



Center for Clinical Standards and Quality /Survey & Certification Group

Ref: S&C: 14-24-ALL

DATE: May 2, 2014

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: State Operations Manual (SOM) Chapters 1, 2 & 3 Selected Updates: Medicare Effective Date Determination for Initial Applicants; Survey & Certification Process for Initial Medicare Applicants; Medicaid-only Hospitals; & Deemed Providers/Suppliers

Memorandum Summary – Updates of Selected Parts of SOM Chapters 1,2,3

Medicare Agreement Effective Date: Section 2008D is being revised to conform more clearly to the governing regulation at 42 CFR 489.13. (See also SC-11-04 and SC-13-60).

Survey Process after Denial of Initial Application: Section 2005 has been revised to reflect the following: an applicant who is denied certification by the Centers for Medicare & Medicaid Services (CMS), based on a finding of substantial noncompliance from the initial survey, may reapply for certification. 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 CMS Regional Office's (RO's) first denial and the RO's receipt of the second reapplication. Applicants who reapply for certification must undergo a subsequent survey.

- Hospital Initial Applicant - at State Survey Agency (SA) or accrediting organization (AO) discretion, the subsequent survey may be focused survey. This same approach may also be used for initial Critical Access Hospital (CAH) conversion surveys.
- Applicants subject to the Life Safety Code (LSC) – if the applicant was in substantial compliance with the LSC on the initial survey, at SA or AO discretion compliance with the LSC does not have to be reassessed.

The RO retains the authority in the above types of cases to require another full survey and should promptly notify the SA or AO if it intends to require a full survey. For all other cases a survey subsequent to a reapplication for certification must always be a full survey.

Medicaid-Only Hospitals are not required to enroll in Medicare but must meet Medicare participation requirements: Most hospitals choose to participate in both the Medicare and Medicaid programs, but a small number participate in Medicaid only. Various SOM sections, including Sections 2053, 2777, 2779, 3005 and 3008 have been revised to update provisions concerning Medicaid. New procedures for handling a Medicaid-only hospital include:

- SA role in determining if the hospital meets Medicare requirements;
- Assigning Medicaid-only CMS Certification numbers (CCNs) within the classification system, including in the Automated Survey Process Environment (ASPEN).
- The role of State Medicaid Agencies (SMAs) and ROs.

Multiple provisions of the SOM related to accreditation have been clarified.

We are revising selected portions of SOM Chapters 1, 2 and 3 in order to address multiple topics, including the survey and certification process for initial applicants for Medicare certification and participation; the determination of the effective date of a Medicare agreement with initial applicants; requirements for hospitals that participate in the Medicaid, but not the Medicare program; and numerous provisions related to the role and requirements for accrediting organizations in the survey and certification process and SA validation surveys.

Summary of Key Revisions

A. Medicare Agreement Effective Date

Section 2008D of the SOM is being revised to clarify how CMS determines the effective date of an initial provider or supplier Medicare agreement, in accordance with the governing provisions at 42 CFR 489.13. (See SC-11-04, November 26, 2010 and SC-13-60, September 9, 2013, for discussion of the application of §489.13 and implications for survey procedures.) The revised text clarifies that the effective date may not be earlier than the date on which all Federal requirements have been met, and provides more detail on applicable Federal requirements. Although demonstrating substantial compliance via a SA survey or deemed status Medicare accreditation, including in some cases submitting an acceptable plan of correction (POC), is generally the last Federal requirement to be met, this may not always be the case. Accordingly, in some cases a date later than a survey or POC submission date may be the appropriate effective date.

B. Process for Applicants Denied Initial Certification & Hospital Applicants Denied CAH Conversion

When an applicant for initial Medicare certification is denied certification as a Medicare provider or supplier based on a finding noncompliance with the applicable Medicare conditions or requirements that resulted from a survey conducted either by the SA or an accrediting organization (AO), the RO issues a denial letter.

We are revising Section 2005 to specify that an applicant who is denied certification by CMS based on a finding of substantial noncompliance from the initial survey, may reapply for certification. 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 and the RO's receipt of the second reapplication. 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. This revision affords applicants denied certification more time to correct their deficiencies without having to restart the enrollment process, since Section 2005 previously limited certification reapplications to three months after the initial denial.

Applicants who reapply for certification must undergo a subsequent survey. Under previous SOM policy in Section 2005, the applicant would always be required to undergo another full, standard survey. In the interest of making more efficient and effective use of limited survey

resources, we are revising SOM Section 2005A2 as follows to provide SAs and AOs the discretion to conduct a more focused survey (similar to a revisit) under the following circumstances:

- If on the first survey an applicant subject to the Life Safety Code (LSC) requirements was in substantial compliance with the LSC, the SA or AO, as applicable, has the discretion to not resurvey for LSC compliance (although it must receive an acceptable Plan of Correction for any lower-level LSC deficiencies before it may recommend certification or deemed status); and
- In the case of an applicant seeking to participate as a hospital, the SA or 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 SA or 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 SA or 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 SA or AO advises the RO that the CAH applicant is not in compliance, 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 seek to be surveyed again for CAH conversion. As with initial hospital applicants, the SA or 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 SA or 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, including for conditions where there were only lower-level deficiencies cited, before the SA or 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 certification 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 SA or AO of this as soon as possible, to facilitate planning for the full survey by the SA or AO.

In all other cases where a prospective provider or supplier is denied certification and reapplies for certification, the subsequent survey must be a full, standard survey.

C. Medicaid-only Hospitals & Certification Process

Medicaid regulations at 42 CFR 440.10 and 42 CFR 440.140 require a hospital to “meet the requirements for participation in Medicare as a hospital” in order to receive Medicaid payment. The provider agreement rule at 42 CFR 489.10 establishes the basic Medicare participation requirements for providers, including hospitals. These requirements include, but are not limited to: compliance with the applicable Conditions of Participation (CoPs) at 42 CFR Part 482;

specified Office of Civil Rights requirements at 42 CFR 489.10(b); and the advanced directives requirements in 42 CFR 489.100 and 42 CFR 489.102.

Most hospitals choose to participate in both the Medicare and Medicaid programs; when they do so, their enrollment in Medicare and issuance of a Medicare provider agreement and associated CCN is sufficient to demonstrate their compliance with the Medicaid regulations at §§440.10 and 440.140. However, a small number of hospitals seek to participate in Medicaid, but not Medicare. In these cases, it is not necessary for the hospital to enroll in the Medicare program in order to satisfy the Medicaid requirements. This memorandum addresses the processes that apply to a “Medicaid-only” hospital, as well as the role and responsibilities of State Medicaid Agencies (SMAs) and ROs.

Hospitals applying for Medicaid-only hospital status must, prior to approval, be surveyed for compliance with all applicable CoPs, either by the SA or under a CMS-approved Medicare hospital or psychiatric hospital accreditation program, that is, an accreditation that may be the basis for a hospital’s being “deemed” to be in compliance with the Medicare CoPs. The SA is responsible for compiling a Medicaid-only certification package that includes:

- The hospital’s request for participation as a Medicaid-only hospital and assignment of a corresponding CMS Certification Number (CCN);
- Either SA certification of CoP compliance or evidence of accreditation by a national accreditation organization (AO) with a CMS-approved Medicare hospital or psychiatric hospital accreditation program, as applicable;
- The same Office of Civil Rights documents as required for Medicare enrollment; and
- The effective date of the SMA’s approval to enroll the hospital in the Medicaid program. Upon receiving notification from the SA confirming compliance with the CoPs and receipt of the appropriate Office of Civil Rights documents, the SMA is responsible for determining the effective date for the hospital’s participation in the State Medicaid program.

Following notification by the SMA of the effective date of its approval of a Medicaid-only hospital, the SA will forward the certification packet to the CMS Regional Office (RO). After review of the certification packet for completeness, the RO will issue an appropriate Medicaid-only hospital CCN to the hospital. CMS established the following CCN series for Medicaid-only hospitals within its Survey and Certification classification system:

- J001-J099 – Medicaid-only Short-term acute care hospitals
- J100-J199 - Medicaid-only Children’s Hospitals
- J200-J299 – Medicaid-only Children’s Psychiatric Hospitals
- J300-J399 – Medicare-only Psychiatric Hospitals
- J400-J499 - Medicaid-only Rehabilitation Hospitals
- J500-J599 - Medicaid-only Long-term care Hospitals
- J600-J999 - Reserved for future use

ASPEN reflects these classifications.

SAs must work with their SMAs to establish a process for notifying the SA of any existing Medicaid-only hospitals, and for processing future requests from hospitals to participate in Medicaid but not Medicare. In the event that the SMA identifies current Medicaid-participating hospitals that do not also participate in Medicare, and which have not been previously certified for compliance by the SA, the hospital must provide the SA proof of current accreditation under an applicable CMS-approved Medicare hospital or psychiatric hospital “deemed status” accreditation program, or the hospital must be surveyed by the SA.

D. Accreditation Update

A number of sections of Chapters 1, 2 and 3 either currently make reference to Medicare deemed status accreditation issues, but in an unclear, inconsistent or inaccurate manner, or omit needed references to accreditation. In some cases, the SOM provisions do not distinguish between accreditation procedures for clinical laboratories and those for all other Medicare deemed status providers and suppliers. We have made numerous clarifying revisions through these chapters to address these issues.

Advance Copy of Revised SOM

An advance copy of the revised SOM is attached for your information. At a later date the on-line SOM will be updated; the official revision may differ slightly from this advance copy.

Contact: Questions concerning this memorandum may also be sent to the Survey & Certification email mailbox at hospitalscg@cms.hhs.gov.

