



Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-09-08

DATE: October 17, 2008

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Accreditation and its Impact on Various Survey and Certification Scenarios

Memorandum Summary

- Almost 7,000 providers and suppliers currently participate in Medicare via deemed status through a Centers for Medicare & Medicaid Services (CMS)-recognized Accreditation Organization (AO), and the number is growing.
- CMS has developed a comprehensive set of frequently asked questions (FAQs) and responses related to the impact of a provider/supplier's accreditation status on various survey and certification activities. Although much of this guidance may be found in various sections of the State Operations Manual (SOM) or in previous Survey and Certification policy memoranda, the FAQs make this information available in one document. In some areas CMS has updated its guidance; the FAQs represent current CMS policy with respect to certification of accredited health care facilities.
- Additionally, new and amended exhibits are attached related to enforcement actions following upon validation surveys based on a representative sample.

Currently there are seven national accreditation organizations (AOs) that offer accreditation programs that are recognized by CMS for purposes of certifying the compliance of almost 7,000 hospitals, critical access hospitals, ambulatory surgical centers, home health agencies, and hospices with Medicare health and safety standards. CMS "deems" these accredited health care facilities as having satisfied the health and safety standards component of the Medicare certification process by virtue of their accreditation through a CMS-recognized "deemed status" program. Furthermore, deemed status facilities remain under the jurisdiction of their AO rather than State Survey Agencies (SAs) for oversight of their ongoing compliance with health and safety standards, unless SAs conducting a validation survey at the direction of CMS find evidence of serious noncompliance.

Questions arise frequently on the role that “deemed status” accreditation plays in CMS’ various survey and certification decisions and processes. Currently the SOM addresses some, but not all of these questions. In addition, some SOM guidance requires updating to reflect CMS policy more precisely. Accordingly, the attached set of FAQs has been prepared to provide comprehensive guidance on the interaction of a health care facility’s accreditation by a CMS-recognized AO “deemed status” accreditation program and the various survey and certification actions that CMS may take with respect to that facility. We will be revising the SOM to incorporate this updated guidance at a later date.

We have also revised or added new SOM Exhibits related to facilities that participate in Medicare via accredited, deemed status. Enclosed for your information are advance copies of Exhibits 37, 196, and 287.

Effective Date: Immediately. Please ensure that all appropriate staff are fully informed within 30 days of the date of this memorandum.

Training: The information contained in this letter should be shared with all survey and certification staff, their managers, and the State/RO training coordinators.

/s/
Thomas E. Hamilton

Attachments: (4)

cc: Survey and Certification Regional Office Management

Attachment A

Accreditation Organizations and Medicare Certification Procedures

Frequently Asked Questions

Note: References to current provisions of Publication 100-7, the State Operations Manual (SOM) are provided where possible. In some instances the guidance provided in this document supersedes or expands upon these SOM provisions. Where there are differences, the guidance in this document represents CMS' policy. The SOM provisions will be revised at a later date.

I. OVERVIEW

I-1. Question: What is the definition of an accredited provider or supplier?

Answer: For the purposes of 42 CFR Part 488, governing Medicare's health care facility survey, certification, and enforcement procedures, §488.1 defines an accredited provider or supplier to mean "a provider or supplier that has voluntarily applied for and has been accredited by a national accreditation program meeting the requirements of and approved by CMS in accordance with §488.5 or §488.6."

I-2. Question: What relevance is accreditation to a health care facility's participation in the Medicare program?

Answer: Previously, in accordance with Section 1865(a) of the Social Security Act (SSA) as it was codified prior to July 15, 2008, any hospital accredited by The Joint Commission (JC, formerly known as the Joint Commission on Accreditation of Healthcare Organizations or JCAHO) is "deemed" to have satisfied the Medicare Hospital Conditions of Participation (CoPs), i.e., Medicare's health and safety standards, if that hospital agrees that JC may release to CMS the most recent accreditation survey or any other information related to the survey. The Medicare Improvements for Patients and Providers Act (MIPPA), enacted July 15, 2008, removed the statutory status of the Joint Commission's hospital program, effective July 15, 2010, putting it on the same footing as all other national accreditation programs.

Section 1865(a) (previously Section 1865(b), renumbered under MIPPA) of the SSA further provides that CMS may recognize national accreditation organizations (AOs) which demonstrate that their health and safety standards and survey and oversight processes meet or exceed those used by CMS to determine a health care facility's compliance with applicable Medicare CoPs or Conditions for Coverage (CfCs). These provisions also apply to the non-hospital accreditation programs of the JC, and after July 15, 2010 will also apply to the JC's hospital accreditation program.

A health care facility that is accredited for Medicare participation purposes by one of the CMS-recognized AOs may be "deemed" by CMS to have satisfied Medicare's health and safety standards. For such facilities, the State Survey Agency (SA) does not conduct a survey to certify or recertify the compliance of the facility with the applicable Medicare CoPs or CfCs. Rather, such facilities remain under the jurisdiction of the AO, not the SA, for oversight of their ongoing

compliance, unless the SA conducts a validation survey at the direction of CMS and CMS determines, as a result of this survey, that the health care facility fails to comply with one or more CoPs or CfCs.

I-3. Question: Are all types of institutional providers and suppliers eligible to participate in Medicare via “deemed status?”

Answer: 42 CFR §§488.5 and 488.6 permit participation via deemed status for ambulatory surgical centers; comprehensive outpatient rehabilitation facilities; critical access hospitals; home health agencies; hospices; hospitals; clinics, rehabilitation agencies or public health agencies providing outpatient physical therapy, occupational therapy or speech pathology services; psychiatric hospitals; religious nonmedical health care institutions; rural health clinics; screening mammography services; skilled nursing facilities; and transplant centers, except for kidney transplant centers.

However, to date AOs have applied for and been approved by CMS only for the following provider/supplier types: ambulatory surgical centers, critical access hospitals, home health agencies, hospices, and hospitals.

Other Medicare provisions allow for accreditation of other provider or supplier types, e.g., clinical laboratories or durable medical equipment. Such providers or suppliers are subject to different Medicare participation requirements than are institutional health care providers or suppliers, and are not covered by these FAQs.

I-4. Question: What AOs have Medicare “deemed status” programs currently recognized by CMS?

Answer: As of October 1, 2008 there are seven AOs recognized for a total of 13 CMS-recognized deemed status programs, in addition to JC’s statutorily sanctioned hospital program.

