressed opposition to our proposal to change the heading of this requirement from ''validation'' review to ''ongoing'' review, suggesting that the change would allow hospitals to be surveyed at any time for validation purposes, instead of as part of a random sample within 60 days of an AO's survey. The commenter stated that this would put deemed status and non-accredited hospitals on an unequal playing field, since hospitals choosing to be accredited by a private AO could be subject to a full validation survey beyond a 60-day period while hospitals surveyed by the state under contract to CMS are not governed by the same set of rules. The commenter further stated that the contracts between the states and CMS are confidentially negotiated and not transparent, and questioned why a hospital would have any incentive to work with an AO when it would be subject to a different set of standards. A number of other commenters also objected to our removing the ''fixed period'' during which a validation survey could be conducted.

Response: The commenters misunderstand both our current requirements and our proposal. Although proposed § 488.8 implements section 1875(b) of the Act, which requires us to conduct an ongoing ''validation'' of an AO's accreditation process, we believe the term ''validation'' in this context may be readily confused with the narrower concept of a validation survey analysis and disparity rate calculation, which is just one component of our overall process for validating, that is, evaluating, an accreditation program on an ongoing basis. The commenters assume incorrectly that we are making changes to when validation surveys may be conducted. That is not the case. It is important to note that section 1864(c) of the Act distinguishes between two types of validation surveys, as does the current provision at § 488.7: Representative sample validation surveys and validation surveys conducted in response to an allegation concerning a deemed status provider or supplier of substantial noncompliance with an applicable Medicare condition or requirement. The commenter appears to believe that only representative sample validation surveys are validation surveys, and we believe that the imprecise language at current § 488.8(d)(2) contributes to such confusion. In our annual report to Congress we calculate disparity rates only for representative sample validation surveys. As previously noted, section 3242 of the SOM requires SAs to conduct representative sample validation surveys no later than 60 calendar days after the scheduled end date of the AO's accreditation survey, and proposed § 488.8 would have no impact on this policy. Thus the commenters' fears are unfounded. We do wish to reiterate, however, that substantial allegation surveys are complaint-driven, and that a provider or supplier may undergo multiple state substantial allegation validation surveys within any given year depending on the number and nature of complaints. We also wish to clarify that state survey agencies are not our ''contractors'' in the sense that term is normally used for organizations from which federal agencies procure services. Instead, SAs are parties with whom we have entered into agreements under section 1864 of the Act, under which we pay the reasonable costs of the activities that states perform for us. The SOM, which is available to the public on our Web site at *http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/*

CMS1201984.html?DLPage=1&DLSort=0&DLSortDir=ascending, contains all of the regulations and subregulatory guidance which establish our expectations for the functions states perform under a section 1864 agreement. In addition, each year, based on the funding budgeted for state survey and certification activities in the federal budget, we communicate to the states how they should prioritize their federal workload, given the limitations on the resources available to cover their costs. Although we do not post these annual workload priorities on our Web site, they are certainly available in response to Freedom of Information Act requests. Thus we disagree that our relationships with the various SAs are not transparent. Finally, we do not understand the commenter's concern about hospitals that seek accreditation being subjected to different standards than those used by the states conducting validation surveys. It is true that hospitals, or any other type of deemed status provider or supplier, may be subject via accreditation to additional standards that exceed Medicare requirements. However, SAs do not evaluate providers' or suppliers' compliance with AO-only standards as part of their federal survey work. To the extent that a provider or supplier is cited as a result of a state validation survey for one or more deficiencies that an AO survey failed to identify, any seeming conflict is most likely the result of problems in an AO's accreditation survey process. We are always looking for ways in which we can better understand the source of these problems and help AOs understand what needs to be done so that their accredited facilities are always in compliance with the Medicare requirements, and do not find themselves surprised by different compliance expectations when the state conducts a survey. We believe that our proposal and our discussion of the comments we have received in this final rule also contribute to clarifying our expectations for AOs as well as providers and suppliers, and to removing providers' and suppliers' misconceptions about our requirements.

Comment: One commenter proposed modifying the language of this provision to state that ongoing review of AOs is applied to CMS-approved accreditation programs only. The commenter also stated that ''onsite observations should be as minimally disruptive as possible and be limited in scope''.

Response: We believe it is clear that the provisions of part 488 apply only to those accreditation programs for which AOs are seeking or have already received our approval. We make every attempt to minimize disruption to the AO's operations when we make onsite observations, and we limit the scope of our observations to matters pertaining to the program under review.

Comment: One commenter requested that CMS identify how it would conduct validation surveys of suppliers of the technical component of advanced diagnostic imaging.

Response: In this final rule we do not apply the provisions of part 488 to accreditation of the technical component of ADI suppliers, so the question is moot.

Comment: We received no comments about our proposal to remove the 20 percent representative sample survey disparity rate as an automatic trigger for our review of an AO's program. However, a number of commenters expressed concern that our reliance upon state validation surveys is seriously flawed. One commenter indicated that issues associated with the current validation survey framework include the following: (1) Assessment is one-way, in that CMS instructs its contractors, the SAs, to use the Medicare conditions as the standard to assess AO performance and that we assess only what the state found and the AO missed. The commenter pointed out that there is no analysis of what the AO found and the SA missed, creating an evaluation bias; (2) CMS must develop a new set of benchmarks, given that the way SAs and AOs make determinations of deficiencies differ too greatly. The commenter indicated the benchmarks need to be as outcome-based as possible, given that AOs should be given flexibility to innovate in their programs and processes; (3) there is variation among the states in how they conduct surveys and interpret findings. The commenter stated that patients and the public would be better served if all surveyors consistently focused on critically important issues that truly affect the delivery of safe, quality health care; (4) AOs consistently hear that states send in large survey teams, frequently including local fire marshals who are very familiar with a facility's physical plant, and that these teams stay at the facility longer than is feasible for AOs that must charge for their time onsite, and who therefore must balance their onsite time between clinical and infrastructure issues according to health and safety risk priorities; (5) there are differing interpretations of the severity of findings, with some AOs not scoring as deficiencies requiring improvement Life Safety Code (LSC) violations that are only low or medium categories of importance. The commenter stated that state surveys might generate a long list of such low-level deficiencies and then make a condition-level finding; (6) CMS frequently determines that a facility's condition constitutes an ''immediate jeopardy situation'' based on a situation that occurred well before the CMS survey, while the commenter (an AO) only makes a determination of an ''immediate jeopardy situation'' if there is a situation that presents itself during the survey that could cause harm to patients or the public.

Similarly, but in less detail, other commenters expressed objections to our reliance upon state representative sample validation surveys. One commenter called for us to establish a process for an AO to request reconsideration of a state's validation survey findings when the state's findings differ from the AO's findings. Another commenter said that state validation surveys are widely reported to be ''punitive'' in nature and often do not accurately reflect a provider's compliance. The commenter also noted variation among states in the size and scope of the survey teams and how deficiencies are identified. The commenter urged development of performance metrics for how the surveys will be used to evaluate AO performance. Another commenter indicated that CMS uses unannounced validation surveys to evaluate the AO's performance. It indicated a clear validation survey process based on unambiguous and understandable performance indicators is necessary to accurately evaluate an AO's performance.

Response: Section 1865(d) and section 1864(c) of the Act provide for validation surveys by SAs of providers and suppliers that have deemed status. Further, section 1875(b) of the Act specifically requires us to conduct a continuing ''validation'' of AO programs provided for in section 1865(a) of the Act and to report our findings annually. While we believe that the term ''validation'' in section 1875(b) of the Act is intended to cover a wider range of AO performance than the results of validation surveys, we do not believe the Act provides us discretion to omit state validation surveys from our analysis of an AO's performance.

With regard to the issue of the validation assessment being one-way and using the Medicare conditions as the standard, we note that section 1864(c) of the Act provides for a state to conduct a survey of a deemed status provider or supplier when we direct it to do so either as representative sample survey or in response to substantial allegation of noncompliance. The state must conduct the survey in accordance

with the requirements of section 1864(a) of the Act and does not have the authority to consider anything other than the applicable Medicare conditions when assessing compliance. Further, for the assertion that our analysis of the results of validation surveys does not consider deficiencies that the AOs found and the state missed, we note that while it is certainly possible that a state could overlook a deficiency that an AO found, given that the state survey occurs up to 60 days after the AO's survey, it is also possible that the surveyed provider or supplier has corrected deficiencies that the AO identified prior to the state's survey. In addition, most AO accreditation programs have standards that exceed those of Medicare. Therefore, an analysis of deficiencies that AOs cited and SAs missed would be of limited value since SAs are not evaluating compliance on these same standards. Implicit in the commenter's statements about benchmarking based on outcomes rather than what states focus on, and on LSC deficiencies it believes are not important, is a concern of the commenter with the substantive regulations that constitute the applicable conditions for a specific provider or supplier type. However, neither a provider/supplier nor an AO has the discretion to disregard Medicare requirements that it does not agree with, or considers ''less important.'' Section 1865(a) of the Act requires the AO's approved Medicare accreditation program to meet or exceed all applicable Medicare requirements. Likewise, we do not have the discretion to evaluate an AO's performance on any other basis than whether it meets or exceeds the applicable Medicare requirements. AOs or providers/suppliers are free to express their concerns with various substantive Medicare requirements and we evaluate such concerns in determining whether to revise requirements where we have the discretion to do so. Indeed, we have revised various conditions in recent years to reduce undue burdens on Medicare providers and suppliers. Once we change a regulation, then an AO may change its standards and survey process accordingly.

