State Operations Manual
Chapter 1 - Program Background and Responsibilities

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(Rev. 123, 10-03-14)

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Background

1000 - Medicare and Medicaid - Background
(Rev. 1, 05-21-04)

The Social Security Act (the Act) mandates the establishment of minimum health and safety and CLIA standards that must be met by providers and suppliers participating in the Medicare and Medicaid programs. The Secretary of the Department of Health and Human Services (DHHS) has designated CMS to administer the standards compliance aspects of these programs.

1000A - Medicare Provisions
(Rev. 1, 05-21-04)

Medicare is a Federal insurance program providing a wide range of benefits for specific periods of time through providers and suppliers participating in the program. Providers, in Medicare terminology, include patient care institutions such as hospitals, critical access hospitals (CAHs), hospices, nursing homes, and home health agencies (HHAs). Suppliers are agencies for diagnosis and therapy rather than sustained patient care, such as laboratories, clinics, and ambulatory surgery centers (ASCs). The Act designates those providers and suppliers that are subject to Federal health care quality standards. Benefits are payable for most people over age 65, Social Security beneficiaries under age 65 entitled to disability benefits, and individuals needing renal dialysis or renal transplantation. The Federal Government makes payment for services through designated fiscal intermediaries (FIs) and carriers to the providers and suppliers. Section 1802 of the Act provides that any individual entitled to Medicare may obtain health services from any institution, agency, or person qualified to participate in Medicare if that institution, agency, or person undertakes to provide that individual such services.

1000B - Medicaid Provisions
(Rev. 123, Issued: 10-03-14, Effective: 10-03-14, Implementation: 10-03-14)

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 (PRTF*s*), and Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID*s*). *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. 123, Issued: 10-03-14, Effective: 10-03-14, Implementation: 10-03-14)

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.)

1002 - Basis for State Agency (SA) Activities Under Title XVIII and Title XIX of the Act

(Rev. 1, 05-21-04)

Section 1864(a) of the Act directs the Secretary to use the help of State health agencies or other appropriate agencies when determining whether health care entities meet Federal standards. This helping function is termed "certification." See 42 CFR 488.1.

Section 1902(a)(9)(A) of the Act requires that a State use this same agency to set and maintain additional standards for the State Medicaid program. Section 1902(a)(33)(B) requires that the State use the agency utilized for Medicare or, if such agency is not the State agency responsible for licensing health institutions, the State use the agency responsible for such licensing to determine whether institutions meet all applicable Federal health standards for Medicaid participation, subject to validation by the Secretary.

The complete Federal requirements are published in the "Federal Register," and they are further explained in this manual. See 42 CFR Part 488.

1004 - Title XVIII Agreements With States

(Rev. 1, 05-21-04)

Agreements between the Secretary and the various States, territories, and the District of Columbia stipulate that SAs designated by the Governors are responsible for the performance of the certification functions created by §1864 of the Act, that the designated agencies will keep necessary and appropriate records to be furnished as required by delegates of the Secretary, and that they will employ management methods, personnel procedures, equal opportunity policies, and merit systems procedures in accordance with agreed upon or established practices. The Secretary agrees to provide funds for the reasonable and necessary costs to the States to perform the functions authorized by the agreements. The lifetime of the agreements is unlimited, but an agreement may be terminated under specific conditions, by action of either of the parties. The Governors have the prerogative to propose modification of the agreements to allow for variations in organizational location of responsibilities within the State for Federal programs and for State health facilities licensure. The SA's responsibility for evaluation and certification may not be re-delegated. However, by arrangements that meet the express approval of the Secretary, subsidiary functions such as the performance of surveys and investigations may be assigned to other State government units or other agencies. When the reorganization of a State government affects the responsibilities of the designated agency, or in any way affects the arrangements previously recognized by the §1864 Agreement, modification or renegotiation of the agreement may be necessary.

The Secretary may, under §1874 of the Act, contract with State or other agencies for services included in sections of the Act other than §1864 when the Secretary finds that such contracts would be in the interest of effective program operations.