Effective Date: This policy is effective immediately. This policy should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

/s/

Thomas E. Hamilton

Attachment

cc: Survey and Certification Regional Office Management

CMS Manual System

Pub. 100-07 State Operations Provider Certification

Department of Health &
Human Services (DHHS)
Centers for Medicare &
Medicaid Services (CMS)

Transmittal

(Advance Copy)

Date:

SUBJECT: Revisions to Chapters 1, 2 and 3

I. SUMMARY OF CHANGES: Guidance is updated to: reflect current policies concerning hospitals enrolled in the Medicaid, but not also the Medicare program; reflect policies and procedures concerning providers and suppliers deemed to satisfy participation requirements on the basis of their accreditation by a CMS-approved Medicare accreditation program; reflect current regulations governing determination of the effective date of the Medicare agreement/supplier approval; and clarify the type of subsequent survey required when an initial applicant for participation in Medicare has been denied initial certification based on an initial survey findings.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: Upon Issuance
IMPLEMENTATION DATE: Upon Issuance

The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual not updated.)
(R = REVISED, N = NEW, D = DELETED) – (Only One Per Row.)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Chapter 1, Section 1000B Medicaid Provisions
R	Chapter 1, Section 1000C Clinical Laboratory Improvement Amendments (CLIA)
R	Chapter 1, Section 1008E Look-Behind Authority
R	Chapter 1, Section 1010 Certification Related Functions of SA
R	Chapter 1, Section 1012A Meaning of Certification
R	Chapter 1, Section 1018C Deemed Providers/Suppliers (Excluding CLIA Laboratories)
D	Chapter 1, Section 1018D Accredited/Deemed HHAs
D	Chapter 1, Section 1018E Accredited/Deemed Hospices
D	Chapter 1, Section 1018F Accredited/Deemed Ambulatory Surgical Centers (ASCs)

D	Chapter 1, Section 1018G Accredited/Deemed CAHs
R	Chapter 1, Section 1018H Deemed CLIA Laboratories
N	Chapter 1, Section 1022 CMS and AO Information Exchange Regarding Deemed Providers/Suppliers (Excluding CLIA)
N	Chapter 1, Section 1022A AO Reporting Requirements
N	Chapter 1, Section 1022B RO Review of AO Communications
N	Chapter 1, Section 1022C RO Reporting Requirements
R	Chapter 2, Section 2003A Assisting Applicant Providers and Suppliers
R	Chapter 2, Section 2003B Initial Certification “Kits”
N	Chapter 2, Section 2003C Deemed Providers/Suppliers, Excluding CLIA
R	Chapter 2, Section 2004 Provider-based Determinations
R	Chapter 2, Section 2005 Medicare Health Care Provider/Supplier Enrollment
R	Chapter 2, Section 2005A Approval or Denial
R	Chapter 2, Section 2005A1 Denial Based on MAC Recommendation
R	Chapter 2, Section 2005A2 Approval or Denial of Certification
R	Chapter 2, Section 2005A3 Reconsideration of Denial
N	Chapter 2, Section 2005A4 Deemed Providers/Suppliers, Excluding CLIA
R	Chapter 2, Section 2005B Recertification
R	Chapter 2, Section 2008A Surveys of New Providers and Suppliers
R	Chapter 2, Section 2008D Effective Date of Provider Agreement or Approval for Suppliers
R	Chapter 2, Section 2016D Reasonable Assurance Surveys
R	Chapter 2, Section 2016E Effective Date of Provider Agreement or Supplier Approval After Reasonable Assurance
R	Chapter 2, Section 2021 Non-deemed Hospitals
R	Chapter 2, Section 2021A Recertification of Non-deemed Hospitals
R	Chapter 2, Section 2022 Deemed Status: Hospitals Accredited by an Accrediting Organization with a CMS-approved Medicare Hospital or Medicare Psychiatric Hospital Accreditation Program
R	Chapter 2, Section 2022A Notice that Participating Hospital Has Been Accredited and Recommended for Deemed Status
R	Chapter 2, Section 2022C Notification of Withdrawal or Loss of Accreditation
R	Chapter 2, Section 2044 Psychiatric Hospitals and Deemed Status
N	Chapter 2, Section 2053 Medicaid-only Hospitals
N	Chapter 2, Section 2053A Initial Certification of Medicaid-Only Hospitals
N	Chapter 2, Section 2053B Certification Surveys of Medicaid-Only Hospitals
N	Chapter 2, Section 2053C Change in Certification
N	Chapter 2, Section 2053D Termination
N	Chapter 2, Section 2053E Complaint Investigation
R	Chapter 2, Section 2202.10A Determining Compliance with OASIS Transmission Requirements
R	Chapter 2, Section 2202.10B HHAs Seeking Participation through Deemed

	Status
R	Chapter 2, Section 2202.10C Exceptions to Demonstrating Compliance with OASIS Submission Requirements Prior to Approval
R	Chapter 2, Section 2202.10D Compliance Dates and PPS
R	Chapter 2, Section 2202.10E Instructions for Handling Medicare Patients in HHAs Seeking Initial Certification
R	Chapter 2, Section 2202.10F Instructions to New HHAs Concerning all Other Patients
R	Chapter 2, Section 2705 SA Survey Team Workload
R	Chapter 2, Section 2764 - SA Completion Instructions for Certification and Transmittal, Form CMS-1539 (Exhibit 9) Items 1 - 18
R	Chapter 2, Section 2777A Medicaid-only Certification
R	Chapter 2, Section 2777D Change in Certification
N	Chapter 2, Section 2777D1 Medicaid NF & Medicaid Distinct Part NF Providers Seeking to Participate as Medicare SNF Provider
N	Chapter 2, Section 2777D2 Medicare- & Medicaid-participating Hospitals Seeking to Become Medicaid-only Hospital
N	Chapter 2, Section 2777D3 Medicaid-only Hospitals Seeking to Participate in Medicare & Medicaid
R	Chapter 2, Section 2778 Objectives of RO Certification Review
R	Chapter 2, Section 2779B CMS Certification Numbers for Medicaid Providers
D	Chapter 2, Section 2779B1 Medicaid-Only Hospitals
R	Chapter 3, Section 3000C CMS Authority to Terminate Medicare and Medicaid Participation
D	Chapter 3, Section 3005C Decision to Terminate or Deny Payment for Medicaid Facilities
R	Chapter 3, Section 3005E Termination of Title XIX-Only NFs, ICFs/IID, Hospitals and Psychiatric Hospitals
R	Chapter 3, Section 3005F Termination Action Based Upon Onsite Survey by RO Staff or RO or SA Validation Survey of a Deemed Provider or Supplier
R	Chapter 3, Section 3008.2 Services for Which Federal Financial Participation (FFP) May Be Temporarily Continued After Termination of a Medicaid Provider or Nonrenewal or Cancellation of an ICF/IID Provider Agreement
R	Chapter 3, Section 3012 Termination Procedures – Substantial Noncompliance; No Immediate Jeopardy (Medicare)
R	Chapter 3, Section 3012.1 Termination of Psychiatric Hospitals
R	Chapter 3, Section 3014 RO Termination Action Based on Onsite Survey of Medicare Provider or Supplier (Excluding SNFs) Conducted by RO Staff
R	Chapter 3, Section 3026B Plan of Correction (PoC)
R	Chapter 3, Section 3102 General Information on IPPS Exclusion
R	Chapter 3, Section 3240 Validation Surveys - General

N	Chapter 3, Section 3241 Objective of Validation Surveys
R	Chapter 3, Section 3242 Representative Sample Validation Surveys of Deemed Providers/Suppliers
R	Chapter 3, Section 3243 Substantial Allegation Validation Surveys of Deemed Providers/Suppliers
D	Chapter 3, Section 3243A General
D	Chapter 3, Section 3243B Setting Up Validation Survey
R	Chapter 3, Section 3244 SA Preparation for Validation Survey
R	Chapter 3, Section 3246 Provider/Supplier Authorization for Validation Survey
R	Chapter 3, Section 3248 Provider/Supplier Refusal to Permit Validation Survey
D	Chapter 3, Section 3250 SA Conducting Sample Validation Surveys
R	Chapter 3, Section 3252 SA Forwarding Validation Survey Records to RO
R	Chapter 3, Section 3254 RO Actions Following Validation Surveys
R	Chapter 3, Section 3254A Providers/Suppliers Found in Compliance Following Validation Survey
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R	Chapter 3, Section 3254C Condition-level Deficiencies That Do Not Pose Immediate Jeopardy
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R	Chapter 3, Section 3254E Plans of Correction
R	Chapter 3, Section 3256 RO Provision of Information to Accreditation Organizations
D	Chapter 3, Section 3256A Documents to be Forwarded to Accreditation Organizations
R	Chapter 3, Section 3257 Reinstatement to Accreditation Organization Jurisdiction
D	Chapter 3, Section 3257A Provider/Supplier Under SA Monitoring
N	Chapter 3, Section 3258 Termination or Other Adverse Accreditation Action for a Deemed Provider or Supplier

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 20xx operating budgets.

IV. ATTACHMENTS:

	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

State Operations Manual

Chapter 1 - Program Background and Responsibilities

(Rev.)

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1000B - Medicaid Provisions

(Rev.)