The allegation that states use larger survey teams and conduct longer surveys than do AOs has been raised in the past for hospital validation surveys. We reviewed our data concerning survey team size and hours and found that states tend to vary the size/length of survey according to the size of a hospital, as measured by the number of certified beds. We found no evidence that states fielded larger survey teams or conducted longer surveys when conducting validation surveys of deemed status hospitals as compared to their surveys of non-accredited hospitals. We note that section 1865(a)(2) of the Act requires us to consider in our review of an AO's Medicare accreditation program the AO's ability to provide adequate resources for conducting required surveys. Regardless of the size of accreditation survey teams, we require them to be able to accurately assess compliance with all Medicare requirements as a condition of our approval.

We note that our methodology for calculating the representative sample validation survey disparity rate gives AOs the benefit of the doubt in a number of ways. We do not compare state and AO surveys where they state found only lower-level deficiencies; instead, we compare only those surveys where they state identified substantial noncompliance, on the theory that substantial noncompliance is likely systemic, and therefore, was likely already present when the AO conducted its survey up to 60 days earlier. However, despite comparing only this more limited subset of surveys, for the denominator in the disparity rate calculation we use all representative sample validation surveys conducted in the given fiscal year. We have been criticized in the past for this methodology and urged to calculate instead a ''disagreement rate'' using for the denominator only those surveys where states found substantial noncompliance. We did in fact report a disagreement rate for several years in our report to Congress, but stopped doing so more recently because we believe it unfairly disregards those surveys in which neither the AO nor the state found substantial noncompliance. Our methodology in calculating the disparity rate gives AOs the benefit of the doubt in that we do not find a disparity between a state and an AO survey so long as the AO has identified a comparable deficiency, even if the AO does not indicate that the deficiency rises to the level of substantial noncompliance. We permit AOs considerable latitude, with the exception of initial Medicare surveys as required at § 489.13, in how they categorize deficiencies and what kinds of enforcement actions they take within their accreditation programs based on the deficiencies they identify. Therefore, we accept all evidence in a survey report of their identification of comparable deficiencies when comparing their findings to state findings for the disparity rate analysis. We see no reason to establish a process for reconsideration of a state's survey findings; we also believe that there is no feasible method for implementing such a reconsideration process.

In response to comments about the variability in state surveys, we acknowledge that there is variability and we employ a variety of mechanisms to assess and improve SA performance. As we noted previously, SAs are not contractors in the normal sense, but this does not mean that we do not provide ongoing oversight of their performance. We are also convinced that variability in SA performance is not relevant to the discussion of our use of validation survey results to evaluate AO performance. Consistently among the SAs and over time the largest source of disparate findings between states and AOs has been AO difficulties in assessing compliance with the LSC, compliance with which is designed to prevent fires in health care facilities and to reduce the adverse impact should a fire occur. Various AO practices may have contributed to their LSC compliance assessment difficulties, including purportedly issuing LSC waivers to providers, though they lack authority to do so, choosing not to issue citations requiring corrective action for what the AO considers to be minor LSC noncompliance, or focusing their survey activities on areas that they consider more important than fire protection requirements. Nevertheless, we expect all AOs with accreditation programs for providers or suppliers that are subject to LSC requirements to be able to assess compliance with the LSC.

We disagree with the comment objecting to our view that a long list of minor LSC deficiencies cited by a state could end up with a finding of substantial noncompliance. In accordance with § 488.26(b), the manner and degree to which a provider or supplier satisfies the standards within a requirement or condition is considered when determining compliance with that requirement or condition. For states or AOs assessing compliance for non-long term care providers and suppliers we have long interpreted this provision to mean that there could be substantial noncompliance as a result of various situations, including a situation where there is pervasive noncompliance on the part of a provider or supplier, even if every single instance of noncompliance on its own does not constitute substantial noncompliance. Such pervasive noncompliance is suggestive of systemic problems that need correction. If an AO systematically disregards what it views as ''minor''

types of noncompliance, it risks missing underlying systemic weaknesses in a provider's or supplier's systems.

We also disagree with the comment concerning state validation surveys being perceived as ''punitive'' in addition to being unannounced. We require both states and AOs to conduct unannounced surveys, and assuring compliance with our regulations is not ''punishment'' but part of our responsibility to protect patients and their families. Further, to the extent that a state survey finds substantial noncompliance, we are required to take appropriate enforcement action to bring the provider or supplier back into compliance or to take adverse action if it fails to do so. We expect that AOs finding the same noncompliance also take swift action within their accreditation programs to bring the provider or supplier back into compliance or to take adverse accreditation action when an accredited provider or supplier fails to correct its deficient practices.

Finally, for the comment about immediate jeopardy, the comment is not directly pertinent to the issue of validation surveys and our calculation of the disparity rate. As noted in this section of this final rule, in calculating the amount of the disparity, we do not consider the level of an AO's citation in its survey report so long as it identifies a deficiency comparable to the one that the state survey team found. Further, the comment incorrectly describes the criteria for immediate jeopardy situations, at least for non-long term care providers or suppliers. Since there are no approved long-term care accreditation programs, the comment incorrectly describes a supposed policy difference that currently exists between AO and state practices in citing an immediate jeopardy. For non-long term care providers and suppliers we assess only their current compliance, at the time of the survey, with the Medicare requirements. However, an event that occurred in the past and involved violations of our requirements may be evidence of current noncompliance with those requirements, unless there is also evidence to indicate that the provider or supplier identified and corrected the deficient practices associated with that event prior to the survey. In such cases there continues to be the potential for similar harm to patients or others in the future. In the case of a past event that clearly met the criteria for an immediate jeopardy determination, which we will discuss further in connection with our proposed revision to § 489.3, failure of the provider or supplier to address the underlying causes of that event may indicate that the immediate jeopardy is still present. We have had discussions with individual AOs that appear to have misunderstood this concept, to make clear to them that it is inappropriate for them to conclude that a past event can never be evidence of an immediate jeopardy situation at the time of the survey.

Comment: Several commenters requested clarification on the criteria that would trigger a program review other than the disparity rate, changes to CMS requirements, or changes to an AO's standards.

Response: In our proposal we indicated that we would consider the AO's survey activity (for example, whether it was conducting timely re-accreditation surveys), the results of validation surveys, and its continued fulfillment of the requirements in our proposal at § 488.5(a). We believe this provides considerable specificity as to the types of factors we consider. We proposed that our consideration would not be limited to these factors, however, because we are unable to anticipate all the situations that potentially could arise which might warrant our evaluation. After due consideration of the public comments we are in this final rule adopting § 488.8(a) without change.

- We proposed at § 488.8(b) to revise the requirement currently set out at § 488.8(d)(1), which addresses the conditions under which we would assess the equivalency of an AO's approved program to the comparable CMS requirements. We proposed at § 488.8(b)(1) to revise the requirement currently set out at § 488.8(d)(1)(i), which addresses the need for us to conduct a comparability review when we impose new requirements or change our survey process. We proposed adding language to the existing requirement 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 us. We indicated that 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, we proposed new language to set out the consequences if an AO failed to submit comparable changes in a timely manner, that is, we may open an accreditation program review in accordance with § 488.8(c). We indicated these proposed provisions would parallel revisions we proposed at § 488.5(a)(20).

We received comments on both this and the parallel provision at proposed § 488.5(a)(20) (adopted in this final rule as § 488.5(a)(19)) concerning how CMS would communicate its notice of regulation changes to AOs, calling for addition of a provision allowing AOs to request an extension of the timeframe for it to respond, and calling for a timeframe for CMS to respond to the AO's proposed revisions. We addressed these concerns in more detail in our discussion of proposed § 488.5(a)(20) (adopted in this final rule as § 488.5(a)(19)). Accordingly, we are making the same types of changes in this final rule at § 488.8(b): We indicate that we will provide written notice of the changes to the AO and that we will specify in this notice a timeframe of not less than 30 calendar days from the date of our notice to submit its proposed equivalent changes. We are stating that we may extend the deadline after giving due consideration to a timely request by an AO for an extension; that we will provide written notice after completion of the comparability review as to whether the accreditation program, including the proposed revisions and implementation timeframe, continues to meet or exceed all applicable Medicare standards; and that if we fail to provide written notice of the results of our comparability review no later than 60 days after receipt of the AO's proposed revisions, then the revised program would be deemed to meet or exceed all applicable Medicare requirements and to have our continued approval. Finally, we are making a technical correction to indicate that the equivalency of the accreditation program's requirements is assessed in light of changes to comparable ''Medicare'' requirements, rather than ''CMS'' requirements, since CMS operates a number of programs that are outside the scope of this regulation.

