Federally Qualified Health Centers

2003A - Assisting Applicant Providers and Suppliers
(Rev.)

Pre-certification assistance to prospective providers and suppliers is a proper certification-related activity. It may take the form of providing them with a copy of the applicable regulations. The objective is to *provide* the party *with information about the requirements of the certification component of the process for enrolling and participating in Medicare, including compliance with the requirements for SNFs and NFs, Conditions of Participation, Conditions for Coverage, or Conditions for Certification, as applicable. T*he effective date of *Medicare* participation *in accordance with 42 CFR 489.13 may not* be earlier than the date on which the *applicant* meets all the federal requirements.

2003B - Initial Certification "Kits"
(Rev.)

When an entity seeks to participate in Medicare, it must first complete and submit an enrollment application. Information on enrollment as well as applicable forms and instructions may be found at http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/index.html. *Entities subject to survey and certification file either a CMS Form 855A -- Medicare Enrollment Application for Institutional Providers, or a CMS Form 855B--Medicare Enrollment Application for Clinics, Group Practices, and Certain Other Suppliers, or, in some cases, both. Prospective providers and suppliers should be aware that the initial review of the Form CMS-855A or Form CMS-855B by the Medicare Administrative Contractor (MAC) and its recommendation for approval must occur before the on-site initial certification survey is conducted and action is taken by the RO.*

CMS has established Internet-based Provider Enrollment, Chain and Ownership System (PECOS) as an alternative to the paper enrollment process. Internet-based PECOS allows provider and supplier organizations to enroll, make a change in their Medicare enrollment, view their Medicare enrollment information on file with Medicare, or check on the status of a Medicare enrollment application via the Internet.

When the MAC completes its review of the application, it either: 1) sends the SA and the RO its recommendation to approve the applicant; or 2) denies the application. ***The SA must not perform a survey of an initial applicant until it has received notice from the MAC that the information provided on the enrollment application has been verified and that the MAC is recommending approval of the application.*** *A SA may, however, start planning for an unannounced survey upon initial contact from an applicant.*

*(**Note** that SA surveys of initial applicants must be consistent with the priorities for Federal survey work, established by CMS each fiscal year. Depending upon available resources, initial surveys are typically a lower priority and SAs generally should not*

perform such work unless all higher priority Federal work will be completed. SAs may consult with the CMS Regional Office (RO) to determine whether a specific initial applicant would address an access to care issue and thus warrants an exception.)

The prospective provider/supplier must contact the SA for Medicare and/or Medicaid certification materials for their provider/supplier type. The SA mails the initial certification materials under cover of the appropriate form letter. (See Exhibits 1A-1F and Exhibit 63*.)* If the applicant has not contacted the SA *before the SA* receives *the MAC's recommendation for approval*, then the *SA* contact*s* the applicant using the phone number listed on the application.

Upon receipt *of the completed certification materials from the prospective applicant*, the SA reviews the *materials* to see that they are properly completed and secures any necessary changes or additional information. It makes sure any required SNF transfer agreements are received. If a distinct part of an organization is being considered for *program* participation, the SA reviews the diagram (or floor plan) submitted to make sure the size and location of the distinct part are clearly shown. The SA works in conjunction with the RO and the *MAC* to gather the appropriate documentation from the entity that supports its position of being a distinct part before forwarding the package to the RO, in order to make a recommendation to the RO. Both copies of the signed provider agreement *or supplier approval* are sent to the RO, along with the Title VI Assurance of Compliance with Civil Rights (Form HHS-690). In title XIX-only cases, the SA sends the Form HHS-690 or comparable form to the SMA.

If the entity indicates that it is requesting *a* provider-based *determination* under the Medicare program, the SA must notify the RO immediately. Distinct Part and Provider-Based are not synonymous terms. Determinations concerning provider-based *status* are made by RO Financial Management *p*ersonnel.

The SA refers questions about enrollment, *MAC*s, payment rules, financial solvency, or title VI clearance to the RO or the State Medicaid agency, as appropriate. For questions concerning the downloading, completion, and submission of the Form CMS-855A or CMS-855B, the provider/supplier should be directed to the CMS Web site or the appropriate *MAC*.

Initial Certifications Involving New Owners who Reject Assignment of the Existing Medicare Agreement

In the case of a prospective applicant that is planning to acquire an existing Medicare-participating provider or supplier, the RO should provide pre-certification assistance to the prospective applicant which includes making the prospective applicant aware of the consequences of accepting or rejecting assignment of the existing provider's/supplier's Medicare agreement. The RO should be consulted if the prospective applicant is considering rejecting assignment of the agreement so that the RO can provide detailed information on the consequences of such action before the prospective applicant makes a final decision and submits an application.

In the case of an applicant that has acquired an existing Medicare-participating provider or supplier and has rejected assignment of that entity's Medicare agreement, that applicant is considered a new applicant seeking initial certification and the SA must prioritize scheduling an initial survey for that applicant accordingly. This includes adhering to workload priorities identified by CMS for surveys of initial applicants to enroll in Medicare. Unless specifically directed by the RO to do so, SAs must not conduct initial surveys unless they are able to complete their higher priority workload. For initial applicants that have an accreditation option, initial certification surveys are the lowest SA priority. When an SA conducts an initial certification survey of an applicant that acquired a provider/supplier but rejected assignment, the RO must review the facts of the case carefully to determine whether the SA deviated from CMS workload priorities as well as the SA's typical practice for initial applicants. Such deviation may raise reasonable doubt that the survey was unannounced.

Section 2700A of the SOM requires all surveys of providers and suppliers (other than clinical laboratories) to be unannounced. This requirement applies to AO as well as SA surveys. An unannounced survey provides an opportunity to assess how the provider or supplier typically operates. On the other hand, if a provider or supplier knows the exact or approximate date of a survey, it may temporarily adjust its typical practices to enhance its compliance at the time of the survey. In doing so, it presents an unrepresentative picture to surveyors of the quality of care typically provided to its patients or residents. It is therefore in the best interest of patients and residents that surveys be unannounced.

Given the lead time normally required to schedule and prepare for a full survey, if an initial survey takes place shortly after the acquisition date, such timing suggests discussion with the new owner prior to the acquisition date to arrange the timing of the survey to occur shortly thereafter, compromising the requirement that the survey be unannounced. While the new owner, like any other initial applicant to the Medicare program, will be expecting to be surveyed at some point, there must be some degree of uncertainty about just when that survey will occur, in order to permit an assessment of compliance when the facility is operating in a typical manner.

The RO may refuse to accept a SA survey certifying compliance or an AO recommendation for deemed status if the survey timing creates reasonable doubt that the survey was unannounced. Each case must be assessed based on the facts specific to it; however, any survey that takes place within fourteen days after the effective date of an acquisition that involves rejection of assignment of the provider agreement may warrant closer review by the RO of the circumstances of the case and the timing of the survey. However, it is also possible that the facts of a specific case may indicate that an initial certification survey taking place at a later date was announced.

See Section 3210 for more information about policies and procedures related to acquisitions of Medicare-participating providers or suppliers.

2003C – Deemed Status Providers/Suppliers, Excluding CLIA

There is an alternative to SA surveys for demonstrating compliance with the applicable CoPs/CfCs/Conditions for Certification. Accreditation based on a survey by a CMS-approved Medicare accreditation program of a national accrediting organization may be used by CMS to "deem" a provider or supplier as complying with the applicable regulatory standards. For certain types of providers/suppliers, for example hospitals or psychiatric hospitals, Medicaid will also accept accreditation under a CMS-approved Medicare accreditation program as evidence of compliance for Medicaid purposes.

Section 1865(a) of the Act provides that CMS may recognize and approve national accrediting organization (AO) Medicare accreditation programs 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 provider's or supplier's compliance with applicable Medicare CoPs, CfCs, Conditions for Certification or requirements.

The regulations which govern Medicare survey, certification, and enforcement procedures are generally found in 42 CFR Part 488. Section 488.1 defines an accredited provider or supplier as "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." Accreditation under a CMS-approved Medicare accreditation program is voluntary and is not required for Medicare participation.

Consistent with Section 1865 of the Act, 42 CFR §§488.5 and 488.6 permit deemed status certification 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, at this time only certain AOs have requested CMS approval of Medicare accreditation programs, and those programs are only for some of these provider/supplier types. A current list of CMS-approved Medicare accreditation programs may be found at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Accreditation.html.

The enrollment and certification requirements also apply to providers/suppliers seeking deemed status through their accreditation by a CMS-approved Medicare accreditation program. AOs with approved Medicare accreditation programs are also required by CMS not to survey initial applicants until they provide evidence that the MAC has reviewed their application and recommended approval.

The prospective provider/supplier seeking deemed status through accreditation must still contact the SA for Medicare and/or Medicaid certification materials for their provider/supplier type. The SA mails the initial certification materials under cover of the

appropriate form letter. (See Exhibits 1A-1F and Exhibit 63.) If the applicant has not contacted the SA before the SA receives the MAC's recommendation, then the SA contacts the applicant using the phone number listed on the application.

In the case of a "deemed" provider or supplier, the SA does not conduct a survey to initially certify or recertify compliance with the applicable Medicare CoPs, CfCs, or requirements. Rather, such providers or suppliers are under the jurisdiction of the AO, not the SA, for oversight of their ongoing compliance, unless the SA conducts a validation survey (either a representative sample or substantial allegation validation survey) at the direction of CMS and CMS determines as a result of such validation survey that the provider or supplier fails to comply with one or more CoPs, CfCs, Conditions for Certification or requirements.

Note that some AOs offer multiple accreditation programs for a given type of provider or supplier, but for each provider/supplier type an AO may offer no more than one CMS-approved Medicare accreditation program. In addition, some AOs may offer only one program for a provider/supplier type, but they offer this program to their customers with and without the option of the AO recommending Medicare deemed status to CMS. Thus, it is possible for a healthcare entity to be "accredited" without being "deemed" for Medicare participation. For certification purposes, CMS considers only accreditation under a CMS-approved Medicare accreditation program where the AO has recommended deemed status. SAs must enter information on the Deemed tab within the certification kit in ASPEN only for those initial applicants that are seeking deemed status on the basis of accreditation under a CMS-approved Medicare accreditation program. CMS has established a process for AOs to provide notice to the applicable CMS Regional Office (RO) when it has accredited a provider or supplier under its CMS-approved Medicare accreditation program and is recommending the provider or supplier for deemed status. The RO forwards these notices to the applicable SA for inclusion in the certification kit that the SA subsequently forwards to the RO. In initial certification cases where there is no AO notice of accreditation under a CMS-approved Medicare accreditation program for the applicant, SAs must not use other sources of information about the applicant being "accredited" to conclude that the applicant is "deemed" and must not enter deemed status for the applicant in ASPEN.

An AO may not conduct an initial certification survey of a prospective provider or supplier for Medicare certification purposes until the MAC has completed its initial review of the enrollment application and has made a recommendation for approval to CMS. CMS requires AOs subject to its oversight to employ a survey process that is comparable to the process required for an SA, which may not conduct an initial survey until it receives notice from the MAC recommending approval of the applicant (see Section 2003B). Accordingly, an AO must also wait until the MAC has made its recommendation before it conducts an initial survey.

The MAC gives the applicant written notice when its review has been completed. Therefore, AOs must inform providers or suppliers seeking to participate in Medicare via the AO's CMS-approved Medicare accreditation program that an initial, unannounced survey will not take place until after the applicant has received notice from the MAC that

it has completed its review of the enrollment application and that the MAC is recommending approval. If the MAC denies approval of the application, the AO must not proceed with a survey.

Notices that the MAC provides to the SA and RO are internal communications among CMS and its contractors. AOs are not entitled to receive copies of the MAC notice from the MAC, SA, or RO, but are expected to obtain copies of the MAC notice that was provided to the applicant.

In the case of an applicant that is planning to acquire an existing Medicare-participating provider or supplier and that is considering rejecting assignment of the prior Medicare agreement, the AO must refer the applicant to the RO, so that the RO can provide detailed information on the consequences of acceptance or rejection of assignment. In the case of an applicant that has acquired an existing Medicare-participating provider or supplier and has rejected assignment, the applicant is considered an initial applicant. Generally, it is not acceptable for the AO to schedule an initial survey to minimize the period of time between the termination of the prior Medicare agreement and the effective date of the new agreement. Surveys conducted either on the date an acquisition is effective or within days thereafter do not qualify as unannounced surveys and also are inconsistent with CMS regulations and policy that require such applicants to be treated in the same way as any other initial applicant. See Section 3210 for more information about policies and procedures related to acquisitions of Medicare-participating providers or suppliers.

The AO is required to notify CMS whenever it newly accredits and recommends Medicare deemed status for a provider or supplier seeking Medicare participation. This notice must be sent to both CO and the applicable RO via a designated email box (See Section 1022). However, the prospective provider or supplier must also provide the SA with documentation of the AO's accreditation decision and recommendation for deemed status. This documentation is included in and becomes part of the certification packet the SA submits to the RO. Therefore, AOs must instruct the prospective provider or supplier to furnish a copy of this documentation to the SA for inclusion in the applicant's certification packet.

2004 - Provider-Based *Determinations*
(Rev.)

"Distinct Part" and "Provider-Based" are not synonymous terms. When a location, department, remote location or satellite is established as being provider-based, it is an integral part of the provider, covered by the provider's Medicare agreement, and therefore subject to the same Medicare conditions of participation as any other part of that provider. Unless covered by a specific exception listed in the rule, the provider-based regulations at §413.65 apply to any provider of services under the Medicare program, as well as to physicians' practices or clinics or other suppliers that are not themselves providers, but which the provider asserts are an integral part of that provider.

Providers are not required to seek a determination from CMS that all of their provider-based components satisfy the provider-based rules at 42 CFR 413.65 , but they may voluntarily seek such determinations. The RO Division of Financial Management makes provider-based determinations in response to a specific request. If a provider requests the SA for a provider-based determination under the Medicare program for one or more of its component services, the SA must notify the RO immediately so that the request can be routed appropriately to the RO Division of Financial Management. In the case of a request concerning an off-campus department, remote location or satellite, the provider's survey and certification file about the locations included under its provider agreement must not be revised to add the new location until and unless the provider is issued a positive determination about its request.