Medicaid and the Children's Health Insurance Program (CHIP) are Federal-State partnerships which provide health coverage to millions of Americans, including children, pregnant women, parents, seniors and individuals with disabilities. In order to participate in Medicaid, Federal law requires States to cover certain population groups (mandatory eligibility groups) and gives them the flexibility to cover other population groups (optional eligibility groups). States establish and administer their own Medicaid and CHIP programs, and determine the type, amount, duration, and scope of services within broad federal guidelines. States are required to cover certain "mandatory benefits," and can choose to provide other "optional benefits". States receive federal matching funds to provide these benefits. Section 1902 (a)(23) of the Act provides Medicaid beneficiaries a free choice of qualified providers willing to furnish covered services. Such freedom of choice may be restricted when the beneficiary receives services through managed care arrangements that are authorized under a number of statutory provisions or through waiver authority (except that freedom of choice of qualified family planning providers and access to federally qualified health centers has special protection).

*In general, many types of health care facilities that participate in the Medicaid and CHIP programs also participate in Medicare, but they are not required to do so. There are, however, some types of facilities that participate only in Medicaid: these include nursing facilities (NFs) that are not also dually certified as Medicare skilled nursing facilities (SNFs), Psychiatric Residential Treatment Facilities (PRTFs), and Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IIDs). Under Medicaid regulations, NFs **are required** to meet virtually the same requirements that SNFs participating in Medicare must meet. **PRTFs and ICF/IIDs** must comply with special Medicaid standards. *There are also cases where Medicaid regulations require that certain healthcare providers that only participate in Medicaid must, among other things, comply with Medicare participation requirements. For example, under 42 CFR 440.10, Medicaid-only hospitals must meet requirements at Section 42 CFR 489.10 and 42 CFR Part 482, and Medicaid-only Home Health Agencies (HHAs) are required under 42 CFR 440.70(d) to meet the requirements at 42 CFR 489.28 and 42 CFR Part 484, in addition to those at 42 CFR 441.16(c).**

1000C - Clinical Laboratory Improvement Amendments (CLIA)

(Rev.)

Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988 establishing quality standards for all laboratories testing to ensure the accuracy, reliability,

and timeliness of patient test results, regardless of where the test was performed. A laboratory is defined as any facility that performs laboratory testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention, treatment of disease, or the impairment of, or assessment of health. CLIA is user-fee funded; therefore, all costs of administering the program must be covered by the regulated facilities, including certificate and survey costs. The final CLIA regulations are based on the complexity of the test method; thus, the more complicated the test, the more stringent the requirements. Three categories of tests have been established: waived complexity, moderate complexity, including the subcategory of provider-performed microscopy, and high complexity. CLIA specifies quality standards for laboratories performing moderate and/or high complexity tests. Waived laboratories must enroll in CLIA, pay the applicable fee and follow manufacturers' instructions. CMS is charged with the implementation of CLIA, including laboratory registration, fee collection, surveys, surveyor guidelines and training, enforcement, approvals of proficiency testing providers, accrediting organizations and exempt States.

(For further details on CLIA, refer to Chapter 6—Special Procedures for Laboratories and Chapter 5—Complaint Procedures which has a CLIA section.)

1008E - Look-Behind Authority

(Rev.)

The Secretary has authority under [§§1902\(a\)\(33\), 1919\(g\)\(3\), and 1910\(b\)\(1\)](#) of the Act to cancel approval of all Medicaid facilities, including NFs, *PRTFs, ICF/IIDs, Medicaid-only hospitals, and HHAs* that do not meet Federal health or safety requirements. Such a determination is in lieu of, or overrides, a determination by the State and is binding on the SMA. Section 1902(a)(33) gives CMS the authority to question State determinations regarding Medicaid facilities' compliance with Federal requirements and authorizes CMS to make independent and binding determinations concerning the extent to which individual institutions and agencies meet requirements for participation.

Section 1919(g)(3)(A) states that if the State determines that an individual NF meets Federal requirements, but CMS determines that the facility does not meet such requirements, CMS' determination as to the facility's noncompliance is binding and supersedes that of the State.

Section 1910(b)(1), the look-behind authority, gives CMS similar authority to terminate the Medicaid approval of ICFs/*IID*. The CMS' decision to cancel the approval or terminate an ICFs/*IID* can be made as the result of complaint or Federal validation surveys or CMS' review of SA survey findings.

CMS also may, under [42 CFR Part 442.30](#), invalidate a Medicaid provider agreement after determining that the agreement does not constitute valid evidence of the provider's compliance with the Federal regulatory requirements. In the latter situation, the effect is to deny and recoup all Federal matching funds in the Medicaid payments to the facilities that were made under the improper agreement. The authority to investigate and either cancel approval or invalidate improper agreements, called "old" look-behind authority, is re-delegated to an office in each CMS RO.

1010 - Certification Related Functions of SA

(Rev.)

The functions that the SAs perform under the agreements in §1864 of the Act are referred to collectively as the certification process. This includes, but is not limited to:

- A. Identifying Potential Participants** - The law guarantees to Medicare beneficiaries that payment will be made for health services furnished in or by entities that meet stipulated requirements of the Act. Identification includes those laboratories seeking to participate in the CLIA program.
- B. Conducting Investigations and Fact-Finding Surveys** - Verifying how well the health care entities comply with the *applicable requirements for nursing facilities (NFs) and skilled nursing facilities (SNFs), Conditions of Participation (CoPs) for providers, Conditions for Coverage (CfCs) for most institutional suppliers, or Conditions for Certification for rural health clinics (RHCs).*
- C. Certifying and Recertifying** - Certifications are periodically sent to the appropriate Federal or State agencies regarding whether entities, including CLIA laboratories, are qualified to participate in the programs.
- D. Explaining Requirements** - Advising providers and suppliers and potential providers and suppliers in regard to applicable Federal regulations to enable them to qualify for participation in the programs and to maintain standards of health care consistent with the CoPs, *requirements, CfCs or Conditions for Certification.*

Also, as mandated by [§§1819\(g\)\(1\)\(B\) and 1919\(g\)\(1\)\(B\)](#) of the Act, States must conduct periodic educational programs for the staff and residents, and their representatives, of SNFs and NFs in order to present current regulations, procedures, and policies.

- E. Operating Toll-Free Home Health Hotline** - Maintain a toll-free telephone hotline to collect, maintain, and continually update information on Medicare-approved HHAs. The hotline is also used to receive complaints and answer questions about HHAs in the State or locality. See [§1864\(b\)](#) of the Act.

The SA is also authorized to perform numerous other functions under a blanket clause of its SA agreement, by special agreement, or by statute. These include:

- F. Identifying Prospective Payment System (PPS) Excluded Institutions** - Certification information helps in identifying institutions or components of institutions that meet special requirements qualifying them to be excluded from the Medicare PPS.

- G. Participating on Validation Surveys of *Deemed Providers/Suppliers*** - These surveys are intended to furnish DHHS and Congress *information on* the validity of *the survey process of accrediting organizations with CMS-approved Medicare accrediting programs under which a provider or supplier may be "deemed" to be in compliance with the applicable CoPs, CfCs, or Conditions for Certification* . Validation surveys include *both* representative sample surveys as well as substantial allegations of non-compliance (complaint) surveys.
- H. Proficiency Testing** - Monitor programs of proficiency testing in laboratories and contribute laboratory compliance findings to use in the CLIA Laboratory Certification Program.
- I. Direct Data Entry** - Enter data from surveys *of deemed and non-deemed providers or suppliers, including revisits*, and complaint investigations into CMS data systems, for example ASPEN *Central Office (ACO) or ASPEN Complaint Incident Tracking System (ACTS)*. Update information about providers, suppliers, and CLIA laboratories in the appropriate system when indicated.
- J. Nurse Aide Training** - Specify and review Nurse Aide Training and Competency Evaluation Programs (NATCEPs) and/or Nurse Aide Competency Evaluation Programs (NACEPs). (See [§§1819\(e\)\(1\) and 1919\(e\)\(1\)](#) of the Act.)
- K. Nurse Aide Registry (NAR)** - Establish and maintain a registry for all individuals who have satisfactorily completed NATCEP or a NACEP. (See [Chapter 4](#), §4145 of this manual and [§§1819\(e\)\(2\) and 1919\(e\)\(2\)](#) of the Act.)
- L. Resident Assessment Instrument (RAI)** - Specify a RAI for use in the LTC facilities participating in Medicare and/or Medicaid. (See [Chapter 4](#), §4145.4 of this manual.)
- M. Records and Reports** - Maintain pertinent survey, certification, statistical, or other records for a period of at least 4 years and make reports in the form and content as the Secretary may require.
- N.** Ensure that *applicants to be certified as Medicare* providers/suppliers have *submitted an enrollment application to the appropriate Medicare Administrative Contractor (MAC) and that the MAC has recommended the applicant for enrollment* prior to conducting an initial survey.

(Note: Approval and certification of hospital organ transplantation centers have unique features. Transplant centers are not separate providers, but participate in Medicare on the basis of the existing provider agreement between the Medicare program and the hospital that houses the transplant center. Therefore, transplant centers are not eligible to enroll separately. Rather, a hospital is required to submit a Form CMS 855A to the MAC to add a transplant center. In accordance

with Section 15.5.2.5.C of the Program Integrity Manual, Publication 100-08: “For purposes of Medicare enrollment, a hospital transplant center is treated similarly to a hospital sub-unit. If the hospital wishes to add a transplant center, it must check the “other” box in section 2A2 of the CMS-855A, write “transplant center” on the space provided, and follow the standard instructions for adding a sub-unit. Unless CMS indicates otherwise, the contractor shall process the application in the same manner it would the addition of a hospital sub-unit; however, no separate enrollment in PECOS need be created for the transplant center.

Hospital transplant centers are subject not only to all applicable CoPs in 42 CFR Part 482, Subparts A, B, C and D, but are also subject to the special transplant CoPs in Subpart E. . Even though there is a separate CCN number issued for each approved transplant center program, this is a function of the operational design of the CCN fields in the data system supporting Federal surveys; transplant center CCNs, unlike other CCNs, do not correspond to separate provider agreements or supplier approvals.)