- We proposed at § 488.8(b)(2) to 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 proposed expanding the timeframe to allow adequate time for us to conduct a comprehensive, detailed review of the AO's proposed changes. In addition, we proposed adding language to clarify that the AO may not implement any changes to its CMS-approved Medicare

accreditation program prior to receiving CMS approval. We stated that the purpose of the proposed new language was to ensure continuing comparability of the AO's accreditation program with the Medicare requirements. We indicated these changes would parallel comparable changes at proposed § 488.5(a)(12)(i), which was actually a technical error, since there was no proposed § 488.5(a)(12)(i), and the actual parallel provision was proposed at § 488.5(a)(19), renumbered as § 488.5(a)(18) in this final rule.

We received comments about this provision in conjunction with our proposal for § 488.5(a)(19). We responded to those comments in our discussion of proposed § 488.5(a)(19), indicating we were, based on the comments, revising § 488.5(a)(19), renumbered as § 488.5(a)(18), and making conforming changes to § 488.8(b)(2). We are revising this provision in conformity with the comments to remove all reference to the effective date of the AO's proposed revisions in determining the timeframe for submission of these proposals to us, and to provide for a default approval process to allow an AO to implement its proposed changes. As noted previously, if we fail to provide written notice of our findings within 60 calendar days after our receipt of the AO's proposed revisions, the program as revised will be deemed to have our continued approval. Further, we have made a correction to add a provision parallel to that at § 488.4(b)(1)(v), clarifying that if an AO implements changes without explicit or deemed approval, we may open a program review for that accreditation program.

- We proposed at § 488.8(c) and § 488.8(c)(1) to revise the requirement currently set out at § 488.8(e), which provides that if a comparability or validation review indicates that an accreditation program is not meeting all applicable 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 proposed revising the standard's title to more accurately reflect the language of the standard that follows and deleting redundant language. We also proposed added 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. We stated, for example, that 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 status facilities, we would add this matter to the review. We further proposed separating the existing standard into two separate parts to more clearly articulate the circumstances that may trigger our opening a review of a CMS-approved accreditation program and the written notice we must provide the AO upon opening such a review. We further proposed at § 488.8(c)(1)(i) to relocate the requirement currently set out at § 488.8(e)(1), which requires that our notice to the AO 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 proposed replacing this language with broader language that more clearly describes current practices related to an accreditation program review. We stated that 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. We proposed at § 488.8(c)(1)(ii) to 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. We indicated that the proposed language would clarify that the AO would not be limited to only one opportunity to offer factual information and documentation. Instead, we stated, such opportunities would be available throughout the accreditation program review process. We proposed at § 488.8(c)(1)(iii) to 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 proposed deleting the language, ''from the validation review,'' and replacing it with the conforming language, ''based on the findings of the accreditation program review.'' Finally, we proposed at § 488.8(c)(1)(iv) to revise the requirement currently set out at § 488.8(f)(2). The current provision states that if CMS determines after 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 proposed revising this provision to include in our required notice to the AO a description of the possible 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 our notice that an accreditation program review is being initiated.

Comment: One commenter proposed that we strengthen this provision by changing the language from ''CMS may initiate a program review . . .'' to ''CMS must initiate . . .'' making this an automatic requirement whenever substantial non-compliance is determined to be present in a CMS-approved program. The commenter also proposed reducing the maximum timeframe for an AO to implement corrective action from 180 days to 60 days, and also urged that we review any survey activity of the AO conducted during this 60-day period. The commenter indicated that allowing 180 days to correct identified deficiencies is much too long since that may subject patients to substandard care.

Response: We appreciate the concerns of the commenter, but believe that reducing the timeframe for an AO to implement corrective action from 180 days to 60 days may not provide adequate time for the AO to identify and implement the systemic changes typically needed to effect sustained improvement. Depending on the nature of the AO program's deficiencies, we have the discretion to employ greater use of validation surveys during this period to ensure patient safety. We also note that we have the authority to immediately withdraw our approval of an accreditation program if we determine that continued approval poses an immediate jeopardy situation for the patients of the AO's accredited entities. For the commenter's suggestion that a program review be mandatory, we do not see the need to limit our discretion in this manner. A program review is a formal process that entails a comprehensive review of an AO's program. We also address specific problems we have identified in an AO's program outside the formal program review process, and have found this to be an efficient and effective way to correct such problems. Therefore, we believe it is essential for CMS to retain discretion about when to use a more focused approach and when to initiate a formal program review. After due consideration of the public comment, we are implementing this provision in this final rule without change.

• We proposed at § 488.8(c)(2) to state explicitly that we review the AO's plan of correction for its acceptability. We received no comments on this provision and are in this final rule adopting it without change.

• We proposed at § 488.8(c)(3) to replace the requirement currently set out at § 488.8(f)(2). The current provision provides us authority to grant conditional ongoing approval of an AO's program with a probationary period of up to 180 days for the AO 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 proposed expanding the current provision to clarify that a probationary period of up to 180 calendar days applies when an AO has failed to meet any of the applicable requirements of subpart A of part 488. We proposed further to clarify that an accreditation program review probationary period could not extend beyond the AO's term of approval. Finally, we proposed to 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.

• We proposed at § 488.8(c)(3)(i) to revise the requirement currently set out at § 488.8(f)(4), which provides 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 proposed clarifying this provision by deleting the language, ''make a final determination'' and replacing it with, ''issue a written determination.'' We further proposed deleting the language, ''criteria described at paragraph (a)(1) of this section,'' and replacing it with, ''requirements of this subpart.''

• We proposed at § 488.8(c)(3)(ii) to revise the requirement currently set out at § 488.8(f)(5), which states that we may remove our recognition of an AO's program if the AO has not made improvements acceptable to us during the probationary period, with the removal of our approval effective 30 days from the date that we provide written notice to the AO. We proposed modifying this provision by expanding the timeframe to account for the process required to publish a notice in the **Federal Register**.

• We proposed at § 488.8(c)(3)(iii) to revise the requirement currently set out at § 488.8(f)(7), which requires us to publish a notice in the **Federal Register** when we withdraw our approval of an AO's accreditation program, including a justification for our decision. We proposed clarifying this provision by specifying that the effective date of our withdrawal of approval would be 60 calendar days from the date of the **Federal Register** notice. We note as a point of information that, if an AO has requested reconsideration in accordance with § 488.8(f) of our decision to withdraw our approval of its accreditation program, we would not publish a notice of our withdrawal of approval until and unless the final reconsideration decision issued in accordance with § 488.211 reaffirms the withdrawal of approval. We received no comments on proposed § 488.8(c)(3), including paragraphs (c)(3)(i) through (iii) and are adopting it in this final rule without change.

• We proposed at § 488.8(d) to revise the requirement currently set out at § 488.8(g), which states that if 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 proposed clarifying this provision by deleting the language, ''deeming authority'' and replacing it with the conforming change, ''CMS-approved accreditation program.''

Comment: One commenter proposed that withdrawal of our approval be automatic if an immediate jeopardy situation is found, stating that this would provide a greater incentive to AOs to remain in compliance.

Response: We believe that an automatic withdrawal of our approval of an accreditation program is unnecessary and would be more vulnerable to challenge. We are confident that we will use our enforcement discretion appropriately to take prompt action should we ever make a determination that a CMS-approved accreditation program's continued approval puts patients in immediate jeopardy. After due consideration of the public comments we are adopting this provision in this final rule with one minor typographical correction.

• We proposed at § 488.8(e) 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. We stated that this provision was 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. We believe notification would afford affected providers or suppliers an opportunity to seek accreditation through another CMS-approved AO accreditation program, or to continue participate in Medicare under the SA's jurisdiction.

Comment: One commenter proposed extending notification to all patients impacted by CMS withdrawing approval of an AO's CMS-approved accreditation program. This notification would be in addition to CMS publishing a notice of such action in the **Federal Register** under this provision as well as the AO's requirement to notify affected providers and suppliers in accordance with the requirements at § 488.5(a)(18).

Response: As we indicated in response to a similar comment on proposed § 488.5(a)(18) (renumbered as § 488.5(a)(17) in this final rule), we believe that it is not necessary to notify patients of a change in the organization responsible for overseeing their provider's or supplier's compliance with the Medicare requirements. Further, we believe that such a requirement would be unduly burdensome to both AOs and providers and suppliers.