2005 - Medicare Health Care Provider/Supplier Enrollment

(Rev.)

The Centers for Medicare & Medicaid Services (CMS) is authorized to collect *enrollment* information in order to ensure that correct payments are made to providers and suppliers under the Medicare program established by Title XVIII of the Act for payment under Part A of Title XVIII [42 U.S.C. §1395f(a)(1) and 1395g(a)] and §1833(e) [42 U.S.C. §13951(e)] for payment under Part B. In addition, CMS is required to ensure that no payments are made to providers or suppliers who are excluded from participation in the Medicare program under §1128 of Title XVIII [42 U.S.C. §1320a-7], or who are prohibited from providing services to the federal government under §2455 of the Federal Acquisition Streamlining Act of 1994 (P.L. 103-355) [31 U.S.C. §6101 note].

The primary use of this information is to verify the eligibility of providers/suppliers to participate in the Medicare program, which will more effectively prevent fraud and abuse. The protocol that CMS uses to ensure that providers/suppliers meet these requirements is referred to as the enrollment process. The enrollment process is also to be used for providers/suppliers that plan to seek certification for participation in Medicare based on deemed status through a CMS-*approved Medicare* accreditation *program*. An applicant *must complete the enrollment application process* in order for CMS to obtain certain required information before a certification survey is conducted or, in the case of an FQHC, the RO countersigns the self-attestation.

Providers/suppliers should be informed of the enrollment and certification process so that they do not have unrealistic expectations about the effective date of their provider or supplier agreement with Medicare, e.g., an applicant should not expect its effective date to be the date it submitted its *enrollment application*. Should the applicant have any questions concerning the enrollment *process* form, *it should be referred to* the following Web site: http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/index.html .

The Medicare enrollment process is not applicable to the Medicaid program. State *Medicaid Agencie*s use their own enrollment process.

2005A– *Approval or Denial*

(Rev.)

2005A1 - Enrollment Denial Based on MAC Review

When the MAC determines, after reviewing the Form CMS 855 application, that an applicant has failed to meet the enrollment process requirements, the MAC will issue a written denial to the applicant. The RO is not involved in the issuance of the denial or in the processing of any request by the applicant for reconsideration or appeal. Reconsideration requests or appeals are handled by the Center for Program Integrity Provider Enrollment Operations Group in the CO.

Additionally, when an applicant is denied enrollment by the MAC, no survey is conducted.

2005A2 – Approval or Denial of Certification Based on Survey Findings

The *SA (*or RO, when applicable *– all references below to SA surveys also apply to surveys conducted by the RO)*, surveys *applicants* that are subject to an on-site certification survey after it receives the recommendation of approval from the *MAC, unless the applicant has the option of participation via deemed status (See Sections 2003C and 2005A4). Additionally, the applicant must be operational and providing care to patients/residents in order for a certification survey to be conducted. (See Section 2008A.) All surveys are unannounced.*

Applicant in Compliance - The *SA* surveys the *applicant* and certifies or recommends Medicare approval if it determines that the *applicant* is in compliance with *all* conditions of participation/coverage*/certification or requirements, as applicable*. *(See Section 2008D for more information on the circumstances under which the SA certifies the applicant is or is not in compliance.)* The *SA* forwards the survey results *and certification kit* to the RO *which determines whether and when all Federal requirements have been met by the applicant. If all Federal requirements have been met, the RO* proceed*s* with the provider*'s* or supplier's Medicare *participation* approval. *(In the case of HHAs, there is a requirement for the MAC to conduct a second verification of the enrollment information after the SA or accrediting organization survey is completed. However, a second MAC review that takes place after the on-site certification survey will only delay the effective date of the HHA's Medicare agreement if that review identifies noncompliance with any Federal requirements. If the HHA is found upon a post-survey second MAC review to continue to meet all requirements, there would be no change in the initial certification effective date previously provided by the MAC to the RO.*

- *In the case of an applicant seeking to participate as a hospital, the AO has the discretion to conduct a new survey of only those conditions for which the applicant was found non-compliant during the prior survey*. *If the AO chooses to conduct such a focused subsequent survey, the hospital applicant must submit an acceptable plan of correction for all noncompliance identified in the prior survey, including for conditions where there were only lower-level deficiencies cited, before the AO may conduct the subsequent survey.*

  NOTE: It is not possible for an initial applicant to seek CAH status; the applicant must first be certified as a hospital, and then subsequently the hospital may apply to convert to CAH status. This is technically a conversion, not an initial application. If the AO advises CMS that it is not recommending the applicant for CAH deemed status or if the RO determines that the applicant does not satisfy the CAH location requirements, then the RO sends a letter denying the hospital's request to convert to CAH status. Unless the denial was based on the applicant not satisfying the CAH location requirements, the applicant may, at the AO's discretion, continue to work with the AO to correct the deficiencies and again seek CAH certification through deemed status. As with initial hospital applicants, the AO has the discretion to conduct a new survey of only those conditions for which the CAH applicant was found non-compliant during the prior survey. *If the AO chooses to conduct such a focused subsequent survey, the CAH applicant must submit an acceptable plan of correction for all noncompliance identified in the prior survey for all noncompliance identified in the prior survey, including for conditions where there were only lower-level deficiencies cited, before the AO may conduct the subsequent survey.*

In all cases the RO retains the authority to require a new full survey if it has concerns about a deemed status recommendation based on a focused survey after a prior survey identified substantial noncompliance. In cases where the RO anticipates that it will require a new full survey, it should notify the AO of this as soon as possible, to facilitate planning for the full survey by the AO.

If the AO continues to find substantial noncompliance on the subsequent survey, the above process may be repeated. However:

- *The applicant may submit no more than two reapplications for certification in connection with one enrollment application; and*

- *No more than six months may elapse between the date of the RO's first denial of certification and receipt by the RO of a second reapplication for certification (for a total of three certification applications).*

If the applicant fails to demonstrate compliance by the end of this six month period, the RO not only issues a final denial of certification, but also sends a written recommendation to the MAC that the enrollment application be closed out as denied. If

the applicant continues to seek enrollment and certification, the RO must receive a new MAC recommendation for approval before it may process a new certification application.

2005B - Deemed Providers/Suppliers Except CLIA – Additional Information

(Rev.)

AO renewal of deemed provider/supplier accreditation:

AOs conduct re-accreditation surveys of Medicare-deemed providers and suppliers on a triennial basis. Upon awarding re-accreditation, the AO also makes a recommendation for the provider's or supplier's continued Medicare deemed status. The provider's or supplier's deemed status continues without interruption.

When the AO notifies CMS of its renewal of accreditation and recommendation of continued deemed status, the RO forwards the notice to the SA and the SA must prepare a recertification kit for the provider or supplier. The recertification packet is sent by the SA to the RO, with the Form CMS-1539 and any other documentation required for that provider/supplier type. (See Exhibit 63 for documentation requirements.) In the remarks section of the Form CMS-1539, the SA indicates it is transmitting an accredited, deemed provider/supplier update.

Termination/Withdrawal; Removal of Deemed Status

The AO must notify CMS whenever a provider's or supplier's accredited status is not renewed, as well as the reason for the loss of accreditation. If the AO notifies CMS that the AO has terminated a provider's or supplier's accreditation, or that the provider or supplier has voluntarily withdrawn from the AO's CMS-approved Medicare accreditation program, the RO must remove the provider's or supplier's deemed status, unless there is evidence of accreditation under another CMS-approved Medicare accreditation program. For example, if the provider or supplier was accredited simultaneously under two CMS-approved programs, and one AO notifies CMS of a termination or withdrawal, the provider/supplier would continue to have deemed status based on the other accreditation. However, if the notice of termination by the first AO indicates that the reason for termination was the provider's/supplier's failure to meet accreditation standards, the RO must consider this a substantial allegation of noncompliance with Medicare standards and must authorize the SA to conduct a complaint investigation.

If one AO provides notice of termination or withdrawal and concurrently another AO recommends deemed status, a recertification packet including the new AO recommendation must be submitted by the SA to the RO. (See also Section 3258.)

If the RO removes the provider's or supplier's deemed status, it places the provider/supplier under the jurisdiction of the SA and must advise the SA of the change in

the provider's/supplier's status. The SA surveys the facility in order to provide assurance that the facility is in compliance with the applicable Medicare conditions. The timing of the SA survey depends on the reason for the provider's/supplier's loss of accreditation:

- *If the AO terminates accreditation due to failure of the provider/supplier to meet accreditation standards, then the SA must conduct a standard survey within 45 calendar days of notification by the RO that deemed status has been removed. If the AO's reason for termination appears to be related to an immediate jeopardy, then the RO instructs the SA to conduct the standard survey as soon as possible.*

- *If the AO terminates accreditation due to voluntary withdrawal or failure to pay fees by the provider/supplier, the SA prioritizes the provider's/supplier's survey on the basis of the current CMS policy concerning survey frequencies and SA workload priorities, using the date of the most recent accreditation survey to calculate the survey interval, unless:*

    - *The facility is a home health agency (HHA). Then the SA must conduct the survey no later than 3 years after the last accreditation survey; or*

    - *The RO exercises its discretion to request the SA to conduct the survey by a specified date.*

CMS may also temporarily remove deemed status (and therefore AO jurisdiction) when a SA or Federal survey team identifies condition-level non-compliance in a deemed provider or supplier during either a representative sample or substantial allegation validation survey. The RO advises the provider or supplier that its deemed status is removed and that it is being placed under SA jurisdiction. However, no change is made to the provider's or supplier's deemed status in the Automated Survey Process Environment (ASPEN). Instead, the placement of the provider or supplier under SA jurisdiction is noted under the Deeming tab within the certification kit in ACO. The provider/supplier remains under SA jurisdiction until it either demonstrates substantial compliance or CMS terminates its Medicare participation. If the provider/supplier demonstrates substantial compliance to the SA, CMS restores its deemed status. Note that there is no prohibition against an AO also conducting its own survey of a provider/supplier that is temporarily under SA jurisdiction.

Other AO adverse actions

The AO is required to inform CMS of significant adverse actions it takes against the accreditation status of a provider/supplier participating through deemed status. However, as long as the accreditation under the AO's CMS-approved Medicare accreditation program is not terminated, the provider/supplier's participation in Medicare is not affected. See Section 3258 for information on actions to take when an AO terminates the accreditation of a deemed provider or supplier.

The AO is also required to inform CMS by close of business the next day when it identifies an immediate jeopardy situation on a survey. In such cases, the RO generally triages this as an immediate jeopardy complaint and directs the SA to conduct a substantial allegation validation survey, based on the information provided by the AO.

2008A - Surveys of New Providers and Suppliers

(Rev)

New providers/suppliers, *including providers/suppliers whose previous Medicare agreement was terminated and are now seeking initial certification,* must be in *full* operation and providing services to patients when surveyed. This means that at the time of survey, the institution must have opened its doors to admissions, be furnishing all services necessary to meet the applicable provider or supplier definition, and demonstrate the operational capability of all facets of its operations. To be considered "fully operational," initial applicants must be serving a sufficient number of patients so that compliance with all requirements can be determined.

A survey evaluates the manner and degree to which the provider or supplier satisfies the various requirements or standards within each condition. Surveyors *must* directly observe the provision of care and services to patients, and the effects of that care, *in addition to interviewing staff and patients and reviewing medical records* to assess whether the care provided meets the needs of individual patients and is in compliance with all requirements. *Surveyors also review selected provider/supplier policy and procedure documents if needed to support or clarify observations suggesting deficiencies.*

When the provider/supplier notifies the SA of full operation, *the SA* documents the file with the date of notification. The SA conducts the survey *in a timeframe* consistent with CMS policy regarding budget and workload priorities.

2008D - Effective Date of *Medicare* Provider Agreement or Approval for Suppliers

(Rev.)

In accordance with 42 CFR 489.13, the effective date of participation in the Medicare program, i.e. the effective date indicated on the provider or supplier agreement issued by the RO, may not be earlier than the date on which the provider or supplier meets all federal requirements. Federal requirements include, but are not limited to:

- *Meeting all Medicare enrollment requirements addressed in 42 CFR 424;*
- *Meeting all Medicare provider agreement requirements addressed in 42 CFR 489.10 and 42 CFR 489.12, and;*

- *Compliance with Medicare health and safety standards, i.e., the Conditions of Participation, Conditions for Coverage, Conditions for Certification, or long term care Requirements, as applicable.*

    - *For an agreement with a federally qualified health center (FQHC), no survey is required to determine compliance. The effective date is the date on which CMS accepts a signed agreement in which the FQHC attests that it meets all Federal requirements. For FQHCs, the RO uses as the effective date of the supplier approval the date that the MAC indicates it determined that the FQHC's enrollment application was complete and approvable.*

    - *A Medicare supplier approval of a laboratory is effective only while the laboratory has in effect a valid CLIA certificate issued under 42 CFR Part 493, and only for the specialty and subspecialty tests it is authorized to perform.*

    - *Other types of providers and suppliers demonstrate compliance with applicable conditions or requirements via a standard survey by the SA (or Federal surveyors/contractors), or by an AO with a CMS-approved Medicare accreditation program.*

        - *If on that survey the provider or supplier meets all health and safety standards (including elements, where applicable), then the effective date of the Medicare agreement is the last day of the survey, **unless** there are other Federal requirements, such as providing evidence of compliance with Civil Rights requirements, that the provider or supplier has not yet met. The date when all other Federal requirements have been met is the effective date of the Medicare agreement.*

        - *If on that survey the provider or supplier does not meet all health and safety standards (including elements, if applicable), then, assuming all other Federal requirements have been met, the effective date of the Medicare agreement would be:*

            - *For SNFs, the date the SNF has been found to be in substantial compliance with the requirements for participation, and, if applicable, has submitted an approvable waiver request. (See 42 CFR 488.301.)*

            - *For non-long term care providers/suppliers, the date when the provider/supplier has:*

                - *Met all applicable conditions; **or***

                - *Has been found to be in substantial compliance, but has standard-level (or element-level, where applicable) deficiencies and the RO (in the case of surveys conducted by contractors), SA or AO has received an acceptable plan of*

correction (POC) and/or CMS receives an approvable waiver request. If a provider or supplier submits both a POC and an approvable waiver request, the later of the dates of the two submissions would be the effective date.