A hospital seeking initial approval to offer organ transplantation services must not only submit a CMS-855A to add a transplant center, but must also notify CMS Central Office of its request. Central Office is responsible for advising SAs (or CMS contract transplant surveyors, as applicable) if and when to conduct initial transplant program surveys. Based on the survey findings, transplant programs may be approved.

1012A - Meaning of Certification

(Rev.)

Certification is when the SA officially recommends its findings regarding whether health care entities meet the Act's provider or supplier definitions, and whether the entities comply with standards required by Federal regulations. State agencies do not have Medicare determination-making functions or authorities; those authorities are delegated to CMS' RO. State agency certifications are the crucial evidence relied upon by the ROs in approving healthcare entities to participate in Medicare.

When the RO approves participation in Medicare, it issues the entity a Medicare provider agreement or supplier approval, and the provider or supplier is then considered “certified.” (Note that in the case of a health care entity seeking to participate in Medicare on the basis of accreditation by a CMS-approved Medicare accreditation program, the accrediting organization (AO) does not “certify” its findings to the RO. Instead, the AO provides a copy of its survey report, indicates the date of accreditation, and recommends “deemed status” for the entity. When the RO approves participation, the provider or supplier is “deemed” to have met the applicable CoPs or CfCs and the RO issues the entity a Medicare provider agreement or supplier approval. The entity is then considered “certified” on the basis of the entity’s deemed status.)

Recertification *surveys are* performed periodically by the SAs, *and reaccreditation surveys are performed periodically by the AOs.*

Regardless of whether the *survey is conducted* for Medicare *or* Medicaid purposes, the SA surveys a *healthcare entity* in exactly the same way to ascertain *and certify* whether it meets the *applicable* Federal health and safety requirements for participation. Except for nursing homes *and entities* that participate in both Medicare and Medicaid and *where Federal Medicaid regulations require a healthcare provider to satisfy the Medicare health and safety standards*, CMS' determination is binding for both programs. For dually participating nursing homes, regardless of whose decision prevails (CMS' or the State's), that decision is adopted by CMS and applied to the entire facility.

Surveys are necessary for the SA to be able to certify *its findings*. The law provides Federal funding for these surveys. SAs *may* survey many institutions simultaneously for Medicare, Medicaid, and State licensure *purposes*, and sometimes for other *inspection* programs, so *when they do so*, the costs *are* equitably allocated *among* the programs *that rely upon the survey findings*. *Accurate accounting of allocation of survey resources is imperative.*

Part of a survey may concern a provider's efforts to prevent environmental hazards due to contagion, fire, contamination, or structural design and maintenance problems. However, a survey is *not* a mere building inspection. *Surveys include, among other things, observation of the manner in which health care services are delivered, or laboratory services are performed, in order to ascertain that the entity is operating in accordance with Federal requirements* to protect health and safety.

Many aspects of the survey *also include* scrutinizing the provider's/*supplier's* records to *determine whether* professional *healthcare* staff members have been properly noting and evaluating the progress of the care *being provided* or managing provider operations with continuing vigilance. Surveys of SNFs, NFs, HHAs, *ESRDs, CMHCs, the psychiatric hospital special conditions, the hospital transplant program conditions* and *ICFs/IID* are conducted in accordance with outcome-oriented protocols, which were designed to concentrate on patient/resident outcomes of care in determining the provider's compliance with the Federal requirements. *For other types of providers/suppliers, surveys may focus more on compliance with "process-oriented" regulatory requirements.*

A provider's/*supplier's* certification *generally* is not *invalidated* merely on grounds that the *it* has moved a short distance or slightly modified the scope of its services. *However, if a provider or supplier relocates to the extent that it no longer serves the same community, the provider or supplier has voluntarily ceased to do business and its Medicare provider agreement or supplier approval must be terminated as a voluntary termination, effective as of the date it ceased to provide services to its original community. (See 42 CFR 489.52(b)(3)) The healthcare entity must seek to enroll as an initial applicant in the Medicare program at its new location. (Note that, for certain types of providers or suppliers such as critical access hospitals, there are specific*

location requirements and even a short move may result in failure to meet all Federal requirements and involuntary termination of its provider agreement or supplier approval.)

See 42 CFR §§488.26, 488.330 and 489.52.

1018C - Deemed Providers/Suppliers (Excluding CLIA Laboratories)

In order to enter into a provider or supplier agreement with the Medicare program, or in many cases a provider agreement with the Medicaid program, a health care entity must satisfy all applicable Federal requirements. For Medicare providers and suppliers subject to certification, Federal requirements include demonstrating compliance with the applicable health and safety standards, i.e., SNF requirements, provider CoPs or supplier CfCs. Generally the prospective provider or supplier demonstrates compliance with health and safety standards when it is certified by a SA as being in compliance and recommended to the RO for approval. Thereafter, the provider or supplier is subject to periodic surveys by the SA to determine whether it continues to meet the applicable long term care requirements, CoPs, CfCs or Conditions for Certification.

However, 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 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, for only 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>.

In the case of a deemed provider or supplier, the SA does not conduct a survey to recertify compliance with the applicable Medicare CoPs, CfCs, or requirements. Rather, such providers or suppliers remain under the jurisdiction of the AO for oversight of their ongoing compliance. The SA may conduct a validation survey (e.g., representative sample or substantial allegation survey) of a deemed provider or supplier when directed to do so by the RO. If the RO determines, based on the findings of such SA validation survey, that the provider or supplier is out of compliance with one or more CoPs, CfCs, Conditions for Certification or requirements, the RO removes the provider's/supplier's deemed status and places it under SA jurisdiction for review until it either comes back into compliance or is terminated.

Note that some AOs offer multiple accreditation programs for a given type of provider or supplier. However, an AO may offer no more than one Medicare accreditation program per provider/supplier type and that program must be approved in advance by CMS. 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 provider or supplier to be "accredited" without being "deemed" to participate in the Medicare/Medicaid programs. For certification purposes, CMS considers as evidence of a provider's or supplier's compliance with the applicable CoPs, CfCs, or requirements only accreditation under a CMS-approved Medicare accreditation program, where the AO has recommended deemed status to CMS .

*SAs must enter information on the deemed tab within the certification kit in ASPEN **only** for those providers and suppliers that have been deemed on the basis of accreditation under a CMS-approved Medicare accreditation program. CMS has established a process for an AO to provide notice to the applicable RO when it has accredited a provider or supplier under its CMS-approved Medicare accreditation program and is recommending the provider or supplier for initial or continued deemed status. The RO forwards these notices to the applicable SA for inclusion in the initial certification packet that the SA subsequently forwards to the RO for approval or denial of the application for a provider agreement or supplier approval.*

1018H - Accredited CLIA Laboratories **(Rev.)**

Because each accrediting organization that has received **approval** under CLIA is approved for specific laboratory specialties or subspecialties, consult the RO for specific guidance. Refer to **Chapter 6** of this manual for additional information on **CLIA** accrediting organizations. **For a current list of accrediting organizations approved for distinct CLIA specialties or subspecialties please go to www.cms.gov/clia/.**

1022- CMS and AO Information Exchange Regarding Deemed Providers/Suppliers (Excluding CLIA)

Timely, accurate and complete information regarding deemed providers and suppliers must be shared between CMS and AOs with CMS-approved Medicare accreditation programs to ensure effective, ongoing oversight of AOs, as well as to ensure deemed provider/supplier compliance with applicable Medicare requirements. As part of CMS’ oversight of deemed providers and suppliers, AOs with CMS-approved Medicare accreditation programs are required to submit data and information concerning deemed facilities to CMS. Likewise, CMS is obligated to share pertinent information concerning facilities, as outlined in SOM sections 3256 and 5100.3.

1022A – AO Reporting Requirements

Under 42 CFR 488.4, AOs with CMS-approved Medicare accreditation programs are required to submit data concerning deemed Medicare providers/suppliers, including notices concerning current deemed status providers/suppliers as well as facilities recommended or not recommended for deemed status.

To facilitate the timely receipt of such information from AOs an electronic process has been established for the AOs to submit reports and notices containing accreditation information regarding these facilities to CMS Central Office and the applicable RO. Eleven electronic mail boxes have been established; one for CMS CO and one for each of the ten CMS ROs.

The Reports and Notices that AOs are required to forward through the electronic mailboxes are noted below:

Types of Documents	Central Office Email Box	Regional Office Email Box
Reports		
<i>Monthly Adverse Action Report</i>	X	
Notices		
<i>Accreditation Status of Facilities Recommended for Deemed Status (includes both initial and re-</i>	X	X

<i>accreditation surveys)</i> <ul style="list-style-type: none"> • <i>Full Accreditation</i> • <i>Conditional Accreditation</i> • <i>Provisional Accreditation</i> • <i>Denial of Accreditation</i> 		
<i>Termination/Withdrawals includes</i> <ul style="list-style-type: none"> • <i>Involuntary (AO-initiated) – as a result of CoP/CfC deficiencies, AO standard deficiencies, AO non-payment, closure or other AO policies.</i> • <i>Voluntary (Facility-Initiated) – change to State Agency or other AO merger, acquisition, or closure.</i> <i>Include reason for involuntary and voluntary terminations/withdrawals and last deemed survey date</i>	<i>X</i>	<i>X</i>
<i>Other Issues</i> <i>Email boxes may be used to transmit other documents that CMS requests in specific cases or that the AO wants to bring to CMS’ attention, e.g., resolution of deficiencies notices</i>	<i>X</i>	<i>X</i>

Required Content of AO Notification Letters to CMS

Purpose:

- *To recommend or not recommend initial deemed status for the purpose of Medicare certification;*
- *To recommend continued deemed status for the purpose of Medicare certification;*
- *To provide notice of change in accreditation status, including but not limited to terminations, withdrawals, and changes resulting from sales or acquisitions;*
- *To provide the status of oversight efforts to correct noncompliance with Medicare CoPs.*

Notice must be sent to CMS, both to CO and the applicable RO, via the electronic mail box at the same time that the provider/supplier is notified of the AO decision/action. Scanned copies with signature of the AO’s authorized representative are preferred.