Comment: Several commenters noted that there might be a contradiction between this proposed provision and the one at proposed § 488.5(a)(18), and that even if there is no contradiction, the two provisions create confusion that needs clarification.

Response: We revised proposed § 488.5(a)(18) (adopted as § 488.5(a)(17) in this final rule) to cross-reference § 488.8(e) for notice requirements for involuntary termination. Further, in reviewing this proposed revision in light of the commenters' observations, we noted that § 488.8(e) assumed that there would be a **Federal Register** notice of a voluntary termination by an AO of its CMS-approved Medicare accreditation program, even though there is currently no such requirement. To avoid confusion about the interaction between § 488.5(a)(17) and § 488.8(e) we are removing all reference in the latter to voluntary terminations. We are also making a technical correction to clarify that, in accordance with § 488.8(g)(1), there are consequences to a provider's or supplier's continued maintenance of its participation in Medicare on the basis of ''deemed status'' when we withdraw our approval of its AO's Medicare accreditation program.

• We proposed at § 488.8(f) to 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 in accordance with subpart D of this part. We proposed clarifying this provision by deleting the language, ''deeming authority'' and replacing it with the conforming change, ''CMS-approved accreditation program.''

Comment: One commenter proposed retaining the existing language referring to ''deeming authority'' and for CMS to publish a definition that communicates the intent of this language. The commenter states that changing this term to ''CMS-approved accreditation program'' will impact recognition, reputation, and marketing for AOs.

Response: Consistent with our action in other areas of this rule, we have removed reference to ''deeming authority'' for AOs and instead refer to their Medicare accreditation programs as ''CMS-approved programs.'' We believe that the current language is misleading, since it implies that AOs have more authority than is permitted them under the Act and implementing regulations. Although an AO with a Medicare accreditation program we have approved may recommend its accredited providers and suppliers to us for deemed status, only CMS has the authority to actually grant deemed status to an accredited provider or supplier. After due consideration of the public comments, we are adopting this provision in this final rule without change.

• We proposed § 488.8(g) to 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 we determine 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 proposed revising this provision by expanding the timeframe for continued deemed status of a provider or supplier to 180 calendar days from the date of our publication of the notice of removal of our approval, so long as the provider or supplier applies for accreditation under another AO's approved program within 60 calendar days of the **Federal Register** notice and also provides timely written notice to the SA of its accreditation application. We indicated that failure to adhere to these timeframes would result in placement of the provider or supplier under SA authority for its continued Medicare participation. We stated that our intent was to avoid duplication of AO and state survey resources.

Comment: One commenter expressed its opposition to this provision, saying that suppliers of the technical component of advanced diagnostic imaging services should not have to submit notice to the SA when applying for another accreditation, since SAs do not oversee such suppliers. It proposed instead that the accreditation period of such suppliers be transferred to another AO when the original AO is no longer approved by CMS, stating that the suppliers should not be penalized when an AO loses its status with CMS.

Response: We agree that it is not appropriate to require suppliers of the technical component of advanced diagnostic imaging services to notify SAs when they apply for accreditation with another AO, after we have removed our approval of the supplier's AO's ADI program. This is one of the many reasons we decided in this final rule to remove all reference to accreditation of suppliers of the technical component of ADI services from part 488. We will consider the commenter's alternative proposal for future rulemaking concerning ADI accreditation.

Comment: Several commenters expressed appreciation for our proposal to lengthen the period of continued deemed status, but questioned why we did not instead extend deemed status until the provider's or supplier's next scheduled accreditation survey. Since all Medicare accreditation programs employ unannounced surveys, we presume the commenters intend that the provider's or supplier's deemed status would be continued until the expiration date of its accreditation under the terminated AO's program. The commenters indicated that we should take this approach, unless we found serious deficiencies in the AO's ability to assess providers on the basis of quality and safety. One commenter also suggested that we require AOs to notify providers or suppliers of their obligation to notify the SA.

Response: If we remove our approval of an AO's Medicare accreditation program, generally it would mean that there is substantial evidence that the AO is unable to provide its accredited providers and suppliers adequate oversight. In this circumstance we believe it is necessary for us to move these providers and suppliers for oversight purposes as quickly as reasonably possible to another AO or to the SA's jurisdiction. Since another AO would need time to process an application, particularly if it were receiving multiple applications, and to conduct an accreditation survey, we believe it is appropriate to afford the provider or supplier sufficient time to accomplish the transition to another AO's program, and we believe that 180 calendar days should be enough time to accomplish this. Since accreditation typically is granted for a 3-year period, we do not believe it would be appropriate to allow up to 3 years for this transition to occur.

Comment: One commenter proposed that we require providers and suppliers to provide written notice to patients when it submits an application to another AO, that we place the provider or supplier under the oversight of the SA during the transition period between AOs, and that we provide patients with information on how to contact the SA with any complaints.

Response: As we indicated in response to similar comments about other provisions, we believe it would be unduly burdensome to require notice to patients when a provider or supplier applies to another accreditation program, and we do not believe this information would be useful to patients. In our view it is also unnecessary to provide patients with special notice about how to contact the SA with any complaints, since it is already routine for patients to submit their complaints about certified providers and suppliers to the SA, regardless of whether they have deemed status or not, and, when appropriate, we authorize substantial allegation validation surveys to investigate the complaint. Therefore SA surveys are conducted when needed during the transition period. For this reason we also believe it is not necessary to formally remove the accredited providers' or suppliers' deemed status immediately upon termination of an AO's Medicare accreditation program. We agree with the commenter who suggested that AOs should be required to notify their accredited providers and suppliers of the need for the latter to notify the SA when they have filed a timely application for accreditation with another AO. We believe that the revised provision at § 488.5(a)(17) adopted in this final rule accomplishes this.

Commenters on this provision, as well as on the provisions we originally proposed at § 488.5(a)(18), § 488.5(a)(19), and § 488.8(e), noted that we were inconsistent in sometimes applying requirements to the situations of both voluntary and involuntary

terminations of an AO's Medicare accreditation program. We have attempted to remove these inconsistencies wherever we have identified them. One such inconsistency is that, while we originally proposed at § 488.8(e) to require AOs to notify their accredited providers and suppliers of both voluntary and involuntary terminations of their programs, proposed § 488.8(g) addressed continued deemed status only in the case of involuntary terminations. We believe that it would not be fair to ''deemed status'' providers and suppliers to extend their deemed status only in the case of involuntary terminations, and that we should instead afford them similar flexibility in the case of an AO's voluntary termination of its Medicare accreditation program. Accordingly in this final rule we have reorganized the provision to contain two paragraphs, one addressing continued deemed status in the case of an involuntary termination, and one addressing it in the case of a voluntary termination. Since, as previously discussed, we do not publish **Federal Register** notices of an AO's decision to voluntarily terminate its approved Medicare accreditation program, in this revised provision, in accordance with public comments, we provide that the 180 calendar day extension of deemed status would begin as of the effective date of the AO's voluntary termination. We are also taking this opportunity to add headings to § 488.8(g)(1) to clarify the different circumstances addressed in each of these provisions.

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

Comment: One commenter requested we provide as much advance notice as possible prior to an onsite visit, noting that the FDA provides 3 to 4 months advance notice as well as optional dates. A number of commenters suggested we revise this provision to indicate that the on-site visit will relate only to programs we have approved, that the scope be reasonable and that the visit not disrupt normal business operations. One commenter asked that we clarify and provide detail on ''auditing meetings,'' and asked whether the process would be different than the one CMS has previously followed. Another commenter stated the provision is too broad, potentially intrusive and an over-reach of government authority. This commenter proposed that the provision be revised to indicate that CMS has the authority to conduct an onsite visit at an AO's corporate office at a mutually agreed time and that the onsite inspection could include, but would not be limited to, the review of relevant documents and interviewing staff. By contrast, another commenter said that our onsite inspections should not be optional and should be conducted during both the application review and the ongoing review process, on a regular basis.