Current CMS-recognized “Deemed Status” Accreditation Programs

Organization	Program Type
Accreditation Association for Ambulatory Health Care (AAAHC)	ASCs
Accreditation Commission for Health Care, Inc. (ACHC)	HHAs
American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF)	ASCs
American Osteopathic Association (AOA) Healthcare Facilities Accreditation Program (HFAP)	ASCs CAHs Hospitals
Community Health Accreditation Program (CHAP)	HHAs Hospices
Det Norske Veritas (DNV)	Hospitals
The Joint Commission (JC)	ASCs CAHs HHAs Hospices Hospitals

I-5. Question: If MIPPA removed the JC’s statutory hospital deeming authority, what does this mean for Medicare-participating hospitals currently accredited by the Joint Commission, or hospitals seeking to enroll in Medicare for the first time via Joint Commission deemed status?

Answer: Under a transition provision in MIPPA, the Joint Commission’s hospital deeming authority remains in force through July 15, 2010. Up until that date, CMS will accept a hospital’s evidence of Joint Commission accreditation as sufficient for Medicare deemed status. This applies to hospitals currently enrolled in Medicare as well as those seeking initial enrollment. In addition, MIPPA also provides that even after July 15, 2010, a hospital whose participation was based on Joint Commission accreditation issued prior to that date will continue to participate in Medicare via deemed status until the normal expiration date of its accreditation. As an example, a hospital could have its Joint Commission accreditation renewed for three years on July 10, 2010. In this scenario, the hospital’s Medicare deemed status participation would continue until July 10, 2013, unless the hospital’s deemed status is removed as a result of a validation survey. See Section V below.

I-6. Question: What will happen to the Joint Commission’s hospital deeming program after the transition period provided in MIPPA?

Answer: The Joint Commission has gone on record indicating its intent to apply for CMS recognition of its hospital accreditation program for Medicare deeming purposes. The Joint Commission will be required to follow the standard process outlined in regulation at §488.4 that CMS employs for all accreditation organizations seeking recognition by CMS for Medicare deeming purposes. This process involves submission of an application containing detailed information about the Joint Commission’s hospital program standards, their comparability to Medicare’s health and safety standards, the Joint Commission’s survey process, etc. When CMS receives a complete application from an accreditation organization seeking initial approval or renewal of its deeming authority, CMS publishes a notice in the Federal Register, inviting comment on the application. After completing its review of all aspects of the application, including comments from the public and conduct of an on-site inspection of the Joint Commission’s corporate headquarters and observation of a Joint Commission hospital survey, CMS will publish its final decision on the Joint Commission’s application in the Federal Record.

I-7. Question: Does CMS review or regulate the fees charged by an AO to providers/suppliers seeking accreditation?

Answer: No. CMS has no jurisdiction over the fees charged by AOs.

I-8. Question: If a health care facility is accredited by an AO, does that always mean that it may seek Medicare participation via “deemed status?”

Answer: No. This is an area where there is considerable confusion. AOs frequently offer, in addition to their CMS-recognized deemed status accreditation program, other accreditation program(s) for a particular type of provider or supplier that are not recognized by CMS. AOs may charge providers/suppliers differential fees for the different types of accreditation. For Medicare participation purposes, the health care facility must be accredited under the AO’s CMS-recognized deemed status accreditation program. Thus, it is not sufficient for a health care facility seeking Medicare participation to document that it is accredited; it must document that a

CMS-recognized AO has accredited it under its recognized deemed status program and that the AO has recommended that CMS grant the facility certification via deemed status.

II. INITIAL ENROLLMENT IN MEDICARE

II-1. Question: If a health care provider/supplier is accredited by a CMS-recognized AO under a deemed status program, is it automatically enrolled in Medicare?

Answer: No. The provider/supplier must complete the standard CMS enrollment and initial certification process and satisfy all applicable federal requirements before it can be enrolled in Medicare. The only difference between a facility with a deemed status accreditation and other facilities is that the AO's recommendation to CMS for the facility to participate via deemed status substitutes for the SA's certification of compliance with the applicable CoPs or CfCs.

II-2. Question: Must an AO wait until the fiscal intermediary (FI) or Medicare Administrative Contractor (MAC) has notified the CMS Regional Office (RO) and SA of the results of its review of a provider's/supplier's CMS 855 enrollment application before the AO can conduct an initial survey to determine compliance with the applicable CoPs or CfCs?

Answer: An AO may not conduct an initial survey of a provider or supplier for Medicare certification purposes until the FI/MAC has completed its initial review of the CMS 855 and made a recommendation for approval to CMS. CMS requires AOs subject to its oversight to employ a survey process that is comparable to the one CMS uses with SAs. CMS instructs SAs in Section 2003B of the SOM to wait until it receives notice from the FI/MAC that it has completed its review of the CMS 855A or 855B, as applicable, before the SA conducts an initial survey. Accordingly, AOs must also wait until the FI/MAC has made its recommendation before it conducts an initial survey.

The FI/MAC gives the provider/supplier notice when its review has been completed; the notice may be in writing or oral. AOs should inform providers/suppliers seeking to participate in Medicare via the AO's Medicare accreditation program that surveys will not take place until after the applicant has received notice from the MAC/FI that it has completed its review of the CMS-855A or 855B. (If the MAC/FI notice is a denial based on a deficiency identified in the review of the CMS 855, then the AO should not proceed with a survey.)

II-3. Question: Can CMS provide the AO a copy of the notice the FI/MAC sends to the SA and RO?

Answer: Documents that the FI/MAC provides to the SA and CMS RO indicating it has finished processing the application of a provider or supplier and making a recommendation regarding enrollment are internal communications among CMS and its contractors. The FI/MAC has the discretion to send a copy of its communication to the SA and RO to the applicant provider/supplier, but generally will not do so if there is any sensitive information in the communication. AOs are not entitled to receive copies of the FI/MAC communications from CMS. The AO should work with the health care facility to get a copy of the notice the FI/MAC sends directly to the applicant indicating that it has completed its portion of CMS' review of the application. In those instances where the FI/MAC has provided oral instead of written notice to

the applicant, the AO should request that the health care facility provide the AO details of the oral notice, including at a minimum the date and time of the notice and the name of the FI/MAC providing the notice.

II-4. Question: Who does the AO notify when it grants accreditation and recommends Medicare certification via deemed status for a provider/supplier seeking initial certification to participate in Medicare?

Answer: The AO is required to notify CMS whenever it newly accredits and recommends Medicare deemed status for a provider/supplier. This notice must be given to both Central Office (CO) and the applicable RO. However, AOs should be aware that the provider/supplier must also provide documentation of the AO's accreditation decision to the SA as part of the certification packet it submits through the SA to the RO. Therefore, AOs should also provide the provider/supplier with a copy of the letter from the AO to CMS, with instructions for the provider/supplier to furnish this documentation to the SA for inclusion in the applicant's certification packet.