Required Information - All Final Accreditation Decision Letters:

- *Name of AO;*
- *Date of notice;*
- *Program type (i.e., the type of provider or supplier being accredited, such as ASC, CAH, HHA, Hospice, Hospital, OPT, Psychiatric Hospital or RHC);*
- *Provider/Supplier name, address, and, if already enrolled in Medicare, CCN;*

- *For providers/suppliers with multiple locations covered under one Medicare agreement – names and addresses for each location;*
- *AO organization/facility number, if utilized;*
- *Identification of applicable CMS RO (e.g.; RO I – Boston, RO IV – Atlanta, etc.);*
- *Type of survey – initial, re-accreditation, complaint, revisit, extension or other;*
- *Beginning and ending date of survey;*
- *Accreditation decision: conditional, full accreditation, denial, etc.;*
- *Effective date of accreditation, accreditation expiration date;*
- *Whether or not the AO is recommending continuing deemed status;*
- *For other than initial surveys, list only Medicare Condition-level deficiencies and include the corresponding CFR citation(s) that have been corrected based on completion of a focused follow up survey;*
- *When applicable, whether an existing accreditation status is being extended to a newly acquired component of the provider, with time period for which accreditation is being extended;*
- *Timeframe for plan of correction; and*
- *Method of follow up – (multiple may apply) document review, full or focused follow up survey*

***Note** – An accreditation decision letter may apply only to one certified provider or supplier. In other words, the AO must make a separate accreditation decision for each separately certified provider or supplier and may not issue a system-level accreditation that applies to multiple providers or suppliers. Likewise, an accreditation decision letter must apply to the whole of a provider or supplier. For example, an AO may not issue an accreditation decision that applies to only one campus of a multi-campus hospital.*

Additional Required Information - Initial Medicare Enrollment Applicants:

- *The effective date of accreditation;*
- *Whether or not the AO is recommending deemed status for the facility; and*
- *The full, complete survey report containing all survey findings, including the deficiency(ies) as well as the evidence that supports the deficiency(ies), must be sent with the decision letter as an attachment.*

The RO reviews the AO survey findings as part of the Medicare certification review process. The RO is not obligated to accept the AO’s recommendation of deemed status if the RO determines that not all applicable Federal requirements have been met.

If the RO determines that all Federal requirements have been met by the prospective provider/supplier, it issues a provider agreement or supplier approval and a CCN to the applicant, including the effective date of such agreement. The effective date of Medicare participation is determined by the RO based on the date when all Federal

requirements have been met, which may be later than the effective date of the AO's accreditation.

Additional Required Information – Deemed Provider/Supplier Accreditation Renewals:

- Whether or not the AO is recommending continued deemed status; and*
- Effective date of accreditation renewal. There must not be any break between this date and the expiration date of the previous accreditation.*

Additional Required Information – Deemed Provider/Supplier Withdrawals or Terminations:

- Reason(s) for withdrawal or termination;*
 - Withdrawals – reasons could include: acquisition, closure, merger, or withdrawal to SA authority.*
 - Terminations – reasons could include: nonpayment of AO fees, failure to meet the accreditation program standards, or failure to satisfy other AO policies and procedures.*
- Date of most recent triennial accreditation survey; and*
- Effective date of termination or withdrawal.*

1022B - RO Requirements for Review of AO Reporting

Each RO is responsible for review and appropriate follow-up action resulting from AO notices. To facilitate AO communication regarding Medicare deemed providers and suppliers, each RO has been assigned a CMS electronic mail (email) box dedicated to receiving notices from and sending communications to the AOs. Designated RO email box owners are responsible for maintaining and updating the access rights for the RO email box.

Each RO develops policies and procedures for the management of its email box to ensure ongoing, timely review of AO notices, and timely follow-up actions, as necessary.

1022C - RO Reporting Requirements to AOs

The RO must provide the AOs with 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.

See also Sections 3256 and 5100.2.

State Operations Manual

Chapter 2 - The Certification Process

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- 2781 - RO Countersigning Provider Agreement
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- 2810 - Organ Procurement Organizations (OPOs) - Citations
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- 2812 - OPO Initial Designation Requirements
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 - 2825A - Citations
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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.* The 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 contacts 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 *personnel*.

The SA refers questions about enrollment, *MACs*, 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 Agencies* 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 proceeds 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.*

However, if the MAC finds the HHA does not meet all Federal requirements during the second review, there would be a delay in the effective date of any provider agreement that might eventually be issued to the HHA applicant until all requirements are determined to be met.)

The RO will issue a provider *or supplier* agreement *with an effective date*, and assign a *CMS Certification Number (CCN)*. (See Section 2008.) The RO will notify the *MAC* of the applicant's approval *for participation* in the Medicare program by sending the Provider Tie-In Notice (Form CMS-2007), and/or a copy of the approval letter that will include the *CCN*. The RO will send the *SA* a copy of the applicant's approval letter.

Applicant Not in Compliance – The *SA* surveys the *applicant* and certifies that the *applicant* is not in compliance with the 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 to the RO, *which* will send the provider/supplier a denial letter. The RO will forward a copy of the denial letter to the *MAC* and to the *SA*. Claims will not be paid if the applicant is not approved *through* both the enrollment and the survey and certification processes.

The applicant is issued a denial letter for noncompliance with the conditions of participation/coverage/*certification*. The applicant may correct the deficiencies and reapply for certification. *The applicant who reapplies for certification must undergo a new survey which is a full, standard survey, except:*

- If on the first survey an applicant subject to the Life Safety Code (LSC) requirements was in substantial compliance with the LSC, the SA has the discretion to not resurvey for LSC compliance (although it must receive an acceptable Plan of Correction for any lower-level LSC deficiencies before it may recommend certification); and*
- In the case of an applicant seeking to participate as a hospital, the SA 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 SA 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 SA 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 SA certifies that the CAH applicant is not in compliance, 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 seek to be surveyed again for CAH conversion.

As with initial hospital applicants, the SA 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 SA 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, including for conditions where there were only lower-level deficiencies cited, before the SA 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 certification 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 SA of this as soon as possible, to facilitate planning for the full survey by the SA.

If the SA continues to find the applicant is not in compliance with the conditions of participation/coverage/certification or requirements, as applicable, 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.

2005A 3 – Reconsideration of Denial

Procedure for *Reconsideration* - An applicant has the right to *request a reconsideration of an initial certification denial decision. See Chapter 3, Sections 3050 – 3054 for reconsideration procedures and timeframes. Note that the RO may not simultaneously process a certification reapplication and a request for reconsideration. However, in accordance with Section 3054A, the applicant may withdraw its reconsideration request and reapply for certification if it has corrected the deficiencies identified on the survey.*

2005A4 – Deemed Providers/Suppliers, Excluding CLIA

Initial Survey by an AO with a CMS-Approved Medicare Accreditation Program

The AO's CMS-approved Medicare accreditation program must provide reasonable assurance that providers or suppliers accredited by the AO meet all Medicare Conditions

of Participation (CoPs) or Conditions for Coverage/Certification (CfCs), as applicable. CMS evaluates and reviews AOs seeking recognition of their accreditation programs for Medicare participation on a number of factors specified in 42 CFR §488.8, including the AO's accreditation standards, survey and oversight processes, and their comparability to CMS' standards and processes. Furthermore, 42 CFR §489.13 governs how CMS determines the effective date of a provider's or supplier's Medicare agreement or approval, including provisions related to certification survey findings.

Accordingly, before the AO makes a recommendation to CMS that an applicant seeking initial certification and enrollment in Medicare be "deemed" to meet Medicare's health and safety standards, the AO must conduct a survey and determine that the applicant meets all requirements for accreditation, including compliance with all applicable Medicare CoPs or CfCs.

Applicant in Compliance

If the applicant is found to comply with all accreditation requirements, the AO may award deemed status accreditation, effective no earlier than the accreditation survey end date, and recommend the applicant to the RO for Medicare certification via deemed status. The AO must inform the applicant and the RO of the results of the initial accreditation survey and of its recommendation of the applicant for certification via deemed status, including the effective date of the applicant's accreditation.

If the applicant is found to be in substantial compliance, but has lower-level deficiencies, then the AO must receive an acceptable plan of correction (POC) for such deficiencies. (See Section 2008D.) Once the AO receives an acceptable POC from the applicant, the AO may award deemed status accreditation and recommend the applicant for Medicare certification via deemed status. The AO may not make the effective date of the applicant's deemed status accreditation prior to the date of receipt of a POC that the AO finds acceptable. The AO must inform the applicant and the RO of the results of the initial accreditation survey, the receipt of an acceptable POC, and its recommendation of the applicant for deemed status, including the effective date of accreditation. The AO must also send its survey report to the RO.