Chapter 4 of this manual contains information on the administration of these agreements.

1006 - CMS' Role
(Rev. 1, 05-21-04)

The primary mission of CMS is to administer the Medicare program and certain related provisions of the Act in a manner which:

- Promotes the timely and economic delivery of appropriate quality of care to eligible beneficiaries;
- Promotes beneficiary awareness of the services for which they are eligible; and
- Promotes efficiency and quality within the total health care delivery system.

Overall policy-making responsibility is centralized in CMS' Baltimore headquarters (CO), where all aspects of the Medicare program, CLIA program, and oversight of the State Medicaid programs are coordinated. CMS CO is responsible for:

- Monitoring, surveillance, and overall administrative control of the certification process, including its financial and surveyor training aspects;
- Establishing operational policy for the certification process;
- Conveying operational instructions and official interpretations of policy to the SAs and CMS' regional offices (ROs); and
- Implementation of the CLIA program.

The CMS ROs have been delegated the authority by the Secretary for assuring that health care providers and suppliers participating in the Medicare, Medicaid, and CLIA programs meet applicable Federal requirements. This is accomplished through various activities. The ROs are responsible for:

- Making final determinations of provider and supplier eligibility for participation in the Medicare and CLIA programs; assembling information on all determinants of eligibility; approving, denying, or terminating provider agreements and supplier participation; CLIA certification; imposing nursing home sanctions and arranging for FI tie-in with new providers;
- Evaluating the performance of SAs in interpreting and applying health and safety standards, their assessments of providers and suppliers for compliance with standards, and their use of appropriate administrative procedures;
- Providing liaison, direction, and technical assistance to SAs in the day-to-day

management of the certification process;

- Interpreting CMS guidelines, policies, and procedures applicable to certification activities;

- Analyzing and negotiating State Medicare certification budgets; analyzing State spending patterns to assure that funds are economically and appropriately used; and allocating SA funds for conducting certification activities;

- Alerting CMS CO to potential or actual health care crises resulting from terminations, natural disasters, and strikes among other occurrences;

- Conducting surveillance and assessments of SA operations and assisting SAs in developing the capability to provide direct assistance to providers and suppliers; reviewing SA certification actions; and providing feedback to States;

- Preparing data based on SA survey findings for input into CMS' Automated Survey Processing Environment (ASPEN), Online Data Input and Edit (ODIE) system, which is a subsystem of the Online Survey Certification and Reporting (OSCAR) system, a database and retrieval program; analyzing OSCAR data, and providing feedback to SAs on certification information tracked by the system; and

- Conducting Federal surveys of providers and suppliers to ensure that standards and procedures are being applied in a uniform and consistent manner.

1008 - Adjudication Authority
(Rev. 1, 05-21-04)

1008A - Medicare Approval
(Rev. 1, 05-21-04)

The authority of the Secretary of DHHS to approve, disapprove, or terminate the Medicare participation of certified providers and suppliers is delegated to CMS' ROs.

The authority of the Secretary of DHHS to approve, disapprove, or terminate the CLIA certification of laboratories is delegated to the CMS ROs.

EXCEPTION

If termination is on the grounds of fraud, program abuse, or noncompliance with peer review requirements, the authority to terminate or to establish eligibility for reinstatement reposes with the Office of Inspector General (OIG), DHHS.

1008B - Medicaid Approval
(Rev. 1, 05-21-04)

With the exception of State-operated Medicaid-only NFs, Medicaid law requires that the same SA that makes the certifications for Medicare provider and supplier eligibility also makes the determinations for Medicaid eligibility. The law also requires that there be a designated State Medicaid Agency (SMA) responsible for the overall management of the Medicaid program. See 42 CFR 431.610. For State-operated Medicaid-only NFs, §1919 of the Act specifies that the Secretary will have enforcement authority. There is in each State an SMA that is ultimately responsible to CMS for the Medicaid program administration. Each SMA must enter into an interagency agreement with the certifying SA to establish the adjudicative function of the certifying SA and provide for the application of Federal certification standards and procedures. The SMA must accept the SA's certification decisions as final, but it exercises its own determination as to whether to enter into agreements with the approved providers. See Subsection E of this manual.