II-5. Question: May an AO accredit a facility and recommend Medicare certification for purposes of the facility's initial enrollment in the Medicare program when it finds noncompliance with the AO's accreditation standards?

Answer: The AO's accreditation program must provide reasonable assurance that entities accredited by the AO meet Medicare requirements. CMS evaluates and reviews AOs seeking recognition of their accreditation programs for Medicare participation on a number of factors specified in 42 CFR §488.8, including the AO's accreditation standards, survey and oversight processes, and their comparability to CMS' standards and processes. Accordingly, CMS requires AOs to employ the same approach when recommending providers/suppliers to CMS for initial Medicare program participation as is used by CMS, in accordance with 42 CFR §489.13, when a SA conducts the initial Medicare survey. Specifically, before the AO can issue accreditation and a recommendation to CMS that a provider/supplier seeking initial enrollment in Medicare be "deemed" to meet Medicare's health and safety standards, the AO must conduct a survey and determine that the applicant meets all applicable Medicare CoPs or CfCs. (The Joint Commission's hospital program has not been subject to this requirement, due to its prior statutory status. However, after July 15, 2010, the Joint Commission's hospital accreditation program will also have to comply with this approach as well as other requirements in order to be recognized by CMS as having deeming authority.)

- If the AO finds the applicant has the equivalent of condition-level deficiencies, the AO must receive an acceptable plan of correction (POC) and conduct a revisit survey to verify that the deficiencies have been corrected and the applicant is in compliance before recommending the applicant for Medicare certification via deemed status. The AO's effective date of its deemed status accreditation may not be prior to the date the AO has verified the correction of the deficiencies.
- If the applicant is in substantial compliance, but has deficiencies below the condition level, then the AO must receive an acceptable POC for such deficiencies and may not make the effective date of its deemed status accreditation prior to the date of receipt of a POC that the AO finds acceptable.

II-6. Question: What role does accreditation play if an accredited hospital that has been deemed to meet Medicare’s CoPs seeks classification as an Inpatient Prospective Payment System (IPPS)-excluded hospital (such as a psychiatric hospital, rehabilitation hospital, long term care hospital, etc.), or if it seeks classification of one of its units as an IPPS-excluded psychiatric or rehabilitation inpatient unit?

Answer: The criteria for exclusion from IPPS used for short-term acute care hospitals are Medicare payment-related criteria, except in the case of psychiatric hospitals. There is no statutory authority for AOs to accredit hospitals or hospital units so that the facilities may be deemed to satisfy Medicare payment criteria; the statutory authority for AOs accrediting hospitals extends only to the health and safety requirements, i.e., the CoPs. This is the case even when some of Medicare’s payment-related criteria also could be viewed as having an impact on patient health and safety. Accredited hospitals seeking IPPS-exclusion for the whole hospital or for excluded units may be deemed to satisfy the Hospital CoPs, but they must undergo additional review by the CMS RO to determine their eligibility for IPPS exclusion.

- In the case of psychiatric hospitals, although 42 CFR 488.6 permits their participation via deemed status, to date no AOs have applied for CMS recognition of a psychiatric hospital accreditation program. Accreditation through a CMS-recognized deemed status hospital accreditation program suffices to demonstrate the psychiatric hospital’s compliance with the basic hospital CoPs, but CMS must separately verify the hospital’s compliance with the special CoPs for psychiatric hospitals before such hospitals may be certified to participate in Medicare.

II-7. Question: In the case of a home health agency (HHA) seeking to participate in Medicare on the basis of a CMS-recognized accreditation program, how are the OASIS requirements verified?

Answer: The SA continues to be responsible for determining whether the HHA meets the OASIS requirements. HHAs seeking initial Medicare certification through a deemed status survey must apply to the SA for user identification numbers and passwords to demonstrate compliance with OASIS submission requirements. (See Section 2210B of the SOM). The AO should not conduct a deemed status survey until the HHA provides documentation that it has transmitted an OASIS test report correctly to the SA.

II-8. Question: May a provider/supplier that is seeking to participate in Medicare and was determined by a SA survey to have failed to demonstrate compliance with Medicare health and safety standards subsequently enter the Medicare program via a recommendation by an AO for “deemed status”?

Answer: A health care facility that failed to demonstrate compliance with Medicare health and safety standards when surveyed by a SA can subsequently seek Medicare certification through a Medicare deemed status survey conducted by an AO. Under these circumstances, the RO must be assured that the deficiencies identified by the SA have been corrected. The procedure CMS follows is the same whether the subsequent survey is conducted by a SA or an AO, and is governed by 42 CFR 489.13(c)(2). In accordance with 42 CFR 488.5(c), for Joint Commission-accredited hospitals, or 42 CFR 488.6(c), for all other accredited facilities, the provider/supplier must authorize the AO to release its most current survey results to CMS. The RO may, therefore, ask the AO to submit its detailed survey findings for the RO’s review. In accordance

with these same regulations, the RO may seek further information and clarification from the AO by interview if the matter remains unclear.

If the AO is aware that the health care facility seeking accreditation for enrollment in Medicare via deemed status was previously found by a SA survey to have condition-level deficiencies, it should ask the facility to provide the AO with a copy of the form CMS 2567 identifying the deficiencies the SA found. This would assist the AO in the conduct of its deemed status survey and in making its subsequent recommendation to CMS. If the health care facility does not provide the CMS-2567 to the AO, the AO may also request the CMS-2567 from the SA, which will follow standard procedures governing the release of a CMS-2567.

The RO will, after reviewing the AO's survey findings and related information, determine whether the health care facility does or does not meet all Medicare requirements. The RO may authorize the SA to conduct a focused validation survey to determine whether the original deficiencies have been corrected before the RO makes its decision. However, in light of constrained resources and the lower priority accorded initial surveys for provider/supplier types that have an accreditation option for entering the Medicare program, ROs will not routinely ask SAs to conduct such follow-up surveys. These same resource constraints also mean that relatively few SAs should be conducting initial surveys of providers/suppliers that have an accreditation option. See CMS survey and certification policy memo S&C-08-03, November 5, 2007, which reiterates CMS' longstanding policy that surveys of providers/suppliers seeking initial enrollment in the Medicare program and which have the option of accreditation in lieu of a SA survey are Tier 4 priority work for the SAs. SAs must accomplish their higher tier work first. Depending on the resources available to CMS for survey and certification activities of SAs, it may not be possible for a SA to conduct initial surveys for new providers/suppliers who have an accreditation option. Thus, we do not anticipate the situation described in the question will occur frequently.

II-9. Question: Is there an established timeframe during which a health care facility that has been denied accreditation by one AO is prohibited from going to another AO?