When the AO notifies CMS of an applicant's accreditation and the AO's recommendation of deemed status for that applicant, the RO reviews the AO's accreditation survey report and other documentation. If the RO accepts the AO's recommendation of deemed status, it forwards the AO's notice of accreditation and recommendation of deemed status to the SA. The SA must prepare an initial certification packet for the provider or supplier. The certification packet is sent by the SA to the RO, with the Medicare Health Insurance Agreement (Form CMS-1561, 1561A or 370, depending on provider/supplier type) submitted to the SA by the applicant, along with any other documentation required for initial certification of that provider/supplier type. (See Exhibit 63 for documentation requirements.) In the remarks section of the Form CMS-1539, the SA indicates that it is transmitting an initial certification kit for an accredited, deemed provider/supplier. Once the RO receives the certification packet, it proceeds as described in Section 2005A2.

The RO must send to the AO in a timely manner a copy of its approval letter to the applicant. Among other things, the copy of the approval letter advises the AO of the CCN assigned to the new provider's/supplier's Medicare agreement, facilitating the AO's ability to report accurate data to CMS on its deemed status providers/suppliers.

If the RO's review of the accreditation survey suggests a problem, including, but not limited to:

- the AO's survey report describes findings which represent substantial noncompliance with a Medicare condition, but the AO awarded accreditation anyway; or*
- the AO's survey report indicated the applicant was required to submit an acceptable POC for lower-level deficiencies, but the AO issued its accreditation effective on a date prior to its receipt of the POC; or*
- the AO conducted an extension survey but the applicant is a new owner that rejected assignment of the prior owner's Medicare agreement and must therefore undergo a full accreditation survey;*

the RO may, consistent with §488.6(c)(2), reject the AO's recommendation of deemed status. In such cases the RO contacts the AO to discuss its concerns and ways the AO may remedy them, if possible. If the problems are not remedied, the RO may issue a denial of certification to the applicant and provides a copy to the AO in a timely manner.

Applicant Not in Compliance

*If the AO finds the applicant's failure to meet its CMS-approved Medicare accreditation program requirements represents substantial noncompliance with accreditation standards, including applicable Medicare CoPs or CfCs, the AO may **not** recommend the applicant for Medicare certification via deemed status. Rather, the AO must inform the applicant and the RO of the results of the initial survey and that it is not recommending the applicant for deemed status. The RO issues a denial of certification based on the AO's information, and provides a copy to the AO in a timely manner.*

The applicant may, at the AO's discretion, continue to work with the AO to correct the deficiencies and again seek initial certification through deemed status. If the applicant is surveyed again by the AO the survey must be a new survey which is a full, standard survey, except:

- If on the first survey an applicant subject to the Life Safety Code (LSC) requirements was in substantial compliance with the LSC, the AO has the discretion to not resurvey for LSC compliance (although it must receive an acceptable Plan of Correction for any lower-level deficiencies before it may recommend deemed status); and*

- *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, the 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/IIID.

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 Number*) 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 <i>Deemed Status</i> Accreditation	§2005B

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 BEDS	12. TOTAL FACILITY BEDS	13. TOTAL CERTIFIED
<u> 0 1 </u> (Hospital)	<u>300</u>	<u>300</u>

14.
LTC Certified Bed Breakdown

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

EXAMPLE 2: 250 bed hospital

Beds are distributed as follows:
200 beds in hospital portion
50 beds Title 18/19 DP SNF/NF

NOTE: Prepare two Forms CMS-1539 identifying the hospital and SNF/NF components.

1. Provider Number

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

7. CATEGORY	12. TOTAL FACILITY BEDS	13. TOTAL CERTIFIED BEDS
01 (Hospital)	<u>200</u>	<u>200</u>

14.
LTC Certified Bed Breakdown

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

1. Provider Number

|X|X|5|0|0|0| (SNF/NF)

7. CATEGORY	12. TOTAL FACILITY BEDS	13. TOTAL CERTIFIED BEDS
02 (SNF/NF)	<u>50</u>	<u>50</u>

14.
LTC Certified Bed Breakdown

|SNF | SNF/NF | NF | ICF/IID |
50

EXAMPLE 3: 400 bed hospital

Beds are distributed as follows:

300 hospital beds

100 beds Title 19 DP NF

NOTE: Prepare two Forms CMS-1539 for hospital and LTC components.

1. Provider Number

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

7. CATEGORY	12. TOTAL FACILITY BEDS	13. TOTAL CERTIFIED BEDS
<u> 0 1 </u> (Hospital)	<u>300</u>	<u>300</u>

14.
LTC Certified Bed Breakdown

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

1. Provider Number

|X|X|A,E, or F|0|0|0| (Title 19 NF)

7. CATEGORY	12. TOTAL FACILITY BEDS	13. TOTAL CERTIFIED BEDS
<u> 1 0 </u> (NF Distinct Part)	<u>100</u>	<u>100</u>

14.
LTC Certified Bed Breakdown

|SNF |SNF/NF |NF |ICF/IID |
100

EXAMPLE 4: 44 bed hospital swing-bed facility

1. Provider Number

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

7. CATEGORY	12. TOTAL FACILITY BEDS	13. TOTAL CERTIFIED BEDS
<u> 0 1 </u> (Hospital)	<u>44</u>	<u>44</u>

14.
LTC Certified Bed Breakdown

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

EXAMPLE 5: 100 bed nursing home (free-standing)

Beds are distributed as follows:
60 beds certified for Medicaid
40 beds not participating in either Medicare or Medicaid

1. Provider Number

| X | X | A,E, or F | 0 | 0 | 0 | (NF)

7. CATEGORY	12. TOTAL FACILITY BEDS	13. TOTAL CERTIFIED BEDS
<u> 1 0 </u> (NF)	<u>100</u>	<u>60</u>

14.
LTC Certified Bed Breakdown

| SNF | SNF/NF | NF | ICF/IID |
60

EXAMPLE 6: 75 bed Medicaid NF (free-standing)

1. Provider Number

|X|X|A, E or F|0|0|0| (Title 19 NF)

7. CATEGORY	12. TOTAL FACILITY BEDS	13. TOTAL CERTIFIED BEDS
<u> 1 0 (NF)</u>	<u>75</u>	<u>75</u>

14.
LTC Certified Bed Breakdown

|SNF|SNF/NF|NF|ICF/IID|
75

EXAMPLE 7: 150 bed SNF/NF and NF

Beds are distributed as follows:
100 beds SNF/NF
50 NF beds

1. Provider Number

|X|X|5|0|0|0| (Title 18 & 19 SNF/NF)

7. CATEGORY	12. TOTAL FACILITY BEDS	13. TOTAL CERTIFIED BEDS
<u> 0 3 (SNF/NF)</u>	<u>150</u>	<u>150</u>

14.
LTC Certified Bed Breakdown

|SNF|SNF/NF|NF|ICF/IID|
100 50

EXAMPLE 8: 100 SNF/NF facility

100 beds - SNF/NF dually participating

NOTE: Blocks A-E within item 14 **must not exceed** the total number of certified beds recorded in item 13. Report dually-participating beds in block B (18/19 SNF). Block F is no longer applicable.

1. Provider Number

| X | X | 5 | 0 | 0 | 0 | (18/19 SNF/NF)

7. CATEGORY	12. TOTAL FACILITY BEDS	13. TOTAL CERTIFIED BEDS
<u> 0 2 </u> (SNF/NF Dually- Participating)	<u>1 0 0</u>	<u>1 0 0</u>

14.
LTC Certified Bed Breakdown

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

100

EXAMPLE #9: 125 bed SNF/NF facility

Beds are distributed as follows:
100 beds - Title 19 NF
25 beds - Title 18/19 SNF/NF DP
See Example #8 Note.

1. Provider Number

| X | X | 5 | 0 | 0 | 0 | (18/19 SNF/NF)

7. CATEGORY	12. TOTAL FACILITY BEDS	13. TOTAL CERTIFIED BEDS
<u> 0 3 </u> (SNF/NF)	<u>1 2 5</u>	<u>1 2 5</u>

14.
LTC Certified Bed Breakdown

| SNF | SNF/NF | NF | ICF/IID |
25 100

EXAMPLE 10: 150 bed Medicaid-only NF

Beds are distributed as follows:
125 beds - Title 19 NF
25 beds - not participating in Medicare or Medicaid

1. Provider Number

| X | X | A, E, or F | 0 | 0 | 0 | (Title 19 NF)

7. CATEGORY	12. TOTAL FACILITY BEDS	13. TOTAL CERTIFIED BEDS
<u> 1 0 </u> (NF)	<u>1 5 0</u>	<u>1 2 5</u>

14.
LTC Certified Bed Breakdown

| SNF | SNF/NF | NF | ICF/IID |
125

EXAMPLE 11: 140 bed NF (free-standing)

1. Provider Number

|X|X|A, E or F|0|0|0| (NF)

7. CATEGORY	12. TOTAL FACILITY BEDS	13. TOTAL CERTIFIED BEDS
<u> 1 0 </u> (NF)	<u>140</u>	<u>140</u>

14.
LTC Certified Bed Breakdown

|SNF|SNF/NF|NF|ICF/IID|
140|

EXAMPLE #12 - 30 bed ICF/IID (free-standing)

1. Provider Number

|X|X|G|0|0|0| (ICF/IID)

7. CATEGORY	12. TOTAL FACILITY BEDS	13. TOTAL CERTIFIED BEDS
<u> 1 1 </u> (IMR)	<u>30</u>	<u>30</u>

14.
LTC Certified Bed Breakdown

|SNF|SNF/NF|NF|ICF/IID|
30|

EXAMPLE #13 - 50 bed NF and ICF/IID facility

Beds are distributed as follows:

30 beds - Title 19 NF

20 beds - Title 19 ICF/IID

NOTE: Prepare two Forms CMS-1539 identifying the NF and ICF/IID components.