2016D - Reasonable Assurance Surveys

(Rev.)

Upon receipt of the initial application packet from the SA, the RO will provide the SA with instructions concerning how to conduct the necessary reasonable assurance surveys.

Two surveys are required for Medicare certification to verify that the reason for termination no longer exists, and that the provider/supplier has maintained continued compliance. *At least one of these surveys must be a full/standard survey to ensure that all CoPs/CfCs are met or the SNF is in substantial compliance. The RO has the discretion to determine whether both surveys will be full/standard surveys, or whether one may be* a partial survey to document compliance with requirements for which there were previous deficiencies. *If the RO decides that one survey will be a partial survey, the RO also decides whether the partial survey will be the first or the second survey.* (CMS, at its discretion, conducts the survey for a ICF/IID it originally surveyed and terminated pursuant to §1910(b)(1) of the Act.)

The reasonable assurance period of time begins on the date of completion of the first survey documenting compliance with requirements for which there were prior deficiencies.

The SA conducts the first of the reasonable assurance surveys as instructed by the RO and submits the results of the survey (this may be submitted on Form CMS-2567) to the RO within 10 working days of the survey. Based on the results of this first survey, the RO determines if the reasons for termination no longer exist, or for SNFs, the deficiencies that caused their termination are at the level of substantial compliance. The RO notifies the SA and the provider/supplier of its determination. If the RO determines that the reasons for termination no longer exist, or for SNFs that the deficiencies that caused the termination are at the level of substantial compliance, the reasonable assurance period begins effective with the last day of this first survey. If not, the provider must reapply.

Once the RO determines that the reasonable assurance period has begun, the SA will schedule a second survey to coincide with the end of the reasonable assurance period.

The SA informs the RO of the scheduled survey date. The SA conducts the survey, completes the Survey Report (as applicable), and prepares a statement to accompany Form CMS-1539 that includes:

- The finding that the deficiencies which led to termination of the provider agreement have (or have not) been corrected;

- The evidence showing that compliance has been maintained, and the reasons for concluding that the deficiencies will not recur; and

- A description of any other deficiencies and, if appropriate, an explanation as to why the facility is nevertheless in compliance with all CoPs or the SNF is in substantial compliance (see §§7203.B and 7300.C).

If the RO determines after the second survey that the reasons for termination continues to exist and/or determines that the provider/supplier does not meet the CoPs or the SNF is not in substantial compliance, the provider/supplier must again begin the reasonable assurance process to gain reentry into the program(s). (See §§7203.B and 7300.C for the exception for SNFs and NFs.)

If an *involuntarily* terminated provider/supplier attempts to *re-enter the Medicare program via deemed status accreditation under a CMS-approved Medicare accreditation program, it must still satisfy the reasonable assurance requirements at 42 CFR 489.57. The RO has the discretion to* deny Medicare reentry *based solely on deemed status accreditation surveys and may instead require two surveys be performed* by the SA if it is not reasonably assured the provider/supplier meets the Medicare conditions. *The RO also has the discretion to accept an accreditation survey for either the first or second of the reasonable assurance surveys. Generally an AO would not conduct both reasonable assurance surveys, but if it is willing to do so and the RO is reasonably assured that the provider/supplier meets the Medicare conditions, the RO may permit the AO to conduct both reasonable assurance surveys.*

In cases *involving readmission of an involuntarily terminated provider seeking deemed status*, 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/*supplier's reentry into the* Medicare *program*. 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.

The regulation at 42 CFR 489.57 does not apply to a provider's voluntary termination of its agreement under the provisions of the regulation at 42 CFR 489.52. In a scenario similar to the situation described above except that the provider's termination from Medicare was voluntary, CMS (the RO) would still be responsible for the if, when and how of the provider agreement under 42 CFR 489.12. However, the provider's accreditation by a recognized accrediting body and subsequent deemed status would

mean that compliance with the CoP would not be one of the unmet requirements under title XVIII of the Act that could be invoked under 42 CFR 489.12(a)(3). This is pointed out because some providers voluntarily withdraw from Medicare in the face of a proposed involuntary termination. A RO could decide to process an involuntary termination in such a case. 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)(3) in a case where a provider facing involuntary termination voluntarily withdrew from Medicare and subsequently attempted to re-enter the program through accreditation *under a CMS-approved Medicare accreditation* program.

The regulation at 42 CFR 489.57 also does not apply to a provider's initial application for Medicare participation. Again, as with a voluntary termination, the CMS (RO) is responsible for the if, when and how of the provider agreement and a decision to deny the provider an agreement must be in accordance with 42 CFR 489.12. Also, if an accrediting organization has determined that the provider is accredited, the provider is deemed to meet the Medicare conditions and we would have satisfactory assurance of compliance with the conditions under 42 CFR 489.12(a)(3). However, as with a voluntary termination, we might look at 42 CFR 488.6(c)(2) in tandem with 42 CFR 489.12(a)(3) in an individual case. This means that we should notify accrediting bodies if and when we deny a provider entry into Medicare based on a State survey agency survey. This includes providers that are surveyed by the State but do not respond to a Statement of Deficiencies.

2016E - Effective Date of Provider Agreement *After Reasonable Assurance*

(Rev.)

If the provider or supplier has maintained compliance throughout the reasonable assurance period, it *may* reenter the program *and be issued a new provider agreement or supplier approval*. The *effective date of the new* Medicare *agreement* and Medicaid FFP is *calculated based on* the date of completion of the second *reasonable assurance* survey. *See Section 2008D for details on the calculation of the effective date.*

2021 – Non-*deemed* Hospitals

(Rev.)

2021A – Recertification of Non-*deemed* Hospitals

(Rev.)

Hospitals that *are certified for* Medicare *participation based on a* SA *survey* should be recertified on a schedule consistent with the survey guidelines for *non-deemed* hospitals issued *by CMS* each fiscal year. A recertification packet for each hospital is to be sent to the RO by the SA. Exhibit 63 has a complete list of documents to be completed and included in the recertification packet. The Certification & Transmittal Form, CMS-1539 (C&T), which is part of the recertification packet, should indicate in the "remarks" section that the C&T is transmitting a non-*deemed* hospital recertification. If the hospital

has undergone a change of ownership *with acceptance of assignment of the Medicare provider agreement by the new owner* since the last recertification survey, also indicate if a Change of Ownership (CHOW) package was forwarded to the hospital by the SA.

In addition, the SA also updates Exhibit 286, the Hospital/CAH Medicare Database Worksheet, with any new information regarding the hospital. It is not permissible to forward the Hospital/CAH Medicare Database Worksheet to the hospital for completion. The SAs are not expected to conduct an onsite visit of the hospital solely to obtain information for the worksheet. However, the SAs may be able to use State licensure data to update the worksheet. The updated Hospital/CAH Medicare Database Worksheet should be forwarded with the recertification packet to the RO. The ASPEN system *must* also be updated to reflect any changes to the information on the Hospital/CAH Medicare Database Worksheet. This policy applies to ALL non-*deemed* hospitals.

2022 – *Deemed Status:* Hospitals Accredited by *an Accrediting Organization with a CMS-approved Medicare Hospital or Medicare Psychiatric Hospital Accreditation Program*

(Rev.)

2022A - Notice that *a* Participating Hospital Has Been Accredited *and Recommended for Deemed Status*

(Rev.)

A hospital accredited *and recommended for deemed status* by *a national accreditation organization with a CMS-approved Medicare hospital accreditation program may be* deemed to meet all CoPs for hospitals (except the SNF Requirements for swing-bed designation and any higher-than-national standards approved by the Secretary for a State under §1863 of the Act). *Additionally, a psychiatric hospital accredited and recommended for deemed status by a national accreditation organization with a CMS-approved Medicare psychiatric hospital accreditation program may be deemed to meet all CoPs for psychiatric hospitals.*

When notified that a participating hospital *or psychiatric hospital* has been accredited *and recommended for deemed status*, the *RO* verifies the accreditation *and recommendation for deemed status and notifies the SA*. The SA executes Form CMS-1539 to report the accreditation *and recommendation for deemed status*.

2022B - Recertification

(Rev.)

Hospitals *or psychiatric hospitals* that receive their Medicare certification via *deemed status based on* accreditation by a CMS-approved Accreditation Organization (AO) should be recertified by the State Survey Agency (SA) on a schedule consistent with the accreditation interval of the AO. *Upon receipt of a notice from the AO indicating that it*

has renewed a hospital's accreditation and is recommending continued deemed status, a recertification *kit should be created in the Automated Survey Processing Environment (ASPEN) or recertification* packet for each deemed hospital *or psychiatric hospital* is to be sent to the RO by the SA. Exhibit 63 has a complete list of documents to be completed and included in the recertification packet. The Certification & Transmittal Form, CMS-1539 (C&T), which is part of the recertification packet, should indicate in the "remarks" section that the C&T is transmitting an accredited hospital recertification.

In addition, the SA also updates the Hospital/CAH Medicare Database Worksheet, Exhibit 286, with any new information regarding the hospital. It is not permissible to forward the Hospital/CAH Medicare Database Worksheet to the hospital for completion. The SAs are not expected to conduct an onsite visit of *a deemed* hospital solely to obtain information for the worksheet. However, the SAs may be able to use State licensure data to update the worksheet. The updated Hospital/CAH Medicare Database Worksheet *must be entered into ASPEN and be included in the recertification kit* forwarded to the RO*; the recertification kit will not upload to the national data base unless a Hospital/CAH Medicare Database Worksheet has been completed*.

2022C - Notification of Withdrawal or Loss of Accreditation

(Rev.)

See Section 2005B.

2044 *- Psychiatric Hospitals and Deemed Status*

(Rev.)

Psychiatric hospitals have a Medicare accreditation option available to them. Prior to this being the case, however, CMS permitted a psychiatric hospital to have deemed status with respect to all hospital conditions (identified as "A" tags in ASPEN) except the special psychiatric CoPs at 42 CFR 482.60-62 (identified as "B" tags in ASPEN). Under this arrangement, the AO was responsible for assessing the psychiatric hospital's compliance with all other hospital CoPs, i.e., those provisions with A tags, and either the SA or CMS' contract surveyors assessed compliance with the special psychiatric CoPs, i.e., the B tags. Currently almost all deemed status psychiatric hospitals are accredited under the approved Medicare psychiatric hospital accreditation program, and their AO is responsible for assessing compliance under ***both*** *the A and B tags.*

Any psychiatric hospital seeking initial participation in Medicare through deemed status must be accredited under a CMS-approved Medicare psychiatric hospital accreditation program. This also is the case for any non-accredited participating psychiatric hospital seeking to switch to deemed status. CMS no longer permits a psychiatric hospital to seek participation through deemed status for the A tags only. However, there are a small number of participating psychiatric hospitals that were deemed to meet the requirements for the A tags only prior to CMS approving a psychiatric hospital Medicare accreditation program. CMS considers these hospitals to have grandfathered deemed status for the A

tags only, and SAs or CMS contract surveyors remain responsible for B tag surveys in these facilities.

If a psychiatric hospital currently has deemed status for the A tags through accreditation by an AO which has a CMS-approved Medicare hospital accreditation program but does not have a CMS-approved Medicare psychiatric hospital accreditation program, and the psychiatric hospital wishes to be deemed for the special psychiatric hospital CoPs, it must seek accreditation from an AO with a CMS-approved Medicare psychiatric hospital accreditation program. In this instance, the psychiatric hospital may not choose to continue its current Medicare hospital accreditation with one AO in addition to obtaining its new Medicare psychiatric hospital accreditation with another AO; it must withdraw from its current Medicare hospital accreditation program and seek or maintain accreditation under a CMS-approved Medicare psychiatric hospital accreditation program only. It is ***not*** *permissible for the psychiatric hospital to both be accredited by one AO under its hospital program and by another AO for the special psychiatric CoPs only.*

*When the SA is responsible for surveying the special psychiatric CoPs of an otherwise deemed psychiatric hospital, t*he SA completes the Medicare/Medicaid Psychiatric Hospital Survey Data, Form CMS-724, and all other relevant survey documents (Form CMS-2567, etc.) for the survey.

2053 - Medicaid-only Hospitals

Many hospitals choose to participate in both the Medicare and Medicaid programs. However, a hospital may choose to only participate in Medicaid. Medicaid regulations at 42 CFR 440.10 and 42 CFR 440.140(a) require a hospital or psychiatric hospital (also referred to in Medicaid as an "institution for mental disease," which is defined at 42 CFR 435.1010) participating in Medicaid to meet the requirements for participation in Medicare in order to receive Medicaid payment. These regulations do not require a hospital or psychiatric hospital to enroll in the Medicare program in order to demonstrate compliance with Medicare participation requirements. The provider agreement rules at 42 CFR 489.10 establish the basic Medicare participation requirements for providers, including requirements for hospital participation. These requirements include, but are not limited to, complying with the following: applicable hospital Conditions of Participation (CoPs) at 42 CFR Part 482; specified Office of Civil Rights requirements; and the advanced directive requirements at 42 CFR 489.100 and 42 CFR 489.102.

2053A- Initial Certification of Medicaid-only Hospitals

Hospitals seeking initial certification to participate in the Medicaid program only must contact the State Agency (SA), in accordance with §§1902(a)(9)(A) and 1902(a)(33) of the Act, to initiate the certification process. Requirements for this process are

established in the Medicaid State Plan's required written agreement (or formal written intra-agency arrangement) between the State Medicaid Agency (SMA) and the SA (See 42 CFR 431.610(f)).