Answer: In the case of an initial application to participate in Medicare, a provider/supplier may go to another AO with an approved deemed-status accreditation program after failing an accreditation survey by the first AO. AOs are encouraged to notify CMS, both CO and the applicable RO, when a health care facility fails to meet Medicare's health and safety requirements and is denied accreditation. After receiving such notice and a subsequent recommendation from another AO that the provider/supplier be deemed as meeting the Medicare requirements, the RO will proceed in the same manner as in the case of failure to pass an initial SA survey under 42 CFR §489.13(c).

II-10. Question: Is there any rule that prohibits a provider/supplier seeking initial Medicare certification from going from an AO to a SA for a survey if the provider/supplier fails the AO's accreditation survey for Medicare?

Answer: There is no prohibition against an applicant provider/supplier going to the SA after failing an accreditation survey from an AO. However, due to constrained SA resources and the lower priority CMS has assigned to initial surveys (see response to question II-8), it is unlikely that the SA will be able to conduct an initial survey for a provider with an AO option in a timely manner. In the case of an existing provider/supplier that was deemed on the basis of its

accreditation, see the FAQs concerning what happens when the AO terminates its accreditation of a provider/supplier due to failure to comply with health and safety standards.

II-11. Question: Do these policies on initial enrollment apply to all provider/supplier types that may participate in Medicare via accreditation by an AO?

Answer: The same policies apply to all institutional provider/supplier types subject to survey and certification requirements for which there are CMS-recognized AO deemed status programs; they do not apply to clinical laboratory or durable medical equipment accreditation programs.

II-12. Question: How is the effective date for participation in Medicare determined?

Answer: In accordance with 42 CFR 489.13(a)(1), for providers and suppliers that are subject to survey and certification requirements or are deemed to meet Medicare requirements via accreditation by a CMS-recognized AO, the RO determines the effective date for participation in Medicare based on the following regulations at §489.13(b) and (c)(2):

“(b) All Federal requirements are met on the date of survey. The agreement or approval is effective on the date the survey (including the Life Safety Code survey, if applicable) is completed, if on that date the provider or supplier meets all applicable Federal requirements as set forth in this chapter. (If the agreement or approval is time-limited, the new agreement or approval is effective on the day following expiration of the current agreement or approval.)

(c) All Federal requirements are not met on the date of survey. If on the date the survey is completed the provider or supplier fails to meet any of the requirements specified in paragraph (b) of this section, the following rules apply:

(1).....

(2) For an agreement with, or an approval of, any other provider or supplier, (except those specified in paragraph (a)(2) of this section), the effective date is the earlier of the following:

(i) The date on which the provider or supplier meets all requirements.

(ii) The date on which a provider or supplier is found to meet all conditions of participation or coverage, but has lower level deficiencies, and CMS or the State survey agency receives an acceptable plan of correction for the lower level deficiencies, or an approvable waiver request, or both. (The date of receipt is the effective date regardless of when CMS approves the plan of correction or the waiver request, or both.)”

III. PROVIDER-BASED STATUS AND SATELLITES

III-1. Question: What happens when an accredited deemed status hospital or Critical Access Hospital (CAH) creates/acquires an off-site provider-based entity/department/remote location or an accredited IPPS-excluded hospital creates a satellite facility?

Answer: Provisions governing satellite facilities and provider-based status are established in Medicare payment rules. See 42 CFR 412.22(h) for a definition of “satellite facilities” and 42

CFR 413.65 for definitions and requirements related to provider-based status. To the extent that additional locations of a provider would be covered under an existing provider agreement, there are survey and certification implications related to such payment policy issues. For example, there are CoP requirements specific to CAHs found at 42 CFR 485.610(e) that govern provider-based status and co-location issues.

CMS follows a similar survey and certification policy for accredited, deemed hospitals or CAHs as it uses for non-deemed ones when they add off-site locations. Whether or when a survey of the new location is conducted *generally* will not affect the timing of when Medicare payments for services at the new site begin, since the creation/acquisition of the off-site location is under the hospital or CAH's existing provider agreement. Although CMS has the authority to conduct a survey of the expanded portion of the hospital/CAH, a survey may not be necessary if the provider furnishes the RO with sufficient information to make a determination about its proposed expansion, either at the time of its initial request or subsequently. In the case of a non-accredited, non-deemed hospital or CAH, if the RO believes a survey is required, it will request an SA survey of the off-site location. Generally, CMS will require a survey where new locations provide inpatient or surgical services, or, in the case of an acquisition of an existing participating provider, where the RO has concerns about that provider's compliance with Medicare's health and safety standards. If the SA conducts the survey of the new site and finds condition-level non-compliance, then standard enforcement action is taken against the whole hospital. (Section 3224 of the SOM will be updated to reflect this guidance).

In the case of an accredited, deemed hospital or CAH that creates or acquires an off-site facility for which it seeks provider-based or satellite status, the AO may enter into an agreement with the provider/supplier to "extend" the hospital's or CAH's accreditation to the expanded facility(ies). In such cases, CMS expects the AO to conduct a survey of the facilities covered by the extension agreement within six months of the date of the agreement. (See Section 3210.1C of the SOM) If the RO has specific concerns about the expanded facility's compliance with health and safety standards, however, it may request an earlier survey date by the AO and/or authorize a SA validation survey.

Note: If a Medicare-participating hospital or CAH, whether deemed or non-deemed, acquires a provider that already participates in Medicare but does not assume that provider's Medicare provider agreement, then a survey of the new location is required after the acquisition and before payment for services begins at the new location. In such a case involving acquisition by an accredited, deemed provider without assumption of the provider agreement, an AO may not extend the new owner's deemed status accreditation to the newly-acquired facility. See the FAQs concerning changes of ownership (CHOWs).

IV. RENEWAL OF DEEMED ACCREDITATION

IV-1. Question: Does CMS do anything when an AO renews the accreditation of a deemed provider/supplier?

Answer: CMS periodically updates its survey and certification files on providers/suppliers that participate via deemed status based on accreditation. Ideally, the update interval should correspond to the AO's accreditation expiration/renewal date indicated in its latest decision letter for the provider/supplier. An update packet is sent by the SA to the RO, with the Form CMS-

1539 and any other documentation required for that provider type. (See Exhibit 63 of the SOM for documentation requirements) In the remarks section of the Form CMS-1539, the SA indicates it is transmitting an accredited, deemed provider/supplier update.

V. VALIDATION SURVEYS

V-1. Question: How is it that SAs conduct surveys of accredited providers/suppliers?