Response: Our proposal was not intended to modify our existing policy and practices for on-site inspections of accrediting organizations. Generally we work with an AO in advance to find a mutually convenient time for both our observation of surveys and our visit to their corporate offices, and we intend to continue to do so. However, we reserve the right to make an unannounced visit or survey observation, should there be circumstances that warrant our doing so. We also do not believe it is necessary to state in this provision that we only assess the performance of an AO's CMS-approved accreditation programs when we are on-site, since we believe that is clear in § 488.4. We are surprised by the comment that this provision is overly broad and overreaches our authority, since it is almost identical to the provision currently at § 488.9, which was last adopted on November 23, 1993 and which has not been a source of controversy. In our proposal we changed the term ''validation review process'' to ''ongoing review process,'' to conform to changes we made in § 488.8(a) through (c). We also added language making it explicit that we may conduct the onsite inspection at any time. Finally, we added language to make it explicit that we may observe accreditation surveys. The existing regulatory at § 488.9 already contains the following language: ''. . . 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, the evaluation of survey results or the accreditation decision-making process, and interviews with the organization's staff.'' We believe verification of all of these aspects of a Medicare accreditation program is necessary for us to determine whether the program meets or exceeds all applicable Medicare requirements, as required under section 1865 of the Act. For the commenter who called for these inspections to be mandatory, we believe that this is a matter best left to enforcement discretion. For example, if an AO has two CMS-approved Medicare accreditation programs with renewal dates in close proximity, to make efficient use of our limited resources, including travel resources, we have sometimes conducted only one corporate on-site visit to address both programs, although we continue to conduct separate survey observations. We also note that it is already our practice to conduct on-site inspections outside the application review process, when circumstances warrant our doing so, and we would continue to have the authority to do so under the revised regulation. After consideration of the public comments, we are in this final rule adopting this provision without change.

10. Validation Surveys (§ 488.9)

We proposed revising the title of this section, indicating that proposed § 488.9 sets out the language currently at § 488.7 addressing validation surveys. We stated that the regulatory language would remain unchanged, with the exception of deleting language related to a plan of correction that no longer reflects current SA practice; and deleting language regarding compliance with the LSC that would be duplicative of proposed language at § 488.12(a)(2). In addition, we proposed minor changes to conform this section to the rest of the final rule.

Comment: Several commenters stated this provision broadened the scope of the statutory provision governing substantial allegation validation surveys. They cited the statutory language, which authorizes the Secretary to enter into an agreement with states to survey ''. . . because of substantial allegations of the existence of a significant deficiency or deficiencies which would, if found to be present, adversely affect health and safety of patients . . .'' and suggested that this language is narrower than a ''substantial allegation of noncompliance.'' One commenter provided as an example that there may be a substantial allegation that a provider is noncompliant in dating and timing medical record entries, but this type of noncompliance does not rise to the level of a significant deficiency that affects health and safety. The commenter went on to state that CMS conducts between 3500 and 5000 complaint surveys in accredited

hospitals each year and yet only finds significant problems in 4 percent to 6 percent of those surveys, which is a tremendous waste of resources for the federal government and an unnecessary burden for hospitals.

Response: There has been no modification of our longstanding interpretation of the statutory language at section 1864(c) of the Act in our proposed rule and we are neither broadening nor narrowing the application of our statutory authority to conduct substantial allegation validation surveys. We note, however, that in response to similar comments we modified the definition of ''substantial allegation of noncompliance'' at § 488.1 in response. We did not, however, remove reference to substantial noncompliance by a provider or supplier with any applicable Medicare condition or requirement, because we believe such noncompliance adversely affects the health and safety of patients and thus an allegation of such noncompliance should be investigated by the SA. The commenter who gave the example of hospital medical record noncompliance related to dating and timing entries not rising to the level of endangering patient health and safety misunderstands the definition of a substantial allegation of noncompliance, since the allegation would have to represent substantial noncompliance with the hospital Medical Records CoP to be a substantial allegation warranting a validation survey. We would evaluate whether the manner or degree of noncompliance alleged appeared to suggest such substantial noncompliance with the Condition before authorizing a validation survey, since there could be cases where systemic failure of hospital staff to date and time medical record entries could, in fact, endanger the health and safety of the hospital's patients. We further note that in our response to comments on our proposed definition of ''substantial allegation of noncompliance'' at § 488.1 we indicated that we are revising revised the definition in this final rule to follow the Act's use of the term ''would'' instead of our proposed terminology suggesting that an allegation if present ''could or may'' affect the health and safety of patients and residents. This should reassure commenters who expressed concerns about the scope of substantial allegation validation surveys.

For wasting federal resources on substantial allegation validation surveys, we note for the record that the number of such surveys since FY 2012 has hovered around 3400, not 5,000, and that 7.4 percent have resulted in findings of substantial noncompliance. We also point out that the statutory and regulatory threshold for conducting a validation survey is not that an allegation must be accurate, but rather that if the alleged noncompliance was found to be present, it would represent substantial noncompliance. It is to be expected that a significant portion of substantial allegation surveys would not result in citations of substantial noncompliance, either because the allegation was never true, or because the provider or supplier corrected its deficient practices prior to our survey. We also note that we have been emphasizing in recent years to the states and our regional office staff that a complaint concerning a ''deemed status'' provider or supplier must meet the threshold of being a substantial allegation for a federal survey to be authorized. We also wish to point out that states often have broader authority to investigate complaints under their licensure authority, and that such state licensure complaint investigations are sometimes confused by providers or suppliers with federal substantial allegation validation surveys, since often the same personnel conduct both.

Comment: One commenter stated that hospitals report that it appears the numbers of citations have a direct impact on whether a validation survey is completed and that surveys not based on a representative sample cannot truly validate the AO's performance. Along these lines another commenter indicated that facilities selected by CMS for validation surveys have the least number of AO findings and that to be a truly representative sample, the validation survey site selection should not consider the number of findings on the accreditation survey, unless those findings meet the basis for a substantial allegation survey.

Response: We are puzzled as to what the commenters are referring, and their characterization of our selection process for validation surveys is inaccurate. At the time that we select providers or suppliers for inclusion in our representative sample for those validation surveys that are full surveys conducted within 60 days of the AO's accreditation survey the AO has not yet conducted its survey. Therefore, we do not and could not base our selection of the sample on an AO's findings.

Comment: A number of commenters reiterated their general criticisms of validation surveys conducted by states by stating that there is variation among the SAs in their survey findings and that state surveys should not be used as the benchmark for judging AO surveys.

Response: We addressed the substance of these criticisms in response to comments concerning § 488.8(a)(2) and believe our response is applicable here as well.

Comment: One commenter stated that validation surveys are essential to determine the adequacy of an AO's accreditation process and recommended that we require at least one validation survey annually for each year AO.

Response: Between the two different types of validation surveys under our current oversight program every AO has undergone more than one validation survey per year, with the exception of AOs that have only recently been approved for their first Medicare accreditation program. Further, section 1875 of the Act requires us to report annually on the performance of each CMS-approved Medicare accreditation program. Therefore, we do not believe it is necessary to include in the regulation a specific requirement as to the minimum number of validation surveys to be performed each year.

Comment: One commenter proposed CMS take immediate enforcement action related to deficiencies identified in a state substantial allegation validation survey instead of directing the SA to conduct another survey. The commenter indicated that a second survey is duplicative and wastes resources, and delays enforcement action that may negatively impact the health and safety of home health patients.

Response: We generally agree that it is preferable for us to take prompt enforcement action when a validation survey identifies substantial noncompliance with Medicare requirements, and we revised Chapter 5 of the SOM, concerning complaint investigations accordingly. Specifically, in sections 5110.2–2 and 5110.3 we clarify that we have the discretion to proceed immediately with enforcement action. However, when the validation survey was a substantial allegation validation survey that was narrowly focused assessing compliance with only a few of the applicable conditions, we believe that it is important for us to have the flexibility to exercise our enforcement discretion to determine whether the provider or supplier complies with a broader range, or even all, of the other Medicare conditions. After considering the public comments we are in this final rule adopting this provision with one technical correction at § 488.9(a)(2), to use the term ''substantial allegation of noncompliance'' rather than ''substantial allegation,'' to match the term used in the definition at § 488.1.

11. State Survey Agency Review: Statutory Provisions (§ 488.10)

We proposed to revise § 488.10 to implement section 125 of MIPPA (revising section 1865(a) of the Act) to clarify that our 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 SAs 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 proposed revising this provision by separating it into two separate provisions, § 488.10(c) and § 488.10(d). We proposed modifying this provision by updating the regulatory citation to implement changes associated with section 125 of MIPPA. We further proposed modifying this provision to make it clear that the regulations would apply to all national AOs with CMS-approved accreditation programs, and all provider or supplier types.

Comment: We received one comment from a commenter who stated that the statute requires that validation surveys fall into two categories and then quoted the exact language at section 1864(c) of the Act regarding the two types of validation surveys. The commenter called for our regulatory text to adhere more closely to the statutory language and recommended we reword the provision as follows: ''Section 1864(c) of the Act authorizes the Secretary to enter into agreements with SAs for the purpose of conducting validation surveys in institutions accredited by an accreditation program recognized by the Secretary on a selective sample basis, or where the Secretary finds that a survey is appropriate because of substantial allegations of the existence of a significant deficiency or deficiencies which would, if found to be present, adversely affect the health and safety of patients.''