The SMA must approve the hospital's request for enrollment into the Medicaid program prior to the initiation of the certification process by the SA.

2053B- Certification Surveys of Medicaid-only Hospitals

Following verification by the SMA that the enrollment application process has been initiated by the hospital, the SA must determine if the hospital seeking Medicaid-only certification demonstrates compliance with requirements for Medicare participation, including all applicable CoPs, through the completion of an on-site survey. Hospitals have the option of establishing compliance with applicable CoPs through accreditation under 42 CFR 488.6(b) by a nationally recognized Accreditation Organization (AO) with a CMS-approved Medicare hospital or psychiatric hospital program. Hospitals choosing this option must provide the SA with a letter issued by the AO confirming its accreditation under a CMS-approved Medicare accreditation program and recommending deemed status as a Medicaid-only hospital. (As with Medicare-participating hospitals, it is possible that a hospital might be accredited, but not have deemed status. The AO letter must indicate the hospital is recommended for deemed status.) However, regardless of whether the survey is conducted by the SA or a CMS-approved AO, the SA must issue a determination to the SMA as to whether the hospital has met all Medicare participation requirements for Medicaid-only hospital participation.

Upon receipt of the SA's determination, the SMA issues an effective date for the hospital's participation in the State Medicaid program. The SA then compiles and forwards a Medicaid-only certification packet to the RO. This packet consists of the hospital's request for an applicable Medicaid-only hospital or psychiatric hospital CMS Certification Number (CCN), the SA's certification of compliance with Medicare CoPs, and the SMA-issued State Medicaid program effective date. After review of all documentation, the RO issues the appropriate Medicaid-only hospital CCN.

2053C-Change in Certification

If the hospital decides to seek participation in Medicare as well as Medicaid, see Section 2777D3.

2053D- Termination

The SMA must terminate the hospital's Medicaid agreement when the SA determines that the hospital does not meet the applicable requirements. See Section 3005C-3.

2053E- Complaint Investigation

All allegations of non-compliance with Federal or State requirements in Medicaid-only hospitals must be referred to the SA.

Under 42 CFR 431.610, the SA in collaboration with the SMA must determine the policies and procedures for the intake, triage and investigation of all allegations of non-compliance in both deemed and non-deemed Medicaid-only hospitals. The SA is solely responsible for reporting complaint investigation findings to the SMA, including a determination whether a Medicaid-only hospital meets Medicare CoPs and other federal requirements in accordance with §1902(a)(33)(B) of the Act.

2202.10A - Determining Compliance With the OASIS Transmission Requirements

(Rev.)

Depending on the method of transmission the HHA chooses, the SA needs to determine compliance in one of the following ways:

- If the new HHA chooses to independently transmit OASIS data from its own office, the State HHA survey team and OASIS coordinator must communicate with each other to establish that the new HHA has successfully transmitted test OASIS data using the appropriate temporary user identification numbers and passwords, prior to onsite survey. The HHA should maintain all copies of validation reports for its records.

- If the new HHA chooses to use a software vendor to meet the OASIS encoding and/or transmission requirement on its behalf, the HHA must still establish connectivity to the OASIS State System via the software vendor. The HHA should have a written contract that describes this arrangement. The HHA or its software vendor must apply for the applicable temporary user identification numbers and passwords from the SA in order to establish connectivity with the OASIS State System. As described above, the HHA survey team and OASIS coordinator must communicate with each other to establish that the software vendor, on behalf of the new HHA, has successfully transmitted test OASIS data using the appropriate temporary user identification numbers and passwords, prior to onsite survey. The HHA should obtain copies of all validation reports from its software vendor for its records.

- If the new HHA chooses to use another certified HHA to meet its transmission requirements, for example, another established HHA in the chain or other established but non-related HHA, the HHA must still demonstrate connectivity to the OASIS State System via the other established certified HHA. The new HHA or other HHA must apply for temporary user identification numbers and

passwords, unique to the new agency, from the SA, in order to establish connectivity with the OASIS State System. The new HHA must have clearly written policies outlining the procedures in place with the other HHA with regard to OASIS collection, encoding and submission to the OASIS State System and the sharing of feedback reports from the OASIS State System with the new HHA.

2202.10B - HHAs Seeking Initial Certification Through *Deemed Status*

(Rev.)

An HHA may choose to obtain initial Medicare certification by electing the deemed status option through an approved AO that has *a CMS-approved Medicare HHA accreditation program*. HHAs seeking initial certification through the deemed status option still must apply to the SA for user identification numbers and passwords in order to demonstrate compliance with OASIS submission requirements prior to approval.

When the SA receives a request from an HHA interested in seeking Medicare deemed status through accreditation, the State ensures that the HHA understands its obligation to meet the OASIS requirements, even when the AO conducts the initial certification survey. This includes compliance with the OASIS collection and transmission requirements.

If the SA receives a certification packet from an HHA seeking Medicare certification based on its accreditation through a deemed status program, it is the SA's responsibility to determine that the HHA meets its OASIS transmission responsibilities. The OASIS transmission responsibility may be met in one of the three ways described above.

2202.10C - Exceptions to Demonstrating Compliance With OASIS Submission Requirements Prior to Approval

(Rev.)

New HHAs that intend to admit or treat only patients to whom OASIS currently does not apply, i.e., patients under 18, maternity, and patients receiving only unskilled care or chore services are not expected to demonstrate compliance with OASIS submission requirements prior to approval.

These HHAs must attest this intention to the SA. After certification, if there is a change in the HHA's policies that includes the acceptance of patients to whom OASIS applies, the HHA is expected to install the necessary communications software and contact the SA and MDCN for the applicable user identification numbers and passwords.

2202.10D - Compliance Dates and PPS

(Rev.)

Compliance with the rest of the CoPs is determined via an onsite survey by the SA and any applicable subsequent actions or revisions required of the HHA following the initial survey. After survey, the new HHA cannot bill Medicare for payment of services to Medicare beneficiaries until the effective date for Medicare participation has been determined by the CMS RO.

Realistically, notification of the effective date may come many weeks after the initial survey of the HHA. In addition, the date of official compliance may vary depending on the outcome of the onsite survey. As described in §2780, the date of compliance is either:

1. The date the onsite survey is completed if, on the date of the survey the HHA meets all CoPs and any other requirements required by CMS; or

2. If the HHA fails to meet any of the requirements as a result of the onsite survey, compliance is the earlier of:

    - The date the HHA meets all requirements; or

    - The date the HHA meets all the CoPs and submits an acceptable plan of correction for standard level deficiencies.

Payment under Medicare for services provided prior to the effective date for Medicare participation is not permitted. As such, it is important that new HHAs seeking payment under Medicare establish the required 60-day episode on or after the effective date of their Medicare participation.

2202.10E - Instructions for Handling Medicare Patients in HHAs Seeking Initial Certification

(Rev.)

If the HHA is confident that it has met all CoPs and all other Medicare requirements at the time the initial survey is completed, the HHA is advised to do a new SOC assessment, (RFA 1) on each of its Medicare patients at the first billable visit after the onsite survey. The HHA should delay encoding and transmitting the assessment until the Medicare provider number is assigned.

Once the provider number has been assigned, the HHA can go back and encode the collected OASIS information, obtain the necessary payment system codes for billing under PPS, and transmit the information to the OASIS State System as production (i.e., “live”) data. The date of this assessment will become day 1 of the HHA’s first 60-day episode under Medicare, as long as the assessment was done in conjunction with a billable visit. Warning messages related to noncompliance with timing requirements are unavoidable and are to be expected in this situation.

If compliance (i.e., the effective date) is not the date of the onsite survey, it will be based on D.2. above, as further outlined in §2780. The HHA should, again, do a new SOC assessment (RFA 1) on each of its Medicare patients at the first billable visit after the anticipated date of compliance, delay encoding and transmitting the assessment until the Medicare provider number is assigned, and continue as outlined in the paragraph above. That is, the HHA should go back and encode the collected OASIS information, obtain the necessary payment codes for billing under PPS, and transmit the information to the OASIS State System as production data. As above, warning messages related to noncompliance with timing requirements are unavoidable and are to be expected in this situation.

If the new HHA did not conduct a SOC (RFA 1), ROC (RFA 3), or Follow-up (RFA 4) OASIS assessment during the time between the effective date for Medicare participation and the date the HHA learns of its approval, the HHA should conduct a SOC assessment, as soon as possible. This assessment can be used to generate the payment code used for billing under Medicare. The SOC date should reflect a date that is consistent with the first billable visit after the effective date for Medicare participation, as stated above.

2202.10F - Instructions to New HHAs Concerning all Other Patients
(Rev.)

For all other patients treated by the HHA (i.e., non-Medicare patients), if a new start of care date is not required by the patient's pay source, the HHA should encode and transmit all OASIS assessments as required by current regulation that were collected after the effective date of Medicare participation. These assessments should be submitted in the production mode using the newly assigned provider number. The HHA should continue with the OASIS assessment schedule already established based on the patient's admission date.

2705 - SA Survey Team Workload
(Rev.)

The Survey Team Composition and Workload Report (*also referred to as the* "CMS-670*" report*) is an integral part of the overall survey process. The SA completes this form for all survey and/or resurvey activities as it provides necessary information on resource use applicable to survey activity of all *Medicare, Medicaid-only, and dual participating* providers and suppliers and CLIA laboratories.

The SA follows these guidelines *in completing this report*:

- If a survey does not include an onsite visit, do not enter arrival, departure, onsite, and travel dates or times on *the* 670. Enter all other appropriate fields;

- Include on *the* 670 the time spent by surveyors-in-training who have a surveyor ID number. However, if the trainee simply observes a survey, exclude his/her time from the form;

- Report only direct, survey-related time on *the* 670. This includes data entry and supervisory review time. Do **NOT** include general administrative time, such as time spent logging onto the CMS Data Center;

- The Type of Survey and Extent of Survey boxes are not **required** for data entry. However, complete these boxes on *the* 670 since the information may be helpful;

- On a combined certification/State licensure survey, enter the **total** time (Federal and licensure) spent on various phases of the survey, even if you conduct the certification survey first, followed by the licensure survey (or vice versa);

- Do not complete *the* 670 for visits conducted solely for licensure purposes;

- Treat multiple complaints investigated at the same time as one complaint survey and enter on one 670;

- If complaints are conducted concurrently with a recertification survey or follow up, report the complaint on a separate 670;

- Include in Column D time spent reviewing complaints in-office as pre-survey preparation hours if a complaint survey is subsequently conducted;

- Prospective Payment System (PPS) surveys are not entered into *CASPER*. Therefore, do not complete Form CMS-670 for PPS surveys;

- Prepare separate 670s for all health, LSC, complaint investigation, and Federal Monitoring Surveys (FMS);

- In cases where the same surveyor performs both health and LSC activities, time that cannot be specifically attributed to one survey or the other must be equally split between the two 670s (one for health and one for LSC);

- Supervisory review time reported on *the* 670 is that level of **routine** review normally conducted on all survey reports. It does not include special quality assurance committee review, team leader review, or team review;

- Do not record time spent tracking nurse aide training and competency reviews on *the* 670;

- In computing travel time, report the **lesser** of time spent in travel from either the surveyor's home to site or office to site;

- Enter on *the* 670 under the appropriate surveyor ID number the time supervisors spend participating in a survey (conducting reviews, exit conferences, etc.);

- Assign SA consultants identification numbers in the event that they participate in surveys. Their time should be included on *the* 670 if they participate;

- If more than 10 surveyors participate in a survey, use continuation forms to input survey data into the system. The *CASPER* system has been reconfigured to accept up to 990 surveyors.

- If errors are made in data entry, change the information by accessing *ASPEN*

- For supervisors who review a CHOW in house, **DO NOT** enter the time in *ASPEN*, unless a survey is conducted in conjunction with the CHOW;

- Do not enter QIO staff on *the* 670 since they are not part of the survey staff;

- Use *the* 670 only for collecting time spent preparing for, conducting, and finalizing a survey of a facility. Do not capture time spent in hearings after a survey has been completed on *the* 670; and

- Record travel to a patient's home as well as time spent in the patient's home on an HHA survey as onsite time, not travel time.

2764 - SA Completion Instructions for Certification and Transmittal, Form CMS-1539 (Exhibit 9)

(Rev.)

Except for the signatures and signature dates, the SA types all entries on Form CMS-1539.

NOTE: Within each item on Form CMS-1539 there are code numbers for data reduction purposes (e.g., (L1), (L2)). These codes are used only for data entry into the ODIE system. Disregard them in completing the form.

Item 1 - Medicare/Medicaid Provider No

Leave this item blank on all initial certifications. The RO assigns the identification numbers for all new providers and suppliers and furnishes the SA with the number via a copy of the acceptance letter. On all subsequent certification actions such as resurveys, CHOWs, and name and address changes, the SA inserts the facility's assigned provider/supplier number.

Provider numbers for hospitals and LTC facilities with multiple components and/or distinct parts are assigned by the RO using the following criteria:

A - Long-Term Care Facilities with Distinct Parts

One provider number is assigned and only one Form CMS-1539 prepared for the following situations (see §2779):

- SNF/NF with a SNF or NF distinct part; and
- SNF with a NF distinct part.

B - LTC Distinct Part Units of Hospitals

Provider numbers are assigned in the following fashion:

1 - Hospital with Distinct-Part SNF

Two provider numbers are assigned, one for the hospital and one for the SNF. Prepare separate Forms CMS-1539 for certification actions regarding each component.

2 - Hospital with Distinct-Part NF

Two provider numbers are assigned, one for the hospital and one for the NF. Prepare separate Forms CMS-1539 for certification actions regarding each component.

3 - Hospital with Distinct-Part SNF/NF

Two provider numbers, one for the hospital and one for the SNF/NF, are assigned. Prepare separate Forms CMS-1539 for certification actions regarding each component.