Answer: In accordance with 42 CFR 488.7, CMS may require a survey of an accredited provider or supplier to validate the AO's accreditation process. There are two types of validation surveys:

- Surveys conducted on a representative sample basis, which may be either comprehensive surveys of all Medicare conditions or focused surveys on a specific condition or conditions; or
- Surveys in response to a "substantial allegation" – generally a complaint. These surveys focus on those Medicare conditions related to the allegations.

SAs conduct validation surveys of accredited providers/suppliers only when they are specifically authorized to do so by the RO. In the case of representative sample surveys, CMS selects the providers/suppliers to be surveyed and the RO assigns the SA to conduct the validation survey within 60 days of the AO survey. In the case of substantial allegations, most complaints are received by the SA, which then forwards to the RO complaints that they believe make substantial allegations of noncompliance with Medicare conditions. The RO reviews the complaint and determines whether it will authorize the SA to conduct a survey, and also determines which conditions the SA should focus its survey on.

CMS also receives complaints directly. Information raising substantial allegations of noncompliance may also come to CMS' attention via means other than complaints, such as press reports. In such cases the RO reviews the information and makes a determination as to whether the SA should conduct a validation survey, and of which conditions. (See Section 5100 of the SOM for more details about procedures for substantial allegation surveys of accredited, deemed providers/suppliers).

V-2. Question: How does a provider/supplier know whether an SA is authorized to conduct a validation survey?

Answer: In the case of a validation survey based on a representative sample, the SA will present a letter to the facility at the beginning of the survey explaining the purpose of the survey. (See Exhibits 37 and 37A in the SOM). In the case of a validation survey based upon a substantial allegation, the SA will explain during the entrance conference that it is there to conduct an investigation related to a complaint.

V-3. Question: May a provider/supplier refuse to allow a SA to conduct a validation survey of the facility?

Answer: No. 42 CFR 488.7(b) requires a provider/supplier selected for a validation survey to authorize the survey as well as to permit SA monitoring of any deficiencies found. Per 42 CFR

488.7(c), a provider/supplier that refuses to cooperate with a validation survey will no longer be deemed to meet the Medicare conditions but will instead be subject to a full review by the SA and may also be subject to termination of its provider agreement under 42 CFR 489.53. The SA will ask the provider/supplier to sign a statement providing the appropriate authorizations. (See Exhibit 287 in the SOM).

V-4. Question: What happens when an SA validation survey of an accredited, deemed provider/supplier finds noncompliance with Medicare conditions?

Answer: The consequences for the accredited deemed provider/supplier depend on 1) whether the SA found noncompliance at the condition-level or a lower level; and, 2) whether the validation survey was a full, comprehensive survey. (See Sections 3240 - 3257 and 5100.2 of the SOM.)

- If the SA ***does not find condition-level noncompliance*** and the RO agrees with this finding, the provider/supplier is in substantial compliance. Although the SA may have found lower-level deficiencies, which are noted to the provider/supplier by the CMS RO via the Form CMS 2567, Statement of Deficiencies and Plan of Correction, it is not necessary for the provider/supplier to submit a POC to the SA, or for the SA to conduct a revisit to verify correction of such deficiencies. Providers/suppliers may choose to submit a POC voluntarily and often do so, since the deficiency findings and any POC submitted will be made publicly available. CMS recommends that AOs periodically ask their accredited, deemed status providers/suppliers whether they were the subject of a validation survey by an SA, and if so, to provide the AO with a copy of any Form CMS 2567 related to the survey. The AO may wish to consider the SA's findings as part of the AO's oversight activities.
- If the SA ***finds condition-level noncompliance as a result of a full survey conducted on a representative sample basis*** and the RO agrees with this finding, the provider/supplier is: notified of the deficiencies via the CMS 2567 and also of the removal of its deemed status; placed under the jurisdiction of the SA; and, placed on track for termination of its provider agreement. The RO also notifies the provider's/supplier's AO of the removal of deemed status and that the facility has been placed on a termination track. CMS will terminate the provider agreement unless the provider/supplier submits an acceptable POC and the SA verifies through a revisit survey that the provider/supplier has come into compliance. The revisit survey focuses on the conditions that were previously deficient. The timeframe for coming into compliance depends on whether the deficiencies posed an immediate jeopardy to patient health and safety. If the provider/supplier fails to make timely correction of its deficiencies, the RO terminates the provider agreement. If the provider/supplier has been determined to have achieved compliance, the RO notifies the provider/supplier that its deemed status has been reinstated.
- If the SA ***finds condition-level noncompliance as a result of a validation survey based on a substantial allegation*** and the RO agrees with this finding, the provider/supplier is notified of the deficiencies via the CMS-2567 and also of the removal of its deemed status and placement under SA jurisdiction; the RO notifies the AO of its removal of deemed status.

- If the *noncompliance poses an immediate jeopardy that was not abated while the SA was on-site for the survey*, then CMS places the accredited provider/supplier on track for termination of its provider agreement, unless it submits a timely, acceptable POC and the SA confirms the removal of the immediate jeopardy situation. Once the immediate jeopardy is removed, if condition-level problems remain, the provider/supplier will remain on a termination track unless it submits a timely, acceptable POC and the SA confirms substantial compliance. If the provider/supplier fails to make timely correction of its deficiencies, the RO terminates the provider agreement. If the provider/supplier has been determined to have achieved condition-level compliance and, if applicable, submits an acceptable POC for all standard-level deficiencies as required by 42 CFR §488.28(a), the RO notifies the provider/supplier that its deemed status has been reinstated. The RO also notifies the provider's/supplier's AO when it takes action to reinstate deemed status or to terminate the accredited provider/supplier.

- If the *noncompliance does not represent immediate jeopardy*, then no POC is required at this stage, and, in accordance with 42 CFR 488.7(a)(3), the SA must subsequently conduct a full survey after it substantiates a condition-level allegation. If the SA's full survey reveals continued or additional condition-level noncompliance, the provider/supplier is again notified of the deficiencies *and is also placed on a termination track*. The provider/supplier must at this time submit an acceptable POC, and the SA must conduct a revisit survey to confirm that the condition-level deficiencies have been corrected. There must be an acceptable POC for all standard-level deficiencies remaining, as required by 42 CFR 488.28(a). If the provider/supplier fails to make timely correction of its deficiencies, the RO terminates the provider agreement. On the other hand, if the provider/supplier has been determined to have achieved compliance, the RO notifies the provider/supplier that its deemed status has been reinstated. The RO also notifies the provider's/supplier's AO when it takes action to reinstate deemed status or to terminate the accredited provider/supplier.