Response: Both the existing and the proposed regulations refer to the two different types of validation surveys referred to in the Act, using the same language: ''conducted on a representative sample basis, or in response to substantial allegations of noncompliance.'' We assume the commenter is building on comments related to proposed § 488.9, which challenged the way in which substantial allegation validation surveys are characterized. Our responses to those comments apply here as well. After considering the public comments we are adopting this provision in this final rule without change.

12. State Survey Agency Functions (§ 488.11)

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

Comment: One commenter requested that we replace the term ''deemed facilities'' with ''deemed organizations,'' saying that not all health care providers operate out of a facility. This commenter also stated that the parameters for conducting validation surveys be the same as that which the commenter recommended for proposed § 488.9, namely that surveys be conducted on a representative sample basis without regard to the number of findings on an AO's survey or in response to substantial allegations which would, if found to be present, adversely affect health and safety of patients.

Response: We indicated our disagreement with the commenter's remarks concerning validation surveys in our response to the comments concerning proposed § 488.9, and our responses there apply equally to what is substantially the same comment here. For the provider's suggestion to substitute ''organizations'' for ''facilities,'' we believe that term is too broad and vague. We also believe the commenter's assumption that the term health care facility refers only to an organization that provides health care services within a ''bricks and mortar'' building is incorrect. However, in reviewing this comment we realized that our proposed language also was not technically precise or consistent with the definitions in part 488. In this final rule, therefore, we are replacing the term ''deemed facilities'' with ''deemed status providers and suppliers.''

13. Effect of Survey Agency Certification (§ 488.12)

Currently § 488.12 addresses provider or supplier certification recommendations made by the SA to CMS and § 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 SA. We proposed modifying this provision by inserting broader language to make it clear that the revised regulations pertain not to hospitals exclusively, but rather to all deemed status providers and suppliers. We further proposed modifying this provision for clarity and conforming changes. We received no comments on this proposal and are adopting it in this final rule without change.

14. Loss of Accredited Status (§ 488.13)

We proposed a new provision at § 488.13 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, whether voluntary or involuntary, by 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 to the provider's or supplier's non-payment of AO fees. We stated that the proposed new provision would address the timing of a SA survey in such circumstances. We received no comments in response to our proposal and are adopting it in this final rule without change.

15. Providers or Suppliers, Other Than SNFs and NFs, With Deficiencies (§ 488.28)

We proposed to revise § 488.28(a) to replace outdated language, such as referring to ''Medicare'' instead of the ''Health Insurance for the Aged and Disabled Program'' and to make explicit in the regulation our longstanding enforcement policy that in immediate jeopardy situations we may require a shorter timeframe for a provider or supplier to come into compliance. We stated that we believed it would be beneficial to make this practice explicit in this proposed rule.

Comment: Several commenters expressed concerns related to how immediate jeopardy is cited.

Response: These issues are addressed in section II.B.17. of this final rule in our discussion of the definition of ''immediate jeopardy'' at § 489.3 in this final rule.

We are also taking this opportunity to make a technical correction in this final rule, replacing the term ''the Secretary'' with ''CMS,'' to be consistent with our usage throughout this rule.

16. Statutory Basis (§ 489.1)

We proposed to revise § 489.1(b), which addresses the scope of part 489. We stated that this proposed revision

would expand which provisions of part 489 apply to suppliers that are subject to certification requirements as well as to providers. We indicated that currently § 489.1(b) indicates that only the regulations at § 489.13, governing the effective date of the provider agreement or supplier approval, are applicable to suppliers that require certification in accordance with § 488.3 and § 488.12 to participate in Medicare, as well as to all providers. We also reported that various supplier-specific rules in this chapter that require certification also establish requirements related to termination of the certified supplier's participation agreement with the Medicare program. However, only some of these supplier-specific certification rules provide for termination of the agreement where the certified 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 stated that we believe that this non-discrimination provision should also apply as a basis for termination of all Medicare-certified suppliers.

Likewise, we pointed out that 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. We indicated that 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 under 42 CFR 1001.1301(a). We stated it would be quicker and more efficient for us to handle such a denial or refusal of access to the certified supplier facility or copying of its records in the same manner as is currently used for providers, that is, CMS termination of the Medicare agreement.

Accordingly, we proposed amending § 489.1(b) to expand the enumeration of provisions of part 489 that apply to suppliers subject to certification, as well as to providers. Because these provisions would apply only to those types of suppliers that require certification and not to all suppliers, we proposed to include language in revised § 489.1(b) describing which types of suppliers would be affected, using the same language currently found at § 489.13. We stated that this language would indicate that the affected types of suppliers participate in Medicare based on surveys conducted by the SA or CMS surveyors, or on the basis of accreditation under a CMS-approved AO's Medicare accreditation program.

We also proposed redesignating the current language in § 489.1(b), which makes the effective date rules at § 489.13 applicable to certified suppliers as well as to providers, as new paragraph § 489.1(b)(1). Further, we proposed 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 in section II.B.18. of this final rule) would apply to certified suppliers as well as to providers.

We received no comments on the proposed revisions. However, we are making a technical correction in this final rule to add the definition of ''immediate jeopardy'' at § 489.3 as a provision that also applies to suppliers. Although this is clear in the wording of the definition itself, we believe to be consistent this should also be addressed in § 489.1 and are revising this latter provision in this final rule accordingly.

17. Definitions (§ 489.3)

We stated that the current 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.'' We indicated that this definition is identical to the one at § 488.301, which, in that context, applies only to long term care facilities, that is, NFs and SNFs. We also noted, however, that the current regulation at § 489.53(d) addresses exceptions permitted for the required notice of termination which we must provide to the provider or supplier. We indicated that 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. Thus, it has been our longstanding policy that the definition of immediate jeopardy at § 489.3 applies to all types of certified health care facilities and not just long term care facilities. Nevertheless, we proposed to revise the definition of immediate jeopardy at § 489.3 to make more explicit that it applies to all types of providers and as well as all types of suppliers subject to certification.

Comment: One commenter proposed to expand the definition to include harm to staff and visitors as well as residents and patients, saying that there are hazardous environments in imaging centers with Magnetic Resonance Imaging (MRI) suites or Computed Tomography (CT) scanners.

Response: We appreciate the commenter's concerns, but believe that it would inappropriately expand the scope of federal surveys to require assessment of potential harm to staff and visitors. An immediate jeopardy must involve non-compliance with a Medicare requirement, and these requirements are focused on the care services provided by a provider or supplier to patients or residents. We also suspect that it would ordinarily be the case that an environment that poses an immediate threat of serious harm to staff or visitors would also pose the same threat to patients or residents, and thus the protections afforded under our requirements to patients and residents would also benefit staff and visitors.

Comment: A number of commenters took issue with including in the definition the phrase ''likely to cause'' serious injury, harm, impairment of death. Most commenters indicated that they believe there is a great deal of subjectivity in the application of this definition, and that as a result there is considerable variability among states and CMS regional offices in immediate jeopardy citation practices. Some of these commenters called for removing the phrase ''likely to cause'' and limiting immediate jeopardy citations to those that have actually caused serious harm. Another commenter suggested substituting the phrase ''more likely than not.'' Some commenters did not request a modification of the definition, but did ask for more specific guidance in the SOM about examples of immediate jeopardy situations.

Response: Our proposal did not introduce the phrase ''likely to cause'' into the definition of immediate jeopardy; rather, this is a longstanding component of the existing definition. Moreover, we believe it is entirely appropriate and necessary for patient safety to treat as immediate jeopardy situations we identify that have the potential to cause serious harm if they are not addressed immediately, regardless of whether we are able to identify any harm already caused by the situation.

The commenters who called for more guidance may not be aware of the SOM, Appendix Q, ''Guidelines for Determining Immediate Jeopardy''. Among the guidance contained in this document is a discussion of the three

components that must all be present to cite immediate jeopardy: Potential or actual harm that is serious; immediacy; and culpability on the part of the provider or supplier. The Appendix provides a detailed, albeit not exhaustive, list of triggers that should lead surveyors to consider whether there is immediate jeopardy, as well as examples of hypothetical and real cases. We acknowledge that there is some variability in the tendency to cite immediate jeopardy, but continue to work with SAs and our Regional Office staff to achieve greater consistency. After consideration of the public comments we are in this final rule adopting this provision without change.

18. Termination by CMS (§ 489.53)

We proposed to revise § 489.53(a), which addresses the basis for us to terminate a Medicare provider agreement. We proposed deleting the language ''with any provider'' from the heading for this provision since we are proposing that several of the termination provisions apply to certified suppliers, as well as providers. We proposed 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 proposed 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 proposed 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. We stated that the current language at § 489.53(a)(2) applies only to providers.

We proposed 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. We stated that the current language at § 489.53(a)(13) applies only to providers.