C - "Swing-Bed" Hospitals

Two numbers are assigned, one for the hospital and one for the swing-bed portion. Prepare one Form CMS-1539.

D - PPS-Excluded Hospitals

Hospitals with psychiatric and/or rehabilitation units that are excluded from the PPS are assigned two and/or three numbers, as appropriate (e.g., XX-0000 and XX-S000 and/or XX-T000). Prepare one Form CMS-1539.

Item 2 - State Vendor or Medicaid Number

The SA completes this item only for those States that assign separate vendor (or Medicaid ID) numbers for internal controls or for billing purposes. The SA should leave this item blank if a State does not have such a system.

Item 3 - Name and Address of Facility

The SA enters the name, address, city, State, and zip code of the facility, and enters the 2-digit State abbreviation and zip code in the available blocks. A post office box without a street address is not sufficient.

Item 4 - Type of Action

In the block provided, the SA enters the appropriate code in accordance with the following explanations: Codes 2 and 4 are self-explanatory. Code 6 and 8 are no longer applicable.

A - Code 1 (Initial Survey)

In addition to initial certifications, the SA selects this code when recommending an initial denial of participation. The SA indicates in Item 15 that it is recommending denial.

B - Code 3 (Termination)

The SA selects this code for involuntary termination, voluntary termination/withdrawal, or change in status requiring a new provider number (e.g., when a NF elects to also participate as a SNF).

C - Code 5 (Sample Validation)

The SA selects this code for a complete survey in an accredited facility for sample validation purposes. The SA completes all appropriate blocks on the form including items 6 (survey date), 8 (accreditation status), and 10 (compliance provision).

D - Code 7 (Onsite Visit)

The SA selects this code for an **onsite** inspection of a facility for some other reason **not** outlined above. Examples include:

1. Onsite revisit to verify that the deficiencies cited on the original survey are corrected and a Form CMS-2567B is completed;

2. Onsite visit to verify that a hospital meets the criteria for hospitals operating with multiple components; and

3. Onsite visit to verify that an HHA's satellite meets the branch/subunit criteria.

E - Code 9

The SA selects this code for any certification action not specified above (e.g., changes in effective date, size, facility name, or address). Whenever action code 9 is selected, the SA shows in Remarks, Item 16, the reason for completing Form CMS-1539.

Item 5 - CHOW Date

When Item 4 is marked CHOW (code 4), the SA enters the date the change occurred (e.g., 060782) in Item 5.

Item 6 - Survey Date

For providers who require a fire safety survey, the SA enters the date the health or fire safety survey is completed, whichever is later. For providers and suppliers who do not need a fire safety survey, the SA enters the date the health survey is completed (e.g., 060283).

Item 7 - Provider/Supplier Category

In the block provided, the SA enters the code that is most descriptive of the facility identified on the form. Some of the provider/supplier codes are further described below:

A - Code 02 - (SNF/NF)

Until Form CMS-1539 is revised to reflect changes made by P.L. 100-203, enter this code in the category block when a nursing home participates in both Medicare and Medicaid in its entirety.

B - Code 03 - (SNF/NF Distinct Part)

Mark code 03 in the block when **any portion** of the facility is designated as a NF or SNF distinct part. For example, enter code 03 if a 150-bed LTC facility has 50 NF distinct-part beds and the remaining 100 beds are SNF/NF dually participating and/or SNF beds only.

C - Code 04 - (SNF)

Enter code 04 in the category block when one of the following apply:

1. Freestanding SNF; or

2. SNF distinct part of hospital.

D - Code 10 - (NF)

Enter code 10 when the facility is a freestanding NF or a NF distinct part of a hospital.

E - Code 11 - (ICF/*IID*)

Enter code 11 in the available block when either the entire facility or part of a facility is certified as an ICF/*IID*.

Item 8 - Accreditation Status

The SA always completes this item for accredited providers. For nonaccredited facilities, the SA enters code 0. For accredited hospitals, ASCs, HHAs, and laboratories, the SA enters code 1 (JCAHO) or code 2 (AOA) to identify those accrediting bodies or enters code 3 for other accrediting organizations such as Community Health Accreditation Program (CHAP), American Association of Blood Banks (AABB), College of American Pathologists (CAP), American Society of Histocompatibility and Immunogenetics (ASHI) and Commission on Office Laboratory Accreditation (COLA).

Item 9 - Fiscal Year Ending Date

The SA enters the ending date (month and day) of the provider's/supplier's fiscal year (e.g., 0630).

Item 10 - State Agency Certification

A - In Compliance With Program Requirements

If "A" is entered in the first block and the facility is not in full compliance with the program requirements, all conditional aspects are coded in the blocks following "A." For example, the SA enters A126 when a hospital is in compliance with the program requirements based on an acceptable PoC, recommended waivers for technical personnel, and limited scope of service.

NOTE: A1 applies to all provider/suppliers with an acceptable PoC.
A2 and A6 apply to hospitals only.
A3 applies to hospitals, SNFs, and NFs only.
A4 is no longer applicable.
A8 and A9 apply to all LTC facilities.
A5 applies to all facilities that undergo a fire safety survey.
A7 no longer applies to SNFs.

B - Not in Compliance With Program Requirements (Termination Development)

If "B" is entered in the first block, the documentation supporting the termination action must accompany Form CMS-1539 and be referenced in Item 16 of Remarks. Item "B" is also selected when an accredited hospital is not in compliance with one or

more of the CoPs surveyed during the sample validation survey or complaint investigation.

C - Not in Compliance With Program Requirements (Denial of Payments for New Admissions for SNF, NF, and ICF/IID)

1 - Denial of Payments Recommended

The SA marks "B" in the first block when a recertified SNF, NF, or ICF/*IID* is not in compliance with the program requirements and is a likely candidate for denial of payments for new admissions. The SA annotates Item 16, "Remarks" to indicate that a denial of payments may be applied.

2 - Resurvey Finds Substantial Compliance

Following a revisit, the SA marks "A" in the first block when the facility is found to be in substantial compliance with the program requirements. The SA annotates Item 16, "Remarks" to show that the denial of payments for new admissions should be ended.

D - Resurvey Does Not Find Significant Progress

Following the revisit, the SA marks "B" in the first block when a facility is still not in compliance with program requirements and significant progress in correcting the deficiencies cannot be documented. The SA annotates Item 16 "Remarks" to show that the denial of payments for new admissions should remain in effect or that a termination action is being initiated.

NOTE: In all cases, the appropriate SA documentation must accompany Form CMS-1539.

Item 11 - LTC Period of Certification

TLAs are required for ICFs/IID. The SA inserts the recommended beginning (FROM) and ending (TO) dates of the TLA. If ICFs/IID are not in compliance with the CoPs, the SA establishes a conditional period of certification subject to automatic cancellation. When this occurs, the SA includes the cancellation date in Item 16, "Remarks."

Item 12 - Total Facility Beds (Complete for Hospitals, SNFs, NFs, and ICF/IIDs)

The SA enters the total number of beds in the facility including those in non-participating and non-licensed components or areas. **The Number of Beds in the Certified Portion of the Facility Must Not Exceed the Number of Total Beds.**

NOTE: The number of total facility beds and beds in the certified portion of the facility on Form CMS-1539 is restricted to the entire facility or the distinct part identified in Items 1 (Provider Number) and 7 (Provider Category).

Item 13 - Total Certified Beds (Complete for Hospitals, SNFs, NFs, and ICF/IIDs)

The SA enters the number of beds in Medicare and/or Medicaid certified areas.

Item 14 - SNF, NF, and ICF/*IID* Certified Bed Breakdown

The total number of beds in the certified portion of the facility recorded in Item 13 must be divided in Item 14 according to type of program (i.e., Box A-18 SNF, Box B-18/19, Box C-19 NF, and Box E-ICF/IID). Boxes D and F are no longer applicable.

The SA completes boxes A, B, C, and E, as appropriate. **These blocks must equal Item 13 (total beds in the certified portion of the facility).**

The examples on the following pages illustrate how Items 1 (*CMS Certification N*umber) and 7 (Provider category) must be completed in conjunction with Items 12-14 for all hospital, SNF, NF, and ICF/IID providers.

Item 15 - Nonparticipating Emergency Hospitals and NFs

The SA enters code 1 or 2 in the block provided.

The SA completes this block when a nonparticipating hospital meets the definition of an emergency hospital in order to claim payment for emergency services rendered to Medicare patients. For participating NFs, the SA enters the appropriate code when the facility meets, or does not meet, the §1861(j) of the Act definition for durable medical equipment (DME) and home health benefit purposes.

Item 16 - State Survey Agency Remarks

The SA uses this space for any required remarks. If the comments exceed the allotted space, the SA continues on a sheet of paper entitled "Item 16 Continuation for CMS-1539." The SA includes the provider number, if known, on the sheet for identification purposes. Whenever Item 4 is completed as "Other," the SA uses "Remarks" to indicate the reason for completing Form CMS-1539. The following is a list of remarks which must be entered whenever appropriate.

Remarks	**SOM Reference**
Exclusion from Certification (Non-PPS)	§§2026, 2048, 2134, and 7016
Loss of *Deemed Status* Accreditation	§20*05B*

Remarks	**SOM Reference**
Certification of Additional Services	§§3220, 3222
RHC Furnishes Home Health Services Determine Whether in HHA Shortage Area	§2246
Waiver(s) Recommended	§§2030, 2140, 2248, 2480, 7014
Multiple Locations	§§2024, 2182, 2184, 2302, 2344
Denial of Payments Is Recommended	§§3006, 7506

EXAMPLE 1

1. Provider Number

| X | X | 0 | 0 | 0 | 0 | (Hospital)

7. CATEGORY	12. TOTAL FACILITY BEDS	13. TOTAL CERTIFIED BEDS
0 1 (Hospital)	3 0 0	3 0 0

14.
LTC Certified Bed Breakdown

| SNF | SNF/NF | NF | ICF/IID |

Handling Public Inquiries

3000C - CMS Authority to Terminate Medicare and Medicaid Participation

(Rev.)

1. Noncompliance with Conditions of Participation (CoPs), Conditions for Coverage, or Requirements for SNFs - The RO is delegated authority to terminate Medicare participation of *any certified* provider *or* supplier because of noncompliance with the applicable regulatory requirements, or Conditions of Participation (CoPs) or Conditions for Coverage (CfCs).

2. Violations of *Medicare* Provider Agreements *or certified Supplier Approvals*, Quality Improvement Organization (QIO) Sanctions, or Program Abuse - The Secretary's authority to terminate provider agreements *or certified supplier approvals* is delegated to the Associate Regional Administrator and may be redelegated to the RO Branch Chief, but other components may also be authorized to find that termination is in order. ***Accordingly, the RO processes terminations on grounds other than noncompliance with the CoPs. See §3032.***

3. "Look Behind" Cancellation of Medicaid Intermediate Care Facility/*Individuals with Intellectual Disabilities* (ICF/IID) Agreements - The ROs are authorized to cancel the approval of an ICF/IID to participate in the Medicaid program when the ICF/IID fails to comply substantially with *the applicable* CoPs. (See §1910(b) of the Act.)

4. Termination of Nursing Facility (NF) Medicaid Agreements - The ROs are, under certain circumstances, authorized to terminate a NF's participation in the Medicaid program. (See §1919(h) of the Act and Chapter 7 of the SOM.)

3005E - Termination of Title XIX-Only NFs, ICFs/*IID, Hospitals and Psychiatric Hospitals*

(Rev.)

Under 42 CFR 431.54(f), the State Medicaid Agency may "lock out," i.e., restrict the participation of a Medicaid provider for a reasonable period if it has found that the provider has abused the Medicaid program. The SMA may take this action in response to, or independent of any SA or accrediting organization recommendation. Note that the Medicaid program, unlike the Medicare program, does not distinguish between "providers" and "suppliers" and the term "provider" applies to both for Medicaid purposes.

In order to determine that a provider has abused the Medicaid program, the SMA must find that in a significant number or proportion of cases the provider has:

- *Furnished services at a frequency or amount not medically necessary (§431.54(f)(2)(i)); or*

- *Furnished Medicaid services of a "quality that does not meet professionally recognized standards of health care." (§431.54(f)(2)(ii)).*

Additional conditions required before imposing any restriction on a provider are found in §431.54(f).

Medicaid-only NFs and ICFs/IIDs

Medicaid regulations provide for terminations, and for ICFs/*IID* cancellations, but do not describe the implementing procedures. Each SMA has procedures for terminating agreements with NFs and ICFs/*IID* when they are not in substantial compliance with program requirements. In any Medicaid-only noncompliance situation, the SA initiates the action, prepares the necessary documents, and forwards them to the SMA, which has responsibility for the termination, nonrenewal, or cancellation of the agreement (see §7300 for the exception regarding State operated NFs). In this case, the SMA notifies CMS and the public of its action and affords the facility notice and opportunity for a hearing before an ALJ prior to termination.

Medicaid-only Hospitals and Psychiatric Hospitals

42 CFR 482.1(a)(5) notes generally that any hospital or psychiatric hospital that participates in Medicaid must meet the Medicare CoPs. Medicaid regulations at 42 CFR 440.10 (hospitals) and §440.140 and 440.160 (psychiatric hospitals) require Medicaid-participating hospitals and psychiatric hospitals to comply with the Medicare CoPs. If a SA survey of a Medicaid-only hospital or psychiatric hospital finds substantial noncompliance, i.e., condition-level noncompliance, including immediate jeopardy, with the CoPs, the SA follows the standard SOM processes for requiring a plan of correction and conducting revisits. If the hospital or psychiatric hospital fails to come into substantial compliance in a timely manner, the SA notifies the SMA, which takes appropriate action in accordance with Federal Medicaid regulations and State plan provisions.