1. Provider Number

| X | X | A,E,or F | 0 | 0 | 0 | (NF)

7. CATEGORY	12. TOTAL FACILITY BEDS	13. TOTAL CERTIFIED BEDS
<u> 1 0 </u> (NF)	<u>30</u>	<u>30</u>

14.
LTC Certified Bed Breakdown

| SNF | SNF/NF | NF | ICF/IID |
30

1. Provider Number

| X | X | G | 0 | 0 | 0 | (IMR)

7. CATEGORY	12. TOTAL FACILITY BEDS	13. TOTAL CERTIFIED BEDS
<u> 1 1 </u> (ICF/IID)	<u>20</u>	<u>20</u>

14.
LTC Certified Bed Breakdown

| SNF | SNF/NF | NF | ICF/IID |
20

Item 17 - Surveyor Signature

The surveyor (or survey team leader) signs and dates Form CMS-1539 after ensuring that the certification documents are complete and accurate.

Item 18 - State Agency Approval

The authorized representative of the SA signs and dates Form CMS-1539 and forwards the certification material to the RO or SMA, as appropriate. His/her signature constitutes for Medicare the official “certification” that the information being reported is correct according to official State files. In Medicaid-only cases, the *SA representative’s* signature on this document represents the adjudicative decision of the SA on the qualifications of the institution to participate in the Medicaid program.

2764.1 - RO Completion Instructions for Certification and Transmittal, Form CMS-1539, *Items 19 - 32* (Rev.)

The main purpose of Form CMS-1539 is to formalize the SA’s certification that a facility meets or does not meet the requirements for participation. The SA completes all applicable parts for the first 18 items (L1-L20) for Medicare/Medicaid providers/suppliers. The RO, or the SMA, complete the remaining items 19-32 (L21-L33), as appropriate. The RO completes as follows:

Item 19 - Determination of Eligibility

Enter code 1 or 2 in the block provided following the RO review of the SA’s findings and certification. Enter code 1 when the provider/supplier is found eligible to participate in the Medicare and/or Medicaid programs. Also enter code 1 when a denial of payment for new admissions is imposed, continued, or lifted. Enter code 2 when a facility is not eligible to participate.

Item 20 - Compliance with Civil Rights Act (Title VI)

For providers/suppliers needing OCR clearance, enter a 1 in the available block if the OCR requirements are met. If not in compliance with title VI, enter a 2 in the box that indicates that the provider is not eligible to participate. For Medicare Part B suppliers not requiring OCR clearance to participate, enter a 3 that indicates not applicable.

Item 22 - Original Date of Participation

Complete for initial certifications only. Determine when the facility is eligible to begin participation in Medicare and/or Medicaid. Enter the date in the blocks provided. The criteria for determining the effective date can be found at [42 CFR 489.13](#) for Medicare and [42 CFR 442.13](#) for Medicaid.

Items 23-25 - ICF/IID Certification Period

For all ICFs/IID, enter the re-certification findings of the SA (i.e., beginning, ending, and/or extension dates) and evidence provided in the certification documents accompanying Form CMS-1539. When an ICF/IID is not in compliance with program requirements and a denial of payment for new admissions is imposed, enter the beginning (Item 23) and ending (Item 24) dates of the **current** re-certification survey. In Item 25 (extension date), enter a date **not exceeding** the end of the fifteenth month following the month in which the sanction will be imposed.

Item 26 - Termination Action

If a provider's or supplier's participation in the Medicare/Medicaid program ends, record the reason (see below) in the accompanying block. Also complete Item 28 (termination date).

1 - Voluntary

Code 1 - Enter when a facility closes or merges.

Code 2 - Enter when a provider or supplier is voluntarily withdrawing because of dissatisfaction with reimbursement.

Code 3 - Enter when a facility is leaving the program because it is at risk of being involuntarily terminated.

Code 4 - Enter when a provider or supplier no longer wishes to participate in the program for some other or unknown reason.

2 - Involuntary

Code 5 - Enter when a facility fails to meet health or safety requirements.

Code 6 - Select this code when a provider fails to abide by the agreement.

3 - Other

Code 7 - Select this code when you terminate a currently assigned provider number. Examples include:

- Medicare SNF or dually-participating SNF/NF elects to participate in the Medicaid program only;
- Medicaid NF elects to participate in the Medicare or Medicare and Medicaid programs; and

- ASC, ESRD, or RHC facility elects to participate as free-standing instead of hospital-based and vice versa.

In any of the above instances, the RO terminates the existing provider number (complete Items 26 and 28) and assign the new provider number. (See [§1060.A.](#))

Item 27 - Intermediate Sanctions (ICF/IID Only)

When an ICF/IID provider is found not to meet the requirements of [§1905\(d\)](#) of the Act and the decision is made to apply an intermediate sanction rather than terminate, complete the pertinent items on Form CMS-1539 as follows:

1 - Suspension of Admissions

Enter the date in Item 27A that the payments for new admissions in the facility will be denied. In addition, mark Item 10 “B” (not in compliance with program requirements). Mark Item 19 A1” (eligible to participate). In Item 25 (extension date) enter a date **not exceeding** the end of the eleventh month following the month in which the denial of payments will be imposed. This date may not be extended.

2 - Rescind Suspension Date

a - Significant Compliance with Program Requirements

Enter the date the denial of payment is rescinded.

The SA will mark Item 10 “A” (in compliance with program requirements) and Item 19 A1” (eligible to participate). In Item 27B, the RO enters the date the denial of payment is rescinded.

NOTE: Items 23 and 24 can only be completed when Item 10 is marked ‘A’ (in compliance with program requirements).

b -Significant Effort or Progress

Item 27b may also be completed when Item 10 is marked “B” (not in compliance with program requirements) and Item 16 (SA Remarks) is documented to show that effort and progress has been made to correct the deficiencies. Item 25 (ICF/IID extension date) remains unchanged. Mark Item 19 “1” (eligible to participate).

NOTE: Pursuant to [42 CFR 442.119\(a\)](#), the denial of payment for new admissions is to be rescinded if the provider can document good faith efforts to correct. Effort would not, however, constitute compliance with program requirements. Therefore, it is conceivable that:

- The denial of payments could be rescinded;
- Effort and progress would be documented;
- The SA would certify “not in compliance”; and
- The extension would remain in effect.

If the deficiencies are not corrected by the 11th month following the initial month of denial, the provider agreement must be terminated.

NOTE: Similar information for SNFs/NFs is extracted from the Form CMS-462L, Adverse Action Extract for SNFs and NFs.

Item 28 - Termination Date

Enter the effective date of the termination action specified in Item 26.

Item 29 - Intermediary/Carrier Number

Enter the five-digit number assigned to the intermediary or carrier servicing the provider or supplier of health services.

Item 30 – Remarks

Use this block for any remarks that cannot be covered in the structured items above. If comments exceed space allotted in this item, document the additional comments on a sheet of paper entitled: “Item 30, Continuation For Form CMS-1539.”

Item 31 - RO Receipt of Form CMS-1539

Enter the date that a certification package is received.

For Medicaid-only providers, the SMA forwards the certification materials to the RO following review and completion. For Medicare, the SA forwards the package directly to the RO.

Item 32 - Determination Approval

Following review of the certification documents an authorized CMS or SMA representative must sign and date Form CMS-1539.

2777A - Medicaid-Only Certifications

(Rev.)

With the exception of State-operated NFs, which are certified by CMS, the SA completes all Medicaid-only certifications and forwards them to the State Medicaid agency (SMA) within 45 days after the survey. The SMA initiates appropriate action based on the SA's certification of the Medicaid-only provider. After this action is completed, the SMA forwards the case (with the exception of Form HHS-441, Assurance of Compliance with the Department of Health and Human Services Regulations under Title V of the Civil Rights Act of 1964, or a comparable form, *which is submitted to the applicable Regional Office of Civil Rights*) to the SA for entry into the *ASPEN* system. Before the initial certification is entered into the *ASPEN* system, the SA assigns a *CCN* to the NF, *hospital* or ICF/IID. The *ASPEN* system screens the facility's current compliance record for Conditions of Participation (CoPs), Requirements (for NFs), and other RO flags.

2777D - Change in Certification

(Rev.)

2777D1 - Medicaid NF and Medicaid distinct part NF providers seeking to participate as Medicare SNF providers

When Medicaid NF and Medicaid distinct part NF providers wish to participate as Medicare SNF providers, the SA sends the most recent survey information obtained during the latest Medicaid survey along with other documentation required for an initial Medicare certification of a SNF ([Exhibit 63](#)) to the RO for official determination of whether to approve the facility and enter into a provider agreement. If these documents provide adequate evidence that the facility is in compliance with the requirements governing program participation, the RO notifies the provider of the effective date of Medicare participation. The effective date is the date requested by the provider, but cannot be earlier than the date the request is filed with the RO or the SA.

The requesting facility must sign a Medicare provider agreement, which will be in effect concurrently with its present Medicaid agreement. The facility will be surveyed for both programs at the end of the current period of Medicaid certification.

A facility may increase its Medicare distinct part by converting Medicaid NF beds to Medicaid/Medicare SNF/NF beds without a survey. In expanding a distinct part, providers must adhere to distinct part organizational requirements and accounting principles.

2777D2 – Medicare- and Medicaid-participating Hospitals seeking to become Medicaid-only hospitals

When a hospital that dually participates in Medicare and Medicaid wishes to voluntarily terminate its Medicare provider agreement, but continue to participate in Medicaid only,

it must provide written notification to the SA and submit a completed Form CMS-855A to the MAC as required in Chapter 15, Section 10 of the Program Integrity Manual, Publication 100-08. In terms of survey and certification, voluntary terminations of the Medicare provider agreement will be processed in accordance with SOM Section 3046. A Non-deemed hospital will be surveyed at the time it ordinarily would have been subject to a recertification survey had it continued to participate in Medicare. In the case of a deemed hospital, it will be surveyed by its CMS-approved AO when its current accreditation is due for renewal.