Further, we proposed adding a new § 489.53(a)(18) to state explicitly that denial of immediate access to an SA or other authorized entity for the purpose of determining, in accordance with § 488.3, whether the provider or supplier meets the applicable requirements, CoPs, CfCs, or conditions for certification, may be grounds for termination of the provider agreement or supplier approval. We indicated that, 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 proposed a technical correction to § 489.53(d)(2)(i). We stated that § 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 § 489.53(d)(2) governs exceptions to the general timeframe in situations involving immediate jeopardy. We indicated that 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. We explained that 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 proposed 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). We stated that the current regulation refers to hospitals with emergency departments found in violation of § 489.24, paragraphs (a) through (e) rather than (a) through (f). We indicated that this proposed clarification would not change current EMTALA citation or enforcement practices.

Comment: One commenter expressed concern that inclusion of the term ''supplier'' would require physicians to accept all Medicare patients and that this is not authorized by statute. The commenter requested the provision be modified to indicate that it does not apply to physicians.

Response: We believe that revised § 489.1(b) makes it clear that the definition of ''immediate jeopardy'' at § 489.3 and the provisions at § 489.13, § 489.53(a)(2), § 489.53(a)(13), and § 489.53(a)(18) apply only to supplier entities which, for participation in Medicare, are subject to a determination by us on the basis of a state or AO survey, that is, suppliers that must be certified by us as meeting CoP, CfC, conditions for certification, or long term care requirements to participate in the Medicare program. Thus, we believe it is clear that the provisions of part 489 do not apply to those types of suppliers that are not subject to our survey and certification requirements. We note in particular that physician suppliers are not subject to surveys or other certification requirements as a condition for their participation in the Medicare program, and that none of the provisions of § 489.53 apply to physician suppliers.

We are making a technical revision in this final rule at § 489.53(a)(13) to replace the word ''photocopying'' with ''copying.'' As more providers and suppliers move from paper medical records to electronic health records, we envision that it could in some cases be more efficient for surveyors as well as providers and suppliers if surveyors obtain digital electronic copies of pertinent medical records, or portions thereof, as well as of any other documents that they require as evidence to support their findings of noncompliance. We believe that the term ''photocopying'' is becoming outdated and that it is preferable to use the more generic term ''copying.'' We are adopting in this final rule the other provisions of § 489.53 as proposed.

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. To date, there have only been a total of nine entities that meet the criteria necessary to become accrediting organizations with CMS-approved Medicare accreditation programs, with the ninth having just been added as recently as July, 2014. Should the number of eligible entities 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. Regulatory Impact Statement

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 $7.5 million to $38.5 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 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 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this 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 2014, that threshold level is currently approximately $141 million. This 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.

V. Waiver of Proposed Rulemaking

We generally publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule in accordance with 5 U.S.C. 553(b) of the Administrative Procedure Act (APA). The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substances of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

This final rule includes several technical corrections that were not included in the proposed rule and for which a notice-and-comment period is unnecessary, because they are purely technical and conforming, or because they clarify possible ambiguities in the proposed rule. Specifically, we are revising:

- § 488.2 to correct our characterization of the statutory reference at section 1832(a)(2)(J) of the Act to refer to ''Requirements for partial hospitalization services provided by CMHCs'' and at section 1881 of the Act to refer to ''Requirements for ESRD facilities'';
- § 488.3(a)(2) to correct a reference to ''parts 482 through 485'' to make the reference to ''parts ''482 through 486'', to cover other types of provider entities for which accreditation is permitted;
- § 488.4(a) not only in response to comments, but also to make a technical correction by referring to a national accreditation program as having ''applied for CMS approval of a provider or supplier accreditation program,'' rather than for ''approval to accredit providers and suppliers'';
- § 488.4(a)(11)(ii) to make stylistic changes and to change the order of two sentences in that provision;
- § 488.5(a)(4)(i) to add the word ''an'' prior to the word ''agreement'';
- § 488.5(a)(12) to clarify that referral to ombudsman or licensing bodies is expected when applicable;
- § 488.5(d)(1)(ii), which was located at § 488.5(e)(2) in our proposal, to remove language that was superfluous because it is already contained in the definition of ''reasonable assurance'';
- § 488.5(e)(2)(i) and (ii), which were located at § 488.5(f) in our proposal, to remove language that was superfluous because it is already contained in the definition of ''reasonable assurance'';
- § 488.6 to restore language that was located at § 488.5(b) and § 488.6(b) indicating that Medicare approval does not substitute for any additional requirements under Medicaid.
- § 488.8(b)(1)(iv) to appropriately cite its reference to a prior paragraph in the same section;
- § 488.8(b)(2)(iii) to enhance clarity and consistency by adding a provision parallel to that at § 488.8(b)(1)(v) indicating we may open an accreditation program review in the event of failure to comply with the requirements of § 488.8(b)(2)(i) and (ii).
- § 488.9(d) to correct a typographical error, changing ''publishes'' to ''publish''; and
- § 488.9(a)(2) to refer to a ''substantial allegation of noncompliance'' rather than to a ''substantial allegation,'' to correspond to the term for which we provide a definition at § 488.1.

The changes outlined in this section are purely technical, and a period of comment is unnecessary because the changes are either purely technical and conforming, or clarify possible ambiguities in the proposed rule. We do not believe any of these changes to be substantive. We believe it would be contrary to the public interest to delay codifying the technical corrections outlined in this section, and therefore find good cause to waive the notice of proposed rulemaking for the technical revisions and corrections.

List of Subjects

42 CFR Part 401

Claims, Freedom of information, Health facilities, Medicare, Privacy.

42 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 is amending 42 CFR chapter IV as set forth below:

PART 401—GENERAL ADMINISTRATIVE REQUIREMENTS

■ 1. The authority citation for part 401 continues to read as follows:

Authority: Secs. 1102, 1871, and 1874(e) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395w–5).

§ 401.126 [Amended]

■ 2. In § 401.126, amend paragraph (b)(2)(i) by removing the reference ''§ 488.6'' and by adding in its place the reference ''§ 488.5''.

§ 401.133 [Amended]

■ 3. In § 401.133, amend paragraph (d) by removing the references ''§ 488.5, § 488.6 or § 493.506'' and by adding in its place the references ''§ 488.5 or § 493.506''.

PART 488—SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

■ 4. The authority citation for part 488 is revised to read as follows:

Authority: Secs. 1102, 1128l, 1864, 1865, 1871 and 1875 of the Social Security Act, unless otherwise noted (42 U.S.C 1302, 1320a–7j, 1395aa, 1395bb, 1395hh) and 1395ll.

■ 5. Section 488.1 is amended by—
■ a. Removing the definitions of ''Accredited provider or supplier'' and ''AOA''.
■ b. Revising the definition of ''Certification''.
■ c. Adding the definitions of ''Conditions for certification'' and ''Deemed status'' in alphabetical order.
■ d. Revising the definition of ''Full review''.
■ e. Adding the definition of ''Immediate jeopardy'' in alphabetical order.
■ f. Removing the definition of ''JCAHO''.
■ g. Adding the definition of National accrediting organization'' in alphabetical order.
■ h. Revising the definitions of ''Provider of services or provider'', ''Reasonable assurance'', ''State survey agency'', and ''Substantial allegation of noncompliance''.
■ i. Removing the definition of ''Validation review period''.

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 means that CMS has certified a provider or supplier for Medicare participation, based on all of the following criteria having been met: The provider or supplier has voluntarily applied for, and received, accreditation from a CMS-approved national accrediting organization under the applicable Medicare accreditation program; the accrediting organization has recommended the provider or supplier to CMS for Medicare participation; CMS has accepted the accrediting organization's recommendation; and CMS finds that all other participation requirements have been met.

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 provider entities, as that term is defined in section 1865(a)(4) of the Act, under a specific program and whose accredited provider entities 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 (such as patient, relative, or third party), including complaints submitted in person, by telephone, through written correspondence, or in newspaper or magazine articles, that would, if found to be present, adversely affect the health and safety of patients or residents and raises doubts as to a provider's or supplier's compliance with any Medicare condition of participation, condition for coverage, condition for certification, or requirements.

* * * * *

■ 6. 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 services provided by CMHCs.

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 ESRD facilities.

1883—Requirements for hospitals that furnish extended care services.

* * * * *

■ 7. 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, part 416, part 418 subpart C, parts 482 through 486, part 491 subpart A, or part 494 of this chapter.

(b) *Special conditions.* The Secretary shall consult with state agencies and national AOs, as applicable, to develop CoP, CfC, 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.

■ 8. Section 488.4 is revised to read as follows:

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

(a) The following requirements apply when a national accrediting organization has applied for CMS approval of a provider or supplier accreditation program and CMS has found that the program provides reasonable assurance for providers or suppliers accredited under the program:

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

(2) CMS may deem the provider or supplier, excluding kidney transplant centers within a hospital and ESRD facilities, to be in compliance with the applicable Medicare conditions or requirements. The deemed status provider or supplier is subject to validation surveys as provided at § 488.9.