Likewise, in the case of a hospital or psychiatric hospital that participates in Medicaid based on accreditation by a CMS-approved Medicare hospital or Medicare psychiatric hospital accreditation program, the accrediting organization (AO) must notify both CMS and the SMA if the facility's accreditation is terminated for any reason. The SMA may in such cases request the SA to conduct a survey to determine the hospital's or psychiatric hospital's compliance with the CoPs, or may proceed directly to take appropriate action in accordance with Federal Medicaid regulations and State plan provisions.

If the SMA decides to restrict the provider's participation in Medicaid, the SMA is responsible for:

- *Giving notice to the provider and opportunity for appeal, in accordance with procedures established by the SMA (§431.54(f)(1));*
- *Notifying CMS and the general public of the provider's restriction and its duration (§431.54(f)(3)); and*
- *Ensuring that restrictions do not result in denying Medicaid recipient reasonable access to services of adequate quality (§431.54(f)(4)).*

If the SMA restricts a Medicaid-only hospital's or psychiatric hospital's Medicaid participation, it gives notice to CMS via the SA. The SA forwards the notice to the RO. The RO terminates the hospital's or psychiatric hospital's Medicaid-only CCN, unless the SMA notice contains a date certain when the provider's participation in Medicaid will resume.

3005F - Termination Action Based Upon Onsite *Survey by RO,* or Validation Survey of a *Deemed Provider or Supplier by RO or SA*

(Rev.)

RO Conducts Survey:

When *substantial noncompliance, including* immediate jeopardy to patient health and safety, is *identified* in the course of a *survey conducted by RO staff,* the RO initiates termination procedures. Survey findings and factual development are the responsibility of the RO. However, the SA may be asked to assist in documenting or developing aspects of the termination. The SA (and the SMA, if the provider/supplier also participates in Medicaid) is notified by the RO of the action taken.

RO or SA Validation Survey of a Deemed Provider or Supplier

Section 1864(c) of the Social Security Act provides that SAs conduct validation surveys of deemed providers and suppliers, at the direction of the CMS RO. The RO may also choose to conduct the validation survey with RO surveyors, or with a mixture of SA and RO surveyors. There are two types of validation surveys:

- *Full, standard surveys of a representative sample of deemed providers and suppliers, and*
- *Focused substantial allegation, i.e., complaint investigation surveys.*

Representative Sample Validation Survey: *If the representative sample validation survey identifies either an immediate jeopardy or substantial, i.e., condition-level, noncompliance and the RO agrees with this finding, the RO initiates termination of the*

deemed provider or supplier, including an opportunity for the provider/supplier to make a timely correction of the deficient practices to avoid termination.

Substantial Allegation Validation Survey:

- *If the survey identifies an immediate jeopardy and the RO agrees with this finding, the RO initiates termination of the deemed provider or supplier, including an opportunity for the provider/supplier to make a timely correction of the deficient practices to avoid termination.*

- *If the survey identifies substantial, i.e., condition-level, noncompliance and the RO agrees with this finding, the RO may either:*

  - *initiate termination of the deemed provider or supplier, including an opportunity for the provider/supplier to make a timely correction of the deficient practices to avoid termination; or*

  - *Require the SA to conduct a full survey of the provider or supplier. Termination action would be initiated if the full survey identifies substantial noncompliance.*

  See Chapter 5, Section 5110 for more details on post-survey procedures after a substantial allegation validation survey.

3008.2 - Services for Which Federal Financial Participation (FFP) May Be *Temporarily* Continued After Termination of a Medicaid Provider Agreement or Nonrenewal or Cancellation of an ICF/IID Provider Agreement

(Rev.)

Federal Financial Participation (FFP) may continue for up to 30 calendar days after the effective date of *termination* if the Medicaid beneficiaries were admitted to the entity before the effective date of termination and the State is making reasonable effort to transfer those beneficiaries to other facilities or to alternate care *or to ensure that they are appropriately discharged*. (See 42 CFR 441.11.) Services for which FFP may be continue*d are*:

- Inpatient hospital services (*for both dually-participating and Medicaid-only hospitals)*;

- Inpatient hospital services for individuals age 65 or older in institutions for mental disease (IMD) (*for both dually-participating psychiatric hospitals and Medicaid-only psychiatric hospitals which are IMDs)*;

- NF services;
- NF services for individuals age 65 or older in IMD;
- Inpatient psychiatric services for individuals under age 21(*for both dually-participating and Medicaid-only psychiatric hospitals)*; and
- ICF/IID services.

3010B - Processing of Immediate Jeopardy Terminations
(Rev.)

When an immediate jeopardy to patient health or safety is documented, the SA and RO complete termination procedures within 23 calendar days. Processing times given here are the maximum allowed. Do not postpone or stop the procedure unless compliance is achieved and documented through onsite verification. If there is a credible allegation that the threat or deficiency has been corrected, the SA conducts a revisit prior to termination if possible.

Deemed Providers/Suppliers:

See Chapter 5, Section 5110.2, for the procedures and timelines applicable when an SA validation survey identifies an immediate jeopardy in a deemed provider or supplier.

Special Procedures for IJ in Psychiatric Hospital *Surveys Conducted by CMS' Contract Surveyors*

When a psychiatric hospital survey is conducted by CMS contract surveyors and they identify immediate jeopardy to patient health or safety, the RO *will make the final* determination *as to whether or not there is* an immediate jeopardy *situation.* The CMS contract surveyors will notify the RO during survey *if possible that* immediate jeopardy to patient health or safety *is identified*. On the last day of the survey, CMS contract surveyors *contact the CMS* Central Office (CO) *and the applicable RO* to certify noncompliance and that an immediate jeopardy exists. The CMS contract surveyors discuss their findings with the provider and tell the providers that they are mailing the RO by overnight express mail completed Forms CMS-1537A and CMS-2567. A copy is also mailed to CO for review. The RO reviews the survey package (Forms CMS-1537A and CMS-2567), and if it determines noncompliance, it mails Form CMS-2567 to the provider. After doing so, the RO follows the 23 calendar day termination procedure as outlined below beginning with the fifth working day.

All Other SA Surveys with IJ Findings: **23-Day Termination Procedures**

1. **Date of Survey -** The date of the survey is the date on which the entire survey is completed, regardless of when the exit conference is held.

2. **Second Working Day -** No later than 2 working days following the survey date. The SA:

   - Telephones the RO that it is certifying noncompliance and that an immediate jeopardy exists; and

   - Notifies the provider/supplier (by overnight express mail, FAX *or e-mail*) of its deficiencies and informs the provider/supplier that it is recommending termination to the RO, which will issue a formal notice. The notice advises the provider/supplier of its right to due process, the expected schedule for termination action, and that the deficiency must be corrected and verified by the SA to halt the termination. If the provider also participates in Medicaid, the SA notifies the SMA of its certification of noncompliance.

3. **Third Working Day -** The SA forwards all supporting documentation to the RO (e.g., statement of deficiencies, correspondence, contact reports, Form CMS-1539). The SA forwards the information by overnight mail to assure that the RO receives it in time to meet the 5-working-day deadline. Upon receipt of the SA information, the RO reviews the documents and makes its determination of noncompliance.

4. **Fifth Working Day -** The provider/supplier and the public are then notified by the RO of the proposed termination action by the most expeditious means available. A press release to the radio and television stations serving the area in which the provider/supplier or institution is located is acceptable if a newspaper notice cannot be arranged in the time allotted. Notice must be made at least 2 calendar days prior to the effective date of termination. (See 42 CFR 488.456(c).)

5. **Tenth Working Day -** If the SA only sent notification of the IJ deficiencies on the second working day to the provider/supplier and RO, and there are other, non-IJ deficiencies, (non-IJ condition and standard level), then the SA must write up another 2567 with the non-IJ deficiencies and forward copies to the provider/supplier, the RO and SMA within ten working days. The SA retains a copy for its records.

6. **Twenty-Third Calendar Day -** The termination takes effect unless compliance is achieved or threat is removed. If the threat has been removed, but deficiencies still exist at the Condition level, the SA gives the provider/supplier up to 67 more calendar days, or 90 calendar days total (23 plus 67). These dates are maximum

times, and participation may be terminated earlier if processing allows. However, the RO must adhere to both the provider/supplier and public notice timeframes.

If the RO disagrees based upon its review of the documentation, the RO discusses the results of the review with the SA and solicits further evidence to support the SA's recommendation. The RO confers with the SA as to the appropriate action to be taken. Should the RO and the SA fail to agree that an immediate jeopardy exists, a revisit will be conducted by the RO and the SA together to ascertain whether or not immediate jeopardy to the patient's health and safety exists or has been removed. If the RO and SA agree that an immediate jeopardy exists, no revisit is necessary by the RO. Under no circumstances should the RO reverse a SA recommendation that an immediate jeopardy has been removed or not removed unless the determination is made on the basis of an onsite determination by Federal surveyors.

Medicaid agreements with facilities that concurrently participate in Medicare should be terminated on the same date the Medicare agreement is terminated. *For NFs that also participate as SNFs (i.e., dually-participating), the State's timing of termination shall control if it does not occur later than six months after the last day of the survey when both CMS and the State find that a facility is not in substantial compliance and the facility's participation should be terminated. (See 42 CFR 488.452.)*

For NFs, ICFs/IID, Medicaid-only hospitals and Medicaid-only psychiatric hospitals, where State law or the State Medicaid plan permits, Medicaid-only facilities with an immediate jeopardy situation should be terminated by the State Medicaid Agency within the above time limits.

3012 - Termination Procedures – *Substantial* Noncompliance*; No Immediate Jeopardy* (Medicare)

(Rev.)

Deemed Providers/Suppliers:

See Chapter 5, Section 5110.3, in the case of a substantial allegation validation survey, or Section 5110.4c, in the case of a representative sample validation survey for the procedures to follow when an SA validation survey identifies substantial noncompliance in a deemed provider or supplier.

All Other Non-Long Term Care Providers/Suppliers

*(*See *§*§7310 - 7313 *and §7400* for SNFs/NFs*)*

Failure to substantially meet one or more Conditions is a cause for termination of participation. "Substantially," for purposes of this section, is defined as meeting the applicable CoPs or CfCs. Any provider/supplier that does not substantially meet the Conditions is considered to be limited in its capacity to furnish services at an adequate

level or quality. Compliance with Conditions; i.e., condition-level deficiencies, can never be certified based upon a PoC or acceptable progress since the law specifically requires that all CoPs or CfCs must be met. If there is **not** an immediate jeopardy to patient health or safety, the RO and the SA use the following schedule:

1. **Date of Survey -** The date of the survey is the date on which the entire survey is completed regardless of when the exit conference is held.

2. **Tenth Working Day –** On the 10th working day, the SA sends a warning letter and the *Form CMS* 2567 containing the deficiencies to the provider/supplier and the RO. The SA informs the provider/supplier in writing that there is a determination of noncompliance and that it is recommending termination to be effective within 90 calendar days from the date of the survey. The recommended termination date is included in the letter. The SA informs the provider/supplier that the termination process provides an opportunity to make corrections and achieve compliance. This opportunity allows the provider/supplier ten calendar days to complete and return a plan of correction on the *Form CMS* 2567. The SA should state in the letter that it will make a revisit within 45 calendar days of the survey if a credible allegation of compliance is received. Termination takes effect as planned if compliance is not achieved. This notice serves as a warning letter to the provider or supplier. The SA allows the provider/supplier 10 calendar days to complete and return the plan of correction).

3. **Forty-Fifth Calendar Day** - If the facility has made a credible allegation of compliance (see §3016.A.), the SA conducts a revisit to determine whether compliance or acceptable progress has been achieved. Only 2 revisits are permitted; one within 45 calendar days and one between the 46th and 90th calendar days. If a second credible allegation of compliance is made prior to the effective date of termination, the SA telephones the RO and submits documentation to support the second revisit (only the second revisit is subject to RO approval). If the facility fails to make a credible allegation, no revisit is necessary.

4. **Fifty-Fifth Calendar Day -** If compliance has not been achieved, the SA certifies noncompliance. The SA forwards the certification and supporting documentation to the RO. The SA notifies the provider/supplier that termination is recommended and alerts the SMA if the provider/supplier is also participating in Medicaid.

5. **Sixty-Fifth Calendar Day -** Within 65 calendar days following the date of survey, the RO determines whether survey findings continue to support a determination of noncompliance.

6. **Seventieth Calendar Day -** The RO sends an official termination notice to the provider/supplier, the public, and the SMA if the provider/supplier also

participates in Medicaid. Notices must be made at least 15 calendar days before the effective date of termination.

7. **Ninetieth Calendar Day** - Termination takes effect if compliance is not achieved. It can take effect in fewer than 90 calendar days if required procedures are completed.

NOTE: All timeframes are maximum. The RO may terminate more quickly as long as the regulatory requirements for notification of the public and provider*/supplier* are satisfied.

3012.1 - Termination of Psychiatric Hospitals

(Rev.)

Deemed Psychiatric Hospitals

See Chapter 5, Section 5110.3 for the procedures to follow when a validation survey of a deemed status psychiatric hospital conducted by the SA identifies substantial noncompliance. For validation surveys conducted by CMS contract surveyors who assess compliance with the special psychiatric conditions (42 CFR 482.61 and 42 CFR 482.62 - the "B" tags), whether as part of a representative sample survey where the SA surveys for compliance with the regular hospital conditions (the "A" tags), or as a substantial allegation survey focused solely on the B tags, contract surveyors send their survey findings within 10 working days from the last day of survey to the CMS RO, not to SAs, with a copy to CMS CO. The CO reviews the survey findings for appropriateness and completeness of documentation and forwards them to the RO with CO's recommendations for issuance of a determination of compliance or noncompliance. The RO makes the determination and notifies the hospital. If any of the regular hospital conditions (the A tags) or either of the two special psychiatric conditions, the B tags) is found not in substantial compliance, the 90 calendar-day termination procedures begin the date of the RO's notice to the hospital with the survey report. The procedures to be followed after the RO issues its notice are the same as in Chapter 5, Section 5110.3, except that in some cases revisits would be conducted by the contract surveyors in addition to or instead of the SA.