2777D3-Medicaid-only Hospitals seeking to participate in Medicare and Medicaid

When a Medicaid-only hospital wishes to participate in both Medicare and Medicaid, it must submit a Form CMS-855A to the MAC. After receipt of the MAC's recommendation to approve the hospital's enrollment in Medicare, the SA sends the survey findings from the most recent Medicaid survey and its certification of Medicare CoP compliance or noncompliance based on that survey, along with other documentation required for an initial Medicare certification (see Exhibit 63), to the RO. The RO determines whether or not to approve the hospital for Medicare participation and enter into a provider agreement.

In the case of a Medicaid-only deemed hospital, after receipt of the MAC's recommendation for approval, the hospital must notify its CMS-approved AO of its application to change its status from a Medicaid-only hospital to a Medicare- and Medicaid (dually)-participating hospital. The hospital must request the AO to send the most recent survey report to the RO. The RO determines whether or not to approve the hospital for Medicare participation and enter into a provider agreement.

The RO has the option of requiring a new full, standard survey if it has concerns based on the most recent Medicaid survey findings.

- *If the RO determines there is substantial compliance with Medicare participation requirements based on the most recent Medicaid survey, it determines the effective date in accordance with 42 CFR 489.13, retires the previously issued Medicaid-only hospital CCN number and issues a Medicare CCN along with the signed Medicare provider agreement. The Medicare participation effective date may be the date requested by the provider, but cannot be earlier than the date the CMS 855A was approved by the Medicare Administrative Contractor (MAC) or, if there are other applicable federal requirements, the date on which all federal requirements were met. See Section 2780 concerning the effective date of the Medicare agreement.*

The Medicare provider agreement is in effect concurrently with the Medicaid agreement. The facility will be surveyed for both programs at the end of the current period of Medicaid certification. In the case of Medicaid-only deemed hospitals, when the AO surveys the hospital when the accreditation is due for renewal, it follows the standard process for notifying CMS of accreditation and recommendation of continued Medicare deemed status.

- *If the RO requires a new full, standard survey and that survey indicates substantial compliance, the RO determines the effective date in accordance with 42 CFR 489.13. The Medicare participation effective date cannot be earlier than the date the survey was completed or, if applicable, the date an acceptable plan of correction was received. See Section 2780 concerning the effective date of the Medicare agreement.*
- *If the survey indicates noncompliance, the RO denies the hospital's Medicare certification application. See Section 2005A2 for the process related to a denial. The SA must also advise the State Medicaid Agency of the substantial noncompliance.*

2778 - Objectives of RO Certification Review *(Rev.)*

The primary objective of the review is to assure that the certification, together with other documents, is adequate evidence of the identity of the certified institution and of its conformance to the laws and regulations governing program participation.

Since the RO certification specialist must process various request forms and notifications and assure that the documentation is complete, **it is of paramount importance that the specialist perform a quality-oriented appraisal.**

Before approving participation, the RO must be certain that the SA's certification of compliance is consistent with the documented findings. The RO considers the impact of deficient standards, elements, or Requirements (for SNFs and NFs) on the respective CoPs or Requirements; the provider's deficiency history profile; recent beneficiary complaints; or other external reports justifying further documentation of a provider's practices and consults with RO health professionals when appropriate.

Other objectives are accomplished by this review. The RO decides whether it agrees with the SA recommendation of compliance or noncompliance and its interpretation of reasonable time and reasonable plans for the correction of deficiencies and waivers. The RO reviews the Statement of Deficiencies and Plan of Correction, Form CMS-2567, to ensure that the SA's documentation supports the SA certification recommendation, acceptable plan of correction (PoC), or waiver request. The RO notes the timeliness and quality of SA processing, and extract information relating to administrative or program problems that the case reveals so that identified program problems can be corrected on the regional or national level.

In the case of hospitals that participate in both Medicare and Medicaid or Medicaid-only or of Critical Access Hospitals (CAHs), the RO must ensure the completion of the Hospital/CAH database worksheet (Exhibit 286) by the SA for all certifications, including initial certifications, regardless of whether the survey was conducted by the SA or AO. The survey kit will not upload without completion in ASPEN of the worksheet.

In Medicaid-only cases, the SA certifies its determination as to the provider's compliance with the participation requirements. *With the exception of PRTFs*, the SMA must accept certification determinations as final and may not enter into a provider agreement with a NF, *HHA, hospital* or *ICF/IID* unless the SA has certified the provider as in compliance with applicable requirements for program participation. It may, however, for good cause, refuse to execute an agreement with a NF, *HHA, hospital* or *ICF/IID* certified by the SA. (See [42 CFR 442.12\(d\)](#).)

Certification documents are official statements of the SA that may not be altered. The RO uses the Request for Additional Information, Form CMS-1666 ([Exhibit 15](#)), to request additional information or documentation. (See [§2776](#).)

If a deficiency is subsequently corrected, the corrective action will be shown on Form CMS-2567 or the Post-Certification Revisit Report, Form CMS-2567B, as appropriate. If the deficiencies have not been corrected at the time of the revisit, they are shown on a new Form CMS-2567. The *CASPER* system accumulates data on the ability of providers and suppliers to meet program participation requirements at the time of the survey. *CASPER* data from Form CMS-2567 and Form CMS-2567B are used to measure the extent of progress providers and suppliers make in complying with program requirements.

In case of an unreconciled interpretive disagreement with the SA, the RO can arrive at a determination disagreeing with the SA, **provided there is evidence to support a contrary decision**. If the RO disagrees with the SA certification, it justifies its rejection in writing and attempts to resolve the disagreement. If necessary, a disagreement over interpretive policy can be referred to CMS CO for resolution.

2779B – CMS Certification Numbers for Medicaid Providers

(Rev.)

For certification purposes, title XIX-only providers are identified by a 6-digit alphanumeric CCN. The first 2 digits identify the State in which the provider is located. The third position, which is an alpha character, identifies the type of facility by level or type of care being provided. The last 3 digits make up a sequential number series beginning with 001.

The RO uses the following groups of alphanumeric numbers for the type of facility as indicated:

A001-A999	NF (Formerly assigned to Medicaid SNF)
B001-B999	NF (Formerly assigned to Medicaid SNF) Expansion of A001-A999
E001-E999	NF (Formerly assigned to ICF)
F001-F999	NF (Formerly assigned to ICF) Expansion of E001-E999
G001-G999	ICF/ <i>IID</i>
H001-H999	ICF/ <i>IID</i> Expansion of G001-G999
K001-K999	Medicaid HHAs
L001-L999	Psychiatric Residential Treatment Facilities (PRTF)
<i>J001-J099</i>	<i>Medicaid-Only Short-term acute care hospitals</i>
<i>J100-J199</i>	<i>Medicaid-Only Children's Hospitals</i>
<i>J200-J299</i>	<i>Medicaid-Only Children's Psychiatric Hospitals</i>
<i>J300-J399</i>	<i>Medicaid-Only Psychiatric Hospitals</i>
<i>J400-J499</i>	<i>Medicaid-Only Rehabilitation Hospitals</i>
<i>J500-J599</i>	<i>Medicaid-Only Long-term Hospitals</i>
<i>J600-J999</i>	<i>Reserved for future use</i>

2780 - Effective Date of Provider Agreement, Form CMS-1561, and Supplier Approval (Rev.)

The effective date of participation in the Medicare program, i.e., of the provider agreement or supplier approval issued by the RO, may not be earlier than the date on which the provider or supplier meets all Federal requirements. See Section 2008D for discussion of Federal requirements. While the on-site initial certification survey is often the final Federal requirement that is met, this is not always the case. For example, when the applicant has not submitted required Office of Civil Rights documentation prior to the survey, the determination of compliance with the requirements of the Office of Civil Rights may be the final requirement that is met and thus be the effective date of the provider agreement or supplier approval. Another example may be if the MAC verification inadvertently occurred after the onsite survey was conducted or, for HHAs, when the second MAC review requires additional information for verification of the information, then the effective date would be on that date.

2780A - Compliance With All *Federal* Requirements ***(Rev.)***

The agreement is effective on the date the onsite survey is completed if, on the date of the survey the entity *not only* meets all Federal health and safety *standards, i.e., the* CoPs, *CfCs* or Requirements (for SNFs), *but also has met all other applicable Federal requirements for Medicare participation.*

2780B - All *Health & Safety Standards* Are Not Met on the Day of the Survey ***(Rev.)***

If on the initial certification survey the provider or supplier does not meet all applicable health and safety standards, 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, i.e., has no deficiency citations; or*
 - *Has been found to be in substantial compliance, but has standard-level deficiencies and the 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.*
- Effective dates of Medicare participation for NFs requesting to participate in the Medicare program as SNFs can be any date during the certification period as long as the provider is in substantial compliance with all requirements and if applicable, have an approved waiver.
- For Medicaid-only facilities, the SA determines whether the PoC is acceptable and whether waiver requests for ICFs/*IID* are approvable. LSC waivers for Medicaid NFs require the RO's approval.

Retroactive *SA* certifications *of compliance with health and safety standards or AO accreditation decisions* prior to the survey *end* date are not permitted under any circumstances.

Chapter 3 - Additional Program Activities

(Rev.)

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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 continued *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 *IPPS* 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 IPPS*. These hospitals need not be evaluated for compliance with the *IPPS* 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 IPPS*, 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 IPPS 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 *IPPS*-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 IPPS* 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* providers *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 refuses 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 track. *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.)