(b) [Reserved]

■ 9. 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 an agreement by the organization to re-survey every accredited provider or supplier, through unannounced surveys, no later than 36 months after the prior accreditation effective date, 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, in accordance with the applicable requirements or conditions of participation or conditions for coverage or certification.

(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 CoP, CfC, 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 information extracted from each accreditation survey for a specified provider or supplier as part of its data submissions required under paragraph (a)(11)(ii) of this section, a copy of all survey reports and related information for applicants seeking initial participation in Medicare, and, upon request from CMS, 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 two business days 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 to avoid conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys or participate in accreditation decisions.

(11) A description of the organization's data management and analysis system for 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. Data to be submitted includes, but is not limited to, accredited provider or supplier identifying information, survey schedules, survey findings, and notices of accreditation decisions. The organization must submit necessary data according to the instructions and timeframes CMS specifies.

(12) The organization's procedures for responding to, and investigating, complaints against accredited facilities, including policies and procedures regarding referrals when applicable to appropriate licensing bodies and ombudsman 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 decision to revoke, withdraw, or revise the accreditation status of a specific deemed status provider or supplier, within three 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) A schedule of all surveys expected to be conducted by the organization for the accreditation program under review during the 6-month period following submission of the application.

(16) 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.

(17) A statement that it will:

(i) Provide written notification to CMS and 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, including the implications for their deemed status in accordance with § 488.8(g)(2); and

(ii) Adhere to the requirements for written notice to its accredited providers or suppliers at § 488.8(e) in the case of an involuntary termination.

(18) A statement that it will provide written notification to CMS of any proposed changes in the organization's CMS-approved accreditation program and that it agrees not to implement the proposed changes without prior written notice of continued program approval from CMS except as provided for at § 488.8(b)(2).

(19) A statement that, in response to a written notice from CMS to the organization of a change in the applicable conditions or requirements or in the survey process, the organization will provide CMS with proposed corresponding changes in the organization's requirements for its CMS-approved accreditation program to ensure continued comparability with the CMS conditions or requirements or survey process. The organization must comply with the following requirements:

(i) The proposed changes must be submitted within 30 calendar days of the date of the written CMS notice to the organization or by a date specified in the notice, whichever is later. CMS will give due consideration to an organization's request for an extension of the deadline.

(ii) The proposed changes will not be implemented without prior written notice of continued program approval from CMS, except as provided for at § 488.8(b)(1)(iv).

(20) A statement acknowledging that, as a condition for CMS's approval of an accreditation program, the organization will agree to permit 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, and will cooperate with CMS to make surveyors and other staff available when needed.

(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 (e)(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 accrediting organization must notify CMS of its decision to voluntarily terminate its approved accreditation program at least 90 calendar days in advance of the effective date of the termination. In accordance with the requirement at § 488.4(a)(17)(i), the accrediting organization must also provide written notice at least 90 days in advance of the effective date of the termination to each of its deemed status providers or suppliers.

(d) *Re-submitting a request.* (1) Except as provided in paragraph (d)(2) 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 satisfies all of the following requirements:

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

(ii) Demonstrates that it can provide reasonable assurance.

(iii) Resubmits the application in its entirety.

(2) 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 a new application for approval of an accreditation program for the type of provider or supplier at issue in the reconsideration until the reconsideration is administratively final.

(e) *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 AO's applications was complete, unless the application was for a skilled nursing facility accreditation program. There is no timeframe for publication of a final notice for a national accrediting organization's application for approval of a skilled nursing facility accreditation program. 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 notices describes how the accreditation program provides reasonable assurance. 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, except in the case of a skilled nursing facility accreditation program, how the organization fails to provide reasonable assurance. In the case of an application for a skilled nursing facility accreditation program, disapproval may be based on the program's failure to provide reasonable assurance, or on CMS's decision to exercise its discretion in accordance with section 1865(a)(1)(B) of the Act. The final notice specifies the effective date of the decision.

■ 10. 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 if they are not required under Medicaid regulations to comply with any requirements other than Medicare participation requirements.

§ 488.9 [Removed]

■ 11. Section 488.9 is removed.

§ 488.7 [Redesignated as § 488.9]

■ 12. Section 488.7 is redesignated as new § 488.9.

■ 13. New § 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.

■ 14. 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 SA.

(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 Medicare requirements if the following conditions exist:

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

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

(ii) CMS specifies in its written notice a timeframe, not less than 30 calendar days from the date of the notice, for the accrediting organization to submit its proposed equivalent changes, including its implementation timeframe, for CMS review. CMS may extend the deadline after due consideration of a written request for extension by the accrediting organization, submitted prior to the original deadline.

(iii) After completing the comparability review CMS provides written notification to the organization whether or not the accreditation program, including the proposed revisions and implementation timeframe, continues to meet or exceed all applicable Medicare requirements.

(iv) If, no later than 60 calendar days after receipt of the organization's proposed changes, CMS does not provide the written notice to the organization required in paragraph (b)(1)(iii) of this section, then the revised program will be deemed to meet or exceed all applicable Medicare requirements and to have continued CMS approval.

(v) If an organization fails to submit its proposed changes within the required timeframe, or fails to implement the proposed changes that have been determined by CMS or deemed to be comparable, 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 of any proposed changes in its accreditation requirements or survey process and must not implement any changes before receiving CMS's approval, except as provided below.

(ii) If, no later than 60 calendar days after receipt of the organization's proposed changes, CMS does not provide written notice to the organization that the accreditation program, including the proposed revisions, continues or does not continue to meet or exceed all applicable Medicare requirements, then the revised program will be deemed to meet or exceed all applicable Medicare requirements and to have continued CMS approval.

(iii) If an organization implements changes that have neither been determined by CMS nor deemed to be comparable to the applicable Medicare requirements, CMS may open an accreditation program review in accordance with paragraph (c) of this section.

(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 publish 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 must notify, in writing, each of its accredited providers or suppliers of the withdrawal of CMS approval and the implications in accordance with paragraph (g)(1) of this section for the providers' or suppliers' deemed status no later than 30 calendar days after the notice 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.* (1) *Involuntary termination.* 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 also provide written notice to the SA that it has submitted an application for accreditation under another CMS-approved accreditation program within this same 60-calendar day timeframe. Failure to comply with the timeframe requirements specified in this section will place the provider or supplier under the SAs authority for continued participation in Medicare and on-going monitoring.

(2) *Voluntary termination by accrediting organization.* When an accrediting organization has voluntarily terminated its CMS-approved accreditation program and provides its accredited providers and suppliers the notice required at § 488.5(a)(17), an affected provider's or supplier's deemed status continues in effect for 180 calendar days after the termination effective date if the provider or supplier submits an application to another CMS-approved accreditation program within 60 calendar days from the date of the notice from the accrediting organization. The provider or supplier must also provide written notice to the SA that it has submitted an application for accreditation under another CMS-approved accreditation program within this same 60-calendar day timeframe. Failure to comply with the timeframe requirements specified in this section will place the provider or supplier under the SAs 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.

■ 15. 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 of noncompliance, the SA 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 SA that performs the validation survey.

(2) If a provider or supplier selected for a validation survey fails to cooperate with the SA, it will no longer be deemed to meet the Medicare conditions or requirements, but will be subject to a review by the SA 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 SA in accordance with § 488.10(a) until the provider or supplier demonstrates compliance.

(2) CMS may take actions for the deficiencies identified in the state validation survey in accordance with § 488.24, or may first direct the SA 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 CoP, CfC, 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.

■ 16. 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.

■ 17. 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 status providers and suppliers as provided in § 488.9.

* * * * *

■ 18. 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 SA and subject to further enforcement actions in accordance with the provisions at § 488.9.

* * * * *

■ 19. 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 SA will conduct a full review in a timely manner.

■ 20. 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 CMS. In the case of an immediate jeopardy situation, CMS may require a shorter time period for achieving compliance.

* * * * *

PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

■ 21. 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 1395hh).

■ 22. 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 SA or CMS surveyors; or, in lieu of an SA or CMS-conducted survey, accreditation by an accrediting organization whose program has CMS approval in accordance with the requirements of part 488 of this chapter at the time of the accreditation survey and accreditation decision, in accordance with the following:

(1) The definition of immediate jeopardy at § 489.3.

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

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

* * * * *

■ 23. 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 conditions for certification has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident or patient.

* * * * *

■ 24. Section 489.53 is amended by revising paragraphs (a) introductory text, (a)(2), (a)(13), and (d)(2)(i) introductory text and adding a new paragraph (a)(18) to 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), (13) and (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 copying of any records or other information by, or on behalf of, CMS, as necessary to determine or verify compliance with participation requirements.

* * * * *

(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—

* * * * *

Dated: March 18, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: May 12, 2015.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

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