Non-deemed Psychiatric Hospitals, Based on CMS Mental Health Surveyors' Survey

The termination process for psychiatric hospitals using CMS mental health surveyors is consistent with the 90 calendar-day timeframe for other providers. However, due to the additional administrative process of sending the survey findings to the CO, day 1 of the 90 day termination timeframe begins on the date the RO receives the psychiatric survey report form findings from CO. The CMS mental health surveyors send the survey findings within 10 working days from the last day of survey to the CO, not to SAs and ROs. The CO reviews the survey findings for appropriateness and completeness of documentation and forwards them to the RO for final review and determination of

compliance or noncompliance. If either of the two special psychiatric conditions is not in compliance (42 CFR 482.61 and 42 CFR 482.62), the 90 calendar-day termination procedures begin the day the RO receives the survey report.

Follow the termination procedures and timeframes below:

- **First Day -** Date of RO receipt of the survey findings from CO.

- **First – Tenth Working Day -** The RO reviews the survey report for adequacy of documentation to determine whether the documentation supports a finding of noncompliance with either psychiatric hospital requirement. (See 42 CFR 482.61 and 482.62.)

The RO notifies the CO via telephone if it does not concur with the CMS mental health surveyors' findings regarding noncompliance with the psychiatric hospital requirements. Note that day 1 of the termination procedures begins the day the RO **receives** the completed psychiatric hospital survey report, not the day the RO reviewed the report for concurrence or nonconcurrence with the findings.

- **Tenth Working Day -** The RO notifies the provider of the cited deficiencies. The RO informs the provider in writing that a determination of noncompliance has been made and that termination will be effective 90 calendar days from the RO's receipt of the survey report form (see Exhibit 180). Also the RO informs the provider that the termination process provides the opportunity to make corrections, and that if it reasonably believes that compliance has been achieved, it should notify the RO immediately. Explain that a revisit will be made within 45 calendar days from the RO's receipt of the survey report form if a credible allegation of compliance is received. However, termination takes effect as planned if compliance is not achieved. This notice serves as a warning notice to the hospital, and it contains the proposed termination date. (The provider is to complete and return the POC to the RO within 10 calendar days.)

- **Forty-Fifth Calendar Day -** If the provider makes a credible allegation of compliance, the RO notifies CO and requests a revisit using the CMS mental health surveyors. The revisit to determine whether compliance has been achieved is to be conducted by the 45th calendar day. If a provider has not alleged compliance by the 45th calendar day, it is not precluded from making an initial credible allegation between the 46th and 90th calendar day.

- **Fifty-Fifth Calendar Day -** If a revisit has been made and compliance has not been achieved, the RO notifies the provider of the deficiencies that are not corrected and of any new deficiencies noted on the revisit.

- **Forty-Sixth - Ninetieth Calendar Day -** If the provider makes a credible allegation of compliance, the RO notifies the CO to schedule a second revisit to

be conducted before the ninetieth day to determine whether compliance has been achieved.

- **Seventieth Calendar Day -** The RO sends an official termination notice to the hospital and a copy to the SMA if the provider also participates in the Medicaid program.

- **Seventy-Fifth Calendar Day -** The RO publishes the public notice.

Non-deemed Psychiatric Hospitals, Based on SA Surveys

The procedures in Section 3012 are followed.

3014 - RO Termination Action Based on Onsite Survey of Medicare Provider or Supplier (Excluding SNFs) *Conducted by RO Staff*

(Rev.)

When *substantial noncompliance, including* immediate jeopardy to patient health and safety, is determined by a survey team *consisting of RO rather than SA surveyors*, whether in the course of a Federal *Look-behind* survey, in response to a complaint, as part of the validation effort of a *deemed provider or supplier*, or to support other program needs, the RO initiates termination procedures *as* provided in §§3010 or 3012. The RO notifies the SA and the SMA of the action being taken. The RO completes the Certification and Transmittal, Form CMS-1539 *in the Automated Survey Processing Environment (ASPEN) and ensures that the CMS National Data Base* is updated to include the termination action. (See Chapter 7 for SNFs and NFs.)

3026B - Plan of Correction (PoC)

(Rev.)

When a PoC has been found to be unacceptable by the SA or RO, the PoC presents evidence that the provider *or supplier* is unable or unwilling to achieve compliance in a reasonable amount of time.

If a provider *or supplier* disagrees with a SA or RO finding of a cited deficiency, *the provider or supplier may, in lieu of submitting a PoC,* state *on Form CMS-2567* the *factual* basis for *disagreeing that a deficiency occurred*. Whenever possible, the provider *or supplier must* reference the specific regulatory provision involved in the disputed issue and *what factual evidence was available at the time of the survey to demonstrate compliance*. *It is not acceptable for the provider or supplier to provide evidence of corrective actions taken after the survey started as a basis for removal of a deficiency citation. It also is not acceptable for the provider or supplier to base its disagreement on*

a different interpretation of the regulatory requirements than that found in CMS guidance.

The original termination date is not changed by the provider's or supplier's disagreement with one or more of the deficiency citations. The RO reviews all of the documentation, including the survey findings and the documentation presented by the provider/supplier before making a determination. (If the RO determines that a deficiency did not exist, it is removed from Form CMS-2567.)

3102 - General Information on *I*PPS Exclusion

(Rev.)

The following hospitals and hospital units are excluded from *the Inpatient Prospective Payment System (IPPS)*:

- Psychiatric hospitals;
- Rehabilitation hospitals;
- Children's hospitals;
- Long-term *care* hospitals;
- *Psychiatric* and rehabilitation units of *IPPS* hospitals; and
- Cancer hospitals.

Certain kinds of *Medicare-participating* hospitals are paid under special provisions and are never subject to *the I*PPS. These hospitals need not be evaluated for compliance with the *I*PPS exclusion criteria:

- Hospitals paid under State cost control systems approved by CMS;
- Hospitals paid under demonstration projects approved by CMS;

When a hospital is excluded from *the I*PPS, the exclusion extends to all components of the hospital. No unit or other component of an excluded hospital can be considered separately for exclusion. *Note that a co-located, separately certified hospital or a separately certified hospital-within a hospital is not a component of the hospital with which it shares a campus. For example,* if a *separately certified Medicare-participating short-term acute care IPPS hospital is* located in the same building as a psychiatric hospital, it is not considered part of the psychiatric hospital and is not excluded *from the IPPS* based on the exclusion of the psychiatric hospital.

Certification for IPPS Exclusion

Certified psychiatric hospitals do not need to undertake any additional certification action with respect to their IPPS exclusion. Other hospitals as well as IPPS hospitals or critical access hospitals (CAHs) containing psychiatric and/or rehabilitation units which they believe meet the criteria of §3106 must notify CMS through the SA if they are seeking IPPS-exclusion status for the hospital or unit(s).

***Note** that it is not permissible to have beds that are used sometimes for excluded unit services and other times for other types of hospital services; the beds must be dedicated exclusively to either psychiatric or rehabilitation services. (This is also the case of distinct part psychiatric and rehabilitation units in CAHs.) Moreover, beds may not be used interchangeably for psychiatric or rehabilitation services; if a hospital has both types of excluded units, they must be separate and distinct from each other. (This also applies to a CAH with both types of distinct part units.)*

The SA sends to a hospital that is seeking IPPS-exclusion status for the hospital or for a psychiatric or rehabilitation unit within the hospital the attestation statement and appropriate CMS-437, along with the standard packet of certification forms and documents, within 10 working days of the earlier of the following two dates:

> *Receipt of the hospital's/CAH's letter of intent to open for service and to seek IPPS exclusion; or*
>
> *Receipt of the Medicare Administrative Contractor's (MAC's) recommendation for approval of the Form CMS-855 application.*

The hospital should return the completed certification packet, along with all other requested materials, to the SA no less than 90 days prior to the start of the hospital's first or next cost reporting period, as applicable, in order for the RO to have sufficient time to make a determination to approve or deny the provider's IPPS exclusion status. If the hospital submits the application less than 90 days in advance, CMS will continue to process the application, but the hospital/CAH assumes the risk that the RO review may not be completed in time for payment at the excluded rate to start with the first or next cost reporting period.

Upon receipt of the package of materials from the hospital, the SA acts promptly to review the completed packet and forwards it to the RO as soon as possible.

Excluded or *non-excluded* status for a hospital or hospital unit remains in effect for the entire cost reporting period for which the determination is made. If a change in meeting applicable criteria occurs during a cost reporting period, or the hospital requests *I*PPS exclusion after the start of its cost reporting period, the status determined for that period remains for the duration of the period. For purposes of exclusion, increases or decreases

in the number of beds assigned to a *I*PPS-excluded unit are recognized only at the start of a hospital's cost reporting period.

If a unit is added to a hospital after the start of a cost reporting period, it cannot be excluded from *the I*PPS before the start of the hospital's next cost reporting period.

Psychiatric Unit or Rehabilitation Hospital/Unit IPPS Exclusion Removal

If CMS removes the IPPS exclusion status of a psychiatric unit or a rehabilitation hospital or unit, the hospital may subsequently seek excluded status again. In such cases, the hospital is required to operate for at least twelve months under the IPPS while continuing to provide the applicable psychiatric or rehabilitation services that comply with the exclusion requirements. The hospital must apply for IPPS exclusion status in the same way as a hospital seeking first-time exclusion. ***However, in the case of a hospital or unit that has had its IPPS exclusion status removed, the SA must verify via an on-site survey compliance with the exclusion criteria for psychiatric or rehabilitation services.***

Validation Surveys of Accredited Providers and Suppliers

3240 - Validation Surveys - General

(Rev.)

A *"deemed"* provider or supplier means a provider or supplier *which* has voluntarily applied for and has been accredited by a *CMS-approved Medicare* accreditation program *whose recommendation for deemed status for that provider or supplier has been accepted by the RO. A list of current CMS-approved Medicare accreditation programs may be found at: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/AOContactInformation.pdf*

NOTE: For the purposes of this section, the term "Condition" refers to any Condition of Participation*, Condition for* Coverage*, or Condition for Certification*. (See Chapter VI *for* discussion *of* validation surveys for accredited laboratories.)

SAs may not conduct a Medicare survey of a deemed provider or supplier unless specifically authorized by the RO to do so. Sections 1864(c) and 1865 of the Act provide the basis for conducting validation surveys of *deemed* providers and suppliers. Regulations authorizing such surveys are found in 42 CFR *Part* 488. The CMS may require a survey of a *deemed* provider or supplier to validate the accreditation organization's process. These surveys will be conducted on *either* a representative sample basis (i.e., *representative* sample *validation* survey), or in response to a substantial allegation of noncompliance (i.e., complaint survey).

A *representative* sample validation survey is *usually a standard or full survey of all applicable conditions*.

A substantial allegation/complaint survey *is authorized by the RO in response to a credible allegation which, if substantiated, would result in a condition-level citation. The RO advises the SA which conditions are to be assessed for compliance, based on the nature of the complaint. See Chapter 5, Sections 5100 – 5110 for more information on substantial allegation survey policies, procedures and timeframes*.

The Form CMS 2802 is transmitted from the RO to the SA via the ASPEN Central Office (ACO) system, for a representative sample validation survey, or via the ASPEN Complaint Tracking System (ACTS) for a substantial allegation validation survey. The RO uses this form to:

- *authorize the SA to conduct a validation survey of a particular provider/supplier;*
- *identify the applicable AO(s);*
- *indicate the type of validation survey to be conducted;*
- *indicate, when applicable in the case of a representative sample validation survey, the AO's survey end-date; and*
- *in the case of a substantial allegation validation survey, identify the specific conditions for which the SA must assess compliance.*

If a provider or supplier selected for a validation survey (representative sample or substantial allegation) is found to have one or more condition-level deficiencies, it will no longer be deemed to meet the Medicare Conditions. *The RO advises the provider or supplier that its deemed status is removed and that it is being placed under SA jurisdiction. However, no change is made to the provider's or supplier's deemed status in the Automated Survey Process Environment (ASPEN). Instead, the placement of the provider or supplier under SA jurisdiction is noted under the Deeming tab within the certification kit in ACO.*

3241 - Objective of Validation Surveys

Validation surveys are intended to develop a reasonable estimate of an accreditation organization's performance. Validation surveys are to be conducted in accordance with the survey protocol for the provider/supplier type being surveyed to assure a fair basis for comparing the effectiveness of *CMS-approved Medicare* accreditation programs.

3242 – Representative Sample Validation Surveys of Deemed Providers/Suppliers

The deemed provider/supplier validation survey process is designed to evaluate the performance of a CMS-approved Medicare accreditation program by determining whether a provider/supplier that is deemed to be in compliance with the Medicare conditions on the basis of its accreditation and is, in fact, meeting Medicare health and safety requirements. Such validation surveys are authorized in accordance with §1864 of the Act. Moreover, CMS is required under §1875(b) of the Act to provide an annual report to Congress on the performance of all CMS-approved Medicare accreditation programs approved under Section 1865 of the Act, including a validation of the accreditation process.

The SA conducts validation surveys of deemed provider/supplier types in accordance with established survey protocols for the provider or supplier type.