VI. LOSS OF ACCREDITATION & OTHER AO ADVERSE ACTIONS

VI-1. Question: What happens when accreditation is terminated– either involuntarily by the AO or voluntarily by the provider/supplier whose current participation in Medicare is based on its accreditation?

Answer: The AO must notify CMS, both CO and the appropriate RO, whenever a provider or supplier loses its accredited status, as well as the reason for the termination. If the provider's/supplier's termination by one AO is concurrent with a new recommendation for accredited, deemed status by another CMS-approved AO, then it may remain under AO rather than SA jurisdiction. An update packet including the new recommendation for accredited, deemed status by another AO must be submitted by the SA to the RO. If there is no concurrent recommendation from another AO, the provider's/supplier's deemed status is removed and it is placed under SA jurisdiction. The SA surveys the facility in order to provide assurance that the facility is in compliance with the applicable health and safety standards. When the AO advises CMS that the provider/supplier's accreditation was involuntarily terminated due to failure to

comply with the AO's health and safety standards, the SA is expected to conduct the compliance survey as soon as possible.

VI-2. Question: What happens when an AO takes an adverse action short of termination against the accreditation status of a provider/supplier?

Answer: The AO is required to inform CMS, both CO and the appropriate RO, of significant adverse actions it takes against the accreditation status of a provider/supplier. As long as accreditation is not terminated, the provider/supplier's participation in Medicare is not affected.

The AO is also required to inform CMS when it identifies an immediate jeopardy situation on a survey. CMS may choose to have the SA conduct a validation survey based on a substantial allegation as a result of the information provided by the AO.

VII. CHANGE OF OWNERSHIP

VII-1. Question: If there is a change of ownership (CHOW) for an accredited provider/supplier that has been deemed to satisfy Medicare conditions, what role does its accreditation play in the certification process?

Answer: A provider/supplier must notify CMS via the CMS 855 A or B when a CHOW occurs. When a provider/supplier undergoes a CHOW, the default position is for CMS to assign the previous provider/supplier agreement to the new owner, unless the new owner explicitly rejects assignment. There are several variations on what happens after a CHOW occurs of an accredited, deemed provider/supplier as well as accreditation implications, depending on the actions of the new owner. Several scenarios are described below (see also SOM sections regarding CHOWs for more details):

- *New owner assumes the seller's provider agreement; the seller participated in Medicare as an accredited, deemed provider.*

While accreditation by an AO is not transferable to a new entity, accredited deemed status does not automatically lapse when ownership changes. The accredited deemed provider/supplier should notify its AO within thirty calendar days of the CHOW and whether it intends to seek accreditation. If it does, the provider's/supplier's accredited deemed status is continued, unless the AO advises CMS that it is terminating accreditation. (See Section 3210.1C of the SOM) It is up to the AO to determine whether a new survey of the provider/supplier under the new ownership is needed. In all cases, the AO must notify CMS of its decision either to extend accreditation to the new owner or to terminate accreditation. If accreditation is terminated, see the FAQ concerning loss of accreditation.

Note: The RO has the discretion to authorize a SA survey after the CHOW, even if the provider/supplier has accredited deemed status, and regardless of whether the AO decides to extend its accreditation to the new owner. This would happen if the RO has concerns about the provider's/supplier's compliance with Medicare's health and safety standards.

- ***New owner does not assume the seller's provider agreement; the seller participated in Medicare as an accredited, deemed provider.***

A new owner of a provider/supplier may refuse to accept assignment of the previous owner's provider agreement, which means that the existing provider agreement is voluntarily terminated, effective as of the date ownership changes. The new owner must communicate its refusal to assume the provider agreement in writing to the RO and, for those providers/suppliers required to complete the CMS-855A, indicate in Section 2F of that form that it will not be assuming the provider agreement. If the CHOW occurs without a refusal or acceptance on record, the RO concludes that the provider agreement has been assumed by the new owner.

If the new owner refuses to accept assignment of the seller's provider agreement, but wishes to participate in Medicare, then the new owner is treated in the same way as any new applicant to the program. The new owner must demonstrate that its facility is in compliance with the applicable CoPs or CfCs via an initial Medicare survey, either by the SA or an AO. This applies to both accredited and non-accredited providers/suppliers. ***In this case, for the new owner seeking Medicare participation via accredited deemed status, the AO must conduct a new survey of the entity, issue a new determination as to whether the facility satisfies all requirements for accreditation under the AO's Medicare deeming program, and make a new recommendation to CMS on certification of the facility via deemed status.*** This AO survey can take place only after the CHOW occurs, and after the FI/MAC has processed the new owner's CMS-855A or 855B and made a recommendation to the RO.

The earliest possible effective date for the new provider agreement under the new owner is the date the RO determines that **all** Federal requirements for that provider/supplier type are met. If for any reason the AO chooses not to conduct a survey, or to delay a survey of the new entity, CMS will inform the new owner (applicant) that the facility has not met all Federal requirements. The facility will not be able to participate in Medicare until CMS is assured that the new entity meets all applicable health and safety requirements on the basis of a post-CHOW survey and recommendation for accredited deemed status by the AO, and that the facility meets any other applicable requirements (e.g., capitalization requirements for HHAs, specialty psychiatric hospital requirements; IPPS-exclusion requirements, etc.). In such a circumstance, the new owner may choose to have the SA conduct its survey instead of the AO. (See Section 3210.5A of the SOM).

Note: S&C-08-03, November 5, 2007, reiterates CMS' longstanding policy that surveys of providers and suppliers seeking initial enrollment in the Medicare program and which have the option of accreditation in lieu of a SA survey are Tier 4 priority work for the SAs. SAs must accomplish their higher tier work first. Depending on the resources available to CMS for survey and certification activities of SAs, it may not be possible for a SA to conduct initial surveys for new owners who have an accreditation option and that have chosen not to assume the previous owner's provider agreement.

- ***New owner assumes the seller's Medicare provider agreement and merges the accredited provider into another Medicare-participating provider accredited by the same AO; the new owner maintains the operations of the acquired provider at its original location.***

This scenario would apply only to accredited, deemed providers, since ambulatory surgical centers (ASCs) are the only type of supplier currently deemed and ASCs are not permitted to be provider-based. Typically this type of scenario involves merger of a provider into a hospital or CAH, thereby becoming provider-based.

In this situation, although the acquired entity's provider agreement has been assumed by the new owner, its CMS Certification Number (CCN) is "retired" and only the new owner's CCN number is used for the merged facility. There is no requirement for a new survey post-CHOW by the AO, although the RO has the discretion to authorize an SA validation survey if the RO has concerns about the acquired provider's compliance with Medicare's health and safety standards.

- ***New owner assumes the seller's Medicare provider agreement for a provider that was either non-accredited or accredited and seeks to merge the acquired provider into another accredited deemed Medicare-participating provider that is accredited by a different AO; the new owner maintains the operations of the acquired provider at its original location.***

This scenario would apply only to accredited, deemed providers, since ASCs are the only type of supplier currently deemed and ASCs are not permitted to be provider-based. Typically this type of scenario involves merger of a provider into a hospital or CAH, thereby becoming provider-based.

In this situation, although the acquired entity's provider agreement has been assumed by the new owner, its CMS Certification Number (CCN) is "retired" and only the new owner's CCN number is used for the merged facility. The new owner's AO may choose to enter into an agreement with the new owner to "extend" its existing accreditation to the newly-acquired facility(ies) as if they were deemed to meet Medicare's conditions. If it extends accreditation, the AO will conduct a survey of the newly acquired facility(ies) within six months of the date of the extension agreement. The extension of the accreditation by the AO serves in lieu of conducting a survey at the time of the CHOW and merger. (See Section 3210.1C of the SOM)

- ***New owner does not assume the seller's Medicare provider agreement for a provider that was either non-accredited or accredited and seeks to merge the acquired provider into another, accredited deemed Medicare-participating provider.***

Here, the provider agreement of the seller is terminated by CMS. The AO of the new owner may not extend accreditation to the newly acquired facility under this circumstance. The RO informs the provider that a survey of the acquired facility(ies) will be necessary and that it may not bill Medicare for services provided at the proposed expansion location until a survey is conducted and a compliance determination is made that all pertinent Federal requirements have been met. The AO may conduct a new accreditation survey of the acquired entity only after the CHOW has occurred. The AO notifies CMS whether the acquired facility meets Medicare's health and safety standards and is being recommended for accredited, deemed status.

VIII. TERMINATED PROVIDERS/SUPPLIERS

VIII-1. Question: After a provider/supplier has been involuntarily terminated from the Medicare program, may it re-enter the program via accredited deemed status?

Answer: The RO must be reasonably assured after an involuntary termination that the provider/supplier has corrected its problems. 42 CFR 489.57 states,

“When a provider agreement has been terminated by CMS under §489.53, or by the OIG under §489.54, a new agreement with that provider will not be accepted unless CMS or the OIG, as appropriate, finds- (a) That the reason for termination of the previous agreement has been removed and there is reasonable assurance that it will not recur; and (b) That the provider has fulfilled, or has made satisfactory arrangements to fulfill, all of its statutory and regulatory responsibilities of its previous agreement.”

The RO has the discretion to determine to what extent it will accept accreditation by an AO as part of the reasonable assurance process. The SOM at Section 2016D states,

“...If an involuntary terminated provider/supplier attempts to avoid the reasonable assurance provision at 42 CFR [489.57] by seeking deemed status via accreditation, CMS may deny Medicare reentry. CMS may request a survey performed by the SA if it is not reasonably assured the provider/supplier meets the Medicare conditions.

In such cases, the RO will determine the **IF** (when it is reasonably assured that the reason for the termination will not occur), the **WHEN** (the reinstatement effective date) and the **HOW** (e.g., a survey by the SA) of the provider’s return to Medicare. The RO will make an analysis of the facts in the case and issue a decision because receiving deemed status is a separate issue from reinstatement (Reasonable Assurance) following involuntary termination by CMS under 42 CFR 489.57...”

VIII-2. Question: If a provider/supplier faced with the prospect of an involuntary termination voluntarily withdraws from Medicare prior to the effective date of the involuntary termination, and subsequently seeks readmission to the program on the basis of deemed status, is this acceptable?

Answer: The RO has the discretion to apply the reasonable assurance process under 42 CFR 489.57 and would be expected to do so in this situation. Section 2016D of the SOM allows the RO to continue processing an involuntary termination even after a voluntary withdrawal. However, even if the RO has not done this, Section 2016D also states, “In the absence of having processed an involuntary termination, the RO could apply 42 CFR 488.6(c)(2) in concert with 42 CFR 489.12(a)[(4)] in a case where a provider facing involuntary termination voluntarily withdrew from Medicare and subsequently attempted to re-enter the program through an accreditation program.”

Attachment B

EXHIBIT 37

(Rev.)

MODEL LETTER ANNOUNCING VALIDATION SURVEY OF ACCREDITED, *DEEMED PROVIDER/SUPPLIER*

PLEASE NOTE: Per Section 2700A, all surveys are unannounced; *this letter is to be provided to the facility administrator as part of the survey entrance conference.*

(Date)

Facility Administrator Name

Facility Name

Address

City, State, ZIP Code

Re: CMS Certification Number (CCN)

Dear **(Administrator Name)**:

Section 1865 of the Social Security Act (the Act) provides *that entities* accredited by CMS-*recognized national accreditation organizations may be* deemed to meet the Medicare *health and safety* Conditions.

Section 1864 of the Act authorizes the Secretary to *enter into an agreement with State health or other appropriate agencies to* conduct, on a selective sampling basis, surveys of accredited *deemed facilities subject to Medicare certification requirements. CMS uses such surveys* as a means of validating the accrediting organization's survey *and accreditation process*. In **(Name of State)**, Medicare validation surveys of accredited *deemed providers and suppliers* are conducted by the **(State agency)**. This agency, under agreement with the Centers for Medicare and Medicaid Services (CMS), surveys *institutional providers and suppliers* of Medicare services to determine compliance with the Medicare *health and safety conditions*.

The last accreditation survey of **[Facility Name]**, conducted by **[AO]**, was completed on [date].

Your facility has been selected for a sample validation survey. This is an unannounced survey following procedures established by CMS.

Section 1865 of the Act requires *facilities* deemed to meet the *Medicare conditions* to authorize the accrediting body to release to the Secretary (or to a State agency designated by him), upon his request, a copy of the accreditation survey information of such institution.

(Name)

Page 2

(Date)

You may also be requested to provide or verify *additional information required by CMS for general certification purposes* by a member of the survey team.

During the *validation* survey, the State agency will determine compliance with all *Medicare health and safety requirements applicable to your type of facility*. The survey team will request facility documents to review, require access to all areas of the *facility*, and observe patient services or procedures to assist them in their compliance determination.

If the validation survey results in a finding by the CMS Regional Office that a provider or supplier is out of compliance with one or more Medicare conditions, the provider or supplier will no longer be deemed to meet Medicare conditions and may be subject to termination of its provider or supplier agreement, in accordance with 42 CFR 488.7(d). Additionally, in accordance with 42 CFR 401.133, a copy of the Medicare sample validation survey findings will be subject to public disclosure after the facility has been given an opportunity to review the findings, present comments to CMS, and submit a plan of correction for any deficiencies cited.