CO selects a representative sample of *deemed* provider*s and* suppliers for the SA to conduct a validation survey and forwards this listing *each month* to the ROs. *Upon receipt of the monthly list, the RO electronically issues the applicable Form CMS 2802, depending on the type of provider or supplier, promptly to the SA via the ACO system deeming tab in the recertification/validation kit. The RO also provides CO via the designated Sharepoint site a copy of the Form CMS 2802 once it is issued, for tracking purposes.*

The *representative sample* validation survey *is a standard, i.e. full, survey of ALL conditions applicable to that provider or supplier type*. *Unless the survey is a mid-cycle survey (see below), representative* sample validation surveys *must be* conducted within 60 calendar days following the *scheduled end* date of the accreditation organization survey. *The CO advises the RO of the AO scheduled survey end date, and the RO shares this information with the SA via the electronic version of the applicable Form CMS 2802. The SA must not share this information with any outside parties. The SA must also not request a copy of the AO survey report from the AO, in order to avoid bias in the SA's conduct of an independent survey of the provider or supplier.*

In addition to the traditional representative sample *validation surveys, the CO sample selection may include* deemed facilities *at various* points *in their accreditation cycle (e.g., mid-cycle).* Generally the assignment of such surveys is not tied to the timing of a scheduled AO survey, and thus there is no AO survey end date that determines the timing of the SA's validation survey. *The CO will include any additional instructions (if applicable) for the conduct of such surveys, including the timeframe for completion of the survey by the SA.*

3243 – Substantial Allegation Validation Surveys of Deemed Providers/Suppliers

A substantial allegation/complaint survey is authorized by the RO in response to a credible allegation which, if substantiated, would result in a condition-level citation. The

RO advises the SA which conditions are to be assessed for compliance, based on the nature of the complaint. The SA conducts the complaint investigation in accordance with the established protocols for the provider or supplier type. It is not sufficient for the SA to review only the medical record(s) related to the specific complaint allegation; rather, the SA must assess the provider's/supplier's general, current compliance with each condition specified by the RO on the authorizing Form CMS 2802 transmitted in ACTS.

See Chapter 5, Sections 5100 – 5110 for more information on substantial allegation survey policies, procedures and timeframes

3244 - SA Preparation for Validation Survey

(Rev.)

The SA follows standard survey processes when conducting validation surveys. For example, all validation surveys are unannounced. All substantial allegation validation surveys must include an assessment of compliance with the condition(s) specified by the RO; it is not acceptable for the SA to review only the record and other information related to the specific complaint.

The SA assigns surveyors who normally conduct surveys of non-*deemed* providers *or suppliers* to conduct validation surveys *for the same provider/supplier types*. The *size of the survey team and the time that the* SA *spends on-site must be comparable to that used by the SA for* non-*deemed* providers/suppliers of similar size *or complexity*. Whenever possible, all team members should survey a provider or supplier concurrently. This applies to *staff* who conduct the LSC *portion of a standard* survey as well as to personnel *who conduct the health portion of the survey*. If situations occur where this is not feasible, the SA *must* contact the RO for further direction.

As with any other Federal survey, CMS personnel may be present during the survey to provide assistance and to help assure nationwide uniformity and validity.

3246 - Authorization for *Validation* Survey

(Rev.)

During the entrance conference for either type of validation survey the SA presents to the provider or supplier a letter signed by the SA Director announcing the validation survey (Exhibit 37), as well as an "Authorization by Deemed Provider/Supplier Selected for Accreditation Organization Validation Survey," (Exhibit 287). The SA requires the signature of the provider/supplier CEO or other authorized individual on the authorization document, acknowledging that the provider/supplier must permit the validation survey by the SA to take place, as well as SA monitoring of the correction of any substantial noncompliance found through the validation survey.

3248 – Provider/Supplier Refusal to Permit Validation Survey

(Rev.)

If, after efforts have been made to explain the validation survey protocol procedure, the provider/supplier refuse*s* to *permit* the validation survey to take place, the SA informs the provider/supplier that its "deemed" status will be removed and *the provider/supplier* may also be subject to termination from the Medicare program (and, where applicable, the Medicaid program. [see ref. 489.53(a)(4)] If the provider/supplier continues to refuse to permit the validation survey, the SA notifies the RO. The SA informs the RO of all efforts made to encourage compliance. *The RO notifies the provider or supplier that its participation in Medicare will be terminated, following standard termination procedures.*

3252 - SA Forwarding Validation ***Survey*** Records to RO

(Rev.)

Representative sample validation surveys: The SA submits the appropriate information as specified on the List of Documents in Certification Packet (see Exhibit 63) to the RO or through an update to the ASPEN database within 30 calendar days of completing the survey. In cases where immediate jeopardy exists, the SA submits all the appropriate information specified on the List of Documents in Certification Packet to the RO within two working days of completion of the survey, and enters survey data to the ASPEN database, in a timely manner. The SA also completes the Survey Team Composition and Workload Report (Form CMS-670).

Substantial allegation validation surveys: The SA follows the procedures in Chapter 5, Section 5110.

If the provider/supplier *has been cited as a result of the validation survey for deficiencies at the standard level only, the provider/supplier remains deemed. It is not obligated to submit a plan of correction (PoC), although it may voluntarily choose to do. If the provider/supplier submits a PoC,* the SA *includes it in the survey file*.

3254 - RO Actions Following Validation Survey

(Rev.)

Upon receipt of survey materials, the RO analyzes and considers the SA *findings and* recommendations *and determines whether it agrees with them. If the RO disagrees with the SA's findings or recommendations, it may require the SA to revise the Form CMS 2567 before it is issued to the provider or supplier.* The RO takes necessary action *to make a compliance determination and notify the provider/supplier as soon as possible, in the case of an immediate jeopardy, and* within 30 calendar days *for all other cases. The RO* inputs the information into ASPEN *in a timely manner*.

In the case of a representative sample validation survey only, once the survey report is finalized the RO forwards to CO via the designated Sharepoint site a copy of the Form CMS 2567 and the accompanying correspondence to the facility.

If the validation survey identifies substantial noncompliance, i.e., condition-level deficiencies, the RO removes the provider's or supplier's deemed status. The provider/supplier continues to be accredited by its accreditation organization and is still permitted to participate in the Medicare/Medicaid programs while correcting the deficiencies. However, until the provider/supplier either achieves substantial compliance or its Medicare agreement is terminated, it is subject to the same requirements, survey and enforcement procedures that are applied to non-accredited provider/suppliers found out of compliance following a survey. The SA monitors the provider/supplier until it reaches substantial compliance with all conditions or it is terminated from the Medicare program, and where applicable, the Medicaid program.

3254A – Providers/Suppliers Found in Compliance Following Validation Survey

(Rev.)

If the provider/supplier is in compliance with all Medicare Conditions, the RO notifies the provider/supplier and sends a copy to the SA *and the AO*.

3254B - Providers/Suppliers Found Not In Compliance With One or More Conditions Following Validation Survey and Noncompliance Constitutes Immediate Jeopardy

(Rev.)

If the SA finds deficiencies that pose an immediate jeopardy to patient's health and safety, the SA immediately notifies the RO by phone and then forwards the survey packet to the RO within two working days after the completion of the survey. If after the RO review of the survey packet, the RO determines that there are deficiencies that pose immediate jeopardy (IJ) to patient health and safety, the *provider or supplier* will be placed on the 23-day termination trac*k. See Chapter 5, section 5110.2 for detailed procedures and timeframes for substantial allegation validation surveys.*

In the case of a representative sample validation survey the RO removes the *provider's/supplier's* deemed status and places it under SA survey jurisdiction. *The procedures and timelines in Chapter 5, Section 5110.4b apply.*

3254C – *Condition-level* Deficiencies That Do Not Pose Immediate Jeopardy

(Rev.)

If *the SA determines, and the RO agrees,* that the provider/supplier is out of compliance with one or more Conditions, but the deficiencies **do not** pose immediate jeopardy to patient health and safety, the *SA and* RO follow the *procedures in Chapter 5, Section 5110.3 for substantial allegation validation surveys. For representative sample validation surveys, the RO removes the provider's/supplier's deemed status and places it under SA survey jurisdiction. The procedures and timelines in Chapter 5, Section 5110.4c apply.*

3254E - Plans of Correction

(Rev.)

See §2728B for discussion of the requirements for an acceptable PoC, as well as the options available to the provider/supplier.

See Chapter 5, Sections 5100 – 5110 for information on when the RO must review an SA recommendation on whether or not a PoC is acceptable and when the RO must send a notice to the provider/supplier with a copy to the applicable AO(s).

3256 - RO *Provision* of *Information* to *Accrediting* Organizations

(Rev.)

The RO must provide the AOs copies of every Form CMS 2567 issued to a deemed facility accredited by the AO(s) in a timely manner, i.e., as soon as possible after issuance to the provider/supplier. ROs have the option of sending this material to AOs electronically rather than mailing hard copies. Copies to be provided include all Form CMS 2567s resulting from a SA validation survey, including both representative sample and substantial allegation (complaint) surveys, as well as all Form CMS 2567s issued after the provider's or supplier's deemed status has been removed and the facility has been placed under SA jurisdiction until it can achieve substantial compliance. Copies of any correspondence sent to the provider or supplier related to a Form CMS 2567 must also be provided to the applicable AO(s), as well as correspondence concerning the status of the provider's supplier's Medicare provider agreement or supplier approval (e.g., issuance of an agreement/approval with CCN, notice of potential termination of the agreement/approval, notice of termination of the agreement/approval, etc.).

Note that a provider or supplier may be accredited under a CMS-approved Medicare accreditation program by more than one AO; in such cases all AOs must receive copies.

Forward copies to *the applicable AO(s) using the contact information found at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/AOContactInformation.pdf*
Where RO resources and workload resources permit, the RO should consider sending copies of this information electronically to the AO contact's e-mail address.

3257 - Reinstatement to *Accrediting* Organization Jurisdiction

(Rev.)

A provider/supplier that has been under SA monitoring is returned to deemed status when it is determined that *it is in substantial compliance with the applicable conditions. The provider or supplier is no longer monitored by the SA but is instead under the jurisdiction of the AO. The deeming tab in ASPEN is updated to reflect the end of the SA monitoring.*

The SA may not conduct any further surveys of the provider/supplier without a new authorization from the RO via the applicable Form CMS 2802.

When the provider/supplier is returned to the accreditation organization's jurisdiction, the RO notifies the provider or supplier in writing*, with a copy to the applicable AO(s).*

3258 - Termination or Other Adverse Accreditation Action for a Deemed Provider or Supplier

Termination

A CMS-approved AO must notify CMS, whenever it terminates the accreditation of a Medicare deemed provider or supplier. The notice must be submitted by e-mail simultaneously to:

- *the CMS AO oversight program electronic mailbox; and*
- *the applicable CMS RO electronic mailbox:*

CMS provides the specific electronic mailbox addresses to the AOs.

The AO's notice to CMS notice must provide the effective date of the termination of accreditation, as well as the reason for the termination. The RO forwards the termination notice electronically to the applicable SA.

- ***Accreditation termination is concurrent with switch to another CMS-approved Medicare accreditation program, or provider/supplier was previously also deemed by another AO whose accreditation remains in effect:***

- *Unless there was an involuntary termination for failure to comply with the AO's accreditation standards, 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, or if the provider/supplier was previously deemed based on multiple accreditations, each by a different AO, then the provider/supplier remains deemed and under the jurisdiction of the other AO. The recommendation for deeming is sent by the AO to the CMS AO oversight program and the applicable CMS RO, which forwards the AO's recommendation letter electronically to the applicable SA. An update packet including the new recommendation for deemed status by another AO must be submitted by the SA to the RO. The SA also updates the information in the deemed status tab of the provider's/supplier' certification information in ASPEN to reflect both the termination of the first AO's accreditation and, where there was a switch to another AO, the accreditation by the second AO.*

- *If the termination was involuntary due to failure to comply with the AO's accreditation standards and if the provider or supplier's deemed status has not already been removed due to a prior enforcement action, the RO must consider this a substantial allegation of noncompliance with Medicare standards and must authorize the SA to conduct a complaint investigation. survey. The SA surveys the provider/supplier within 45 days (or, if the RO's reason for termination suggests an immediate jeopardy, according to the immediate jeopardy timeline for complaints) in order to provide assurance that the facility is in substantial compliance with the applicable health and safety standards. If the SA's survey finds no condition-level deficiencies, the provider/supplier retains deemed status under the other/new AO. If the SA finds condition-level deficiencies, then deemed status is removed in the same manner as for any other survey of a deemed provider/supplier.*

- ***Accreditation termination is not concurrent with switch to another AO, or provider/supplier was not previously deemed by multiple AOs:***

  If there is no concurrent recommendation of deemed status for the provider/supplier from another AO or if the provider/supplier was not previously deemed based on multiple accreditations, each by a different AO, the provider's/supplier's deemed status is removed and it is placed under SA jurisdiction. The SA updates the information in the deemed status tab of the provider's/supplier's certification information in ASPEN to reflect the termination of the AO's accreditation and removal of deemed status. The SA surveys the provider or supplier in order to provide assurance that the facility is in substantial compliance with the applicable health and safety standards. Timing of the SA survey is as follows:

  - *When the AO advises CMS that the provider's/supplier's accreditation was involuntarily terminated due to failure to comply with the AO's accreditation standards, the SA must conduct the compliance survey within 45 days or, if the*

RO's reason for termination suggests an immediate jeopardy, according to the immediate jeopardy timeline for complaints..

- *In all other cases the SA prioritizes the provider's/supplier's survey on the basis of the current CMS policy concerning survey frequencies and SA workload priorities, using the date of the most recent accreditation survey to calculate the survey interval, unless:*

  - *The facility is a home health agency (HHA). then the SA must conduct the survey no later than 3 years after the last accreditation survey; or*

  - *The RO exercises its discretion to request the SA to conduct the survey by a specified date.*

Adverse accreditation action other than termination

When an AO takes an adverse action that is not termination against the accreditation status of a provider/supplier, the AO is required to inform both the CMS CO and the appropriate RO of the adverse action. As long as provider's/supplier's accreditation is not terminated, the provider's/supplier's participation in Medicare is not affected. Generally the RO will not authorize a validation survey by the SA, but it has the discretion to do so in rare circumstances.

Note that none of the above scenarios concerning termination or other adverse accreditation actions apply to the situation where a provider or supplier is acquired by a new owner who rejects assignment of the prior Medicare agreement. In such a situation CMS terminates the provider agreement of the seller as a voluntary cessation of business. It does not matter whether the terminated provider or supplier was deemed, whether under one or multiple CMS-approved Medicare accreditation programs, nor are any further actions taken by CMS or the SA in response to a notification by an AO of an accreditation termination or other adverse accreditation action related to the provider or supplier covered by that prior Medicare agreement. (See Section 2003B.)