If you have any questions regarding this letter, please telephone [Name] at [Telephone number].

Sincerely yours,

State Agency Director

Enclosures:

*Authorization by Deemed Provider/Supplier Selected for Accreditation Organization
Validation Survey*

cc:

CMS, DSC, Regional Office

CMS, CMSO, Division of Acute Care Services

EXHIBIT 287

(Rev.)

**AUTHORIZATION BY DEEMED PROVIDER/SUPPLIER SELECTED FOR
ACCREDITATION ORGANIZATION VALIDATION SURVEY**

To Whom it May Concern:

Certain types of providers and suppliers may be deemed in compliance with the appropriate Medicare Conditions of Participation or Conditions for Coverage program by submitting evidence of accreditation *from a Centers for Medicare and Medicaid Services (CMS)*-authorized accreditation organization. CMS may subsequently require a survey of an accredited provider or supplier to validate the accreditation organization's process.

In signing this form, I acknowledge that I have been advised that **(name of provider/supplier)** has been selected for a validation survey. Furthermore, I acknowledge that, in accordance with the provisions of 42 CFR 488.7(b), I must authorize:

- 1) The validation survey by the State survey agency to take place; and
- 2) The State survey agency to monitor the correction of any deficiencies found through the validation survey.

Signature of Authorizing Individual

Printed/Typed Name of Individual

Name of Provider/Supplier

Date

Attachment D

EXHIBIT 196

(Rev.)

MODEL LETTER ANNOUNCING TO **DEEMED**, ACCREDITED **PROVIDER/SUPPLIER**
AFTER A SAMPLE VALIDATION SURVEY THAT **IT DOES NOT COMPLY WITH ALL**
CONDITIONS OF PARTICIPATION/CONDITIONS FOR COVERAGE

(90-Day Termination Track: Do Not Use When Immediate and Serious Threat to Patient Health or Safety Deficiencies Exist)

(Date)

Administrator Name
Hospital Name
Address
City, State, ZIP Code

Re: CMS Certification Number (CCN)

Dear **(Administrator)**

Section 1865 of the Social Security Act (the Act) and pursuant regulations provide that a *provider or supplier accredited by (name of accreditation organization)* will be “deemed” to meet all of the Medicare Conditions (of Participation (CoPs *or for Coverage (CfCs, as applicable)*) for **(type of provider/supplier)**, *(add for hospitals: with the exception of those relating to utilization review, the special medical record and staffing requirements for psychiatric hospitals, and special requirements for hospital providers of long-term care services (“swing beds”)).* Section 1864 of the Act authorizes the Secretary of the Department of Health and Human Services (the Secretary) to conduct, on a selective sampling basis, surveys of accredited *providers/suppliers* participating in Medicare as a means of validating reliance on the accreditation process.

When a (type of provider/supplier), regardless of its accreditation status, is found to be out of compliance with the (CoPs or CfCs), a determination must be made that the facility no longer meets the requirements for participation as a provider or supplier of services in the Medicare program. Such a determination has been made in the case of (facility name) and accordingly, the Medicare agreement between (facility name) and the Secretary is being terminated.

A validation survey conducted by the (**State agency**) at (**name of facility**) on (**date**) found that the facility was not in compliance with all the (CoPs or CfCs) for (**type of facility**). A listing of all deficiencies found is enclosed (Form CMS-2567, Statement of Deficiencies and Plan of Correction.). These deficiencies have been determined to be of such a serious nature as to substantially limit the facility's capacity to provide adequate care. The date on which the agreement terminates is (**date**). (**Add, in the case of a hospital or CAH: The Medicare program will not make payment for services furnished to patients who are admitted on or after (date of termination). For inpatients admitted prior to (date of termination), payment may continue to be made for a maximum of 30 days of inpatient services furnished on or after (date of termination). You should submit as soon as possible, a list of names and Medicare claim numbers of beneficiaries in your facility on (date of termination) to the (name and address of the RO involved) to facilitate payment for these individuals.**)

We will publish a public notice in the (**local newspaper**). You will be advised of the publication date for the notice. If you feel that these findings are incorrect, you have 15 days from the date of this notice to request an informal review of the findings by this office as provided by 42 CFR 488.456(c)(2). Include in the request any evidence and arguments which you may wish to bring to the attention of the Centers for Medicare & Medicaid Services (CMS). [Public notice language is optional]

Termination can only be averted by correction of the deficiencies within 45 days of your receipt of this letter. Your plan of correction (written on the enclosed statement of Deficiency and Plan of Correction forms) should be returned to us as soon as possible.

An acceptable plan of correction must contain the following elements:

1. The plan for correcting each specific deficiency cited;
2. The plan should address improving the processes that led to the deficiency cited;
3. The plan must include the procedure for implementing the acceptable plan of correction for each deficiency cited;
4. A completion date for correction of each deficiency cited must be included;
5. All plans of correction must demonstrate how the provider/supplier has incorporated its improvement actions into its applicable Quality Assessment and Performance Improvement (QAPI) program, addressing improvements in its systems in order to prevent the likelihood of the deficient practice reoccurring. The plan must include the monitoring and tracking procedures to ensure the plan of correction is effective and that specific deficiencies cited remain corrected and/or in compliance with the regulatory requirements; and
6. The plan must include the title of the person responsible for implementing the acceptable plan of correction.

After termination, if you wish to be readmitted to the program, you must demonstrate to the (**State agency**) and CMS that you are able to maintain compliance. Readmission to the program will not be approved until CMS is reasonably assured that you are able to sustain compliance.

If you do not believe this termination decision is correct, you may request a hearing before an Administrative Law Judge (ALJ) of the Department of Health and Human Services, Departmental Appeals Board. Procedures governing this process are set out in regulations at 42 CFR 498.40 et. seq. A written request for a hearing must be filed no later than 60 days from the date of receipt of this letter. Such a request may be made to the Consortium Survey and Certification Officer,

(address). We will forward your request to the Chief Administrative Law Judge in the Office of Hearing and Appeals.

At your option you may instead submit a hearing request directly (accompanied by a copy of this letter) to the following address. Send a copy of your request to this office also.

*Departmental Appeals Board, Civil Remedies Division
Room G-644-Cohen Building
330 Independence Avenue, S.W.
Washington, D.C. 20201
Attn: Director, Departmental Appeals Board*

A request for a hearing should identify the specific issues, and the findings of fact, and conclusions that you consider to be incorrect. You may be represented by counsel at a hearing at your own expense.

Sincerely yours,

*Consortium Survey and Certification Officer
(or its equivalent)*

cc: (Accreditation Organization)