1008C - Compliance With Title VI of the Civil Rights Act of 1964
(Rev. 1, 05-21-04)

Providers are direct recipients of Federal funds and are thus subject to title VI of the Civil Rights Act of 1964. The U.S. Office for Civil Rights (OCR) has the authority to determine whether Medicare providers comply with this non-discrimination statute, and the conditions of participation (CoPs) make OCR approval a requirement for Medicare approval by CMS. Before OCR will issue its approval, it also determines compliance with §504 of the Rehabilitation Act of 1973, as amended by the Rehabilitation Act Amendments of 1974, which includes a cross reference to the Uniformed Federal Accessibility Standards concerning architectural barriers to the handicapped. The OCR must also determine compliance with the Age Discrimination Act of 1975, and with title IX of the Education Amendments of 1972. See 45 CRF Part 84; see also Exhibit 2 of this manual.

Regarding Medicaid-only providers, the States themselves are considered the direct recipients of the Federal funds and may be considered to have a direct obligation to assure OCR of **their** compliance by assuring that funds go to providers who are in compliance. As with Medicare, determinations of civil rights compliance of providers are under the authority of OCR and are preconditions to approving the provider's participation in the Medicaid program.

1008D - Waivers of Standards
(Rev. 93, Issued: 11-29-13, Effective: 11-29-13, Implementation: 11-29-13)

For a few of the standards, the statute or regulations allow for waivers in the presence of verified temporary shortages of health personnel or in the presence of equivalent alternative patient safeguards. Medicare waiver authority is re-delegated to the ROs. Waivers for NFs to provide licensed personnel on a 24-hour basis repose with the States.

Life safety code waivers for NFs and ICFs/IID are the responsibility of the States [See 42 CFR 483.470(j)(2)(A)].

1008E - Look-Behind Authority

(Rev. 123, Issued: 10-03-14, Effective: 10-03-14, Implementation: 10-03-14)

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.

1008F - Authorization of Certification Expenditures

(Rev. 1, 05-21-04)

Authority to approve Medicare certification budgets and expenditures is re-delegated to CMS' regional administrators (RAs). Authority to approve or disapprove Federal financial participation (FFP) in Medicaid certification expenses is re-delegated to the RAs subject to ratification by CMS.

1008G - Appeals

(Rev. 1, 05-21-04)

All of the appeal authorities do not repose with CMS. All CMS RO notices of adverse

determinations include instructions on the proper filing and addressing of the appropriate appeal.

1008H - Compliance With TRICARE of Uniformed Services and/or Civilian Health and Medical Program of Veterans Administration (CHAMPVA) Requirements

(Rev. 1, 05-21-04)

For the provision of inpatient hospital services pursuant to admissions occurring on or after January 1, 1987, providers are required to participate in the TRICARE/CHAMPVA programs. As mandated by §1866(a)(1)(J) of the Act, providers are subject to implementing regulations governing TRICARE/CHAMPVA programs benefits under title 10, §1079 or §1086 of chapter 55 - Medical and Dental Care of the TRICARE; and title 38, §613 of chapter 17 - Hospital, Nursing Home, Domiciliary, and Medical Care of the CHAMPVA. Such regulations are found in 32 CFR Part 199 for TRICARE and 38 CFR 17.54 for CHAMPVA. Inpatient hospital care to TRICARE and/or CHAMPVA beneficiaries is subject to the specific eligibility and medical service limitations set forth in the regulations. Hospitals are to accept TRICARE and/or CHAMPVA reimbursement for such services as payment in full. The Secretary has authority under §1866(b)(2) of the Act to terminate provider agreements for noncompliance. See 42 CFR 489.25.

NOTE: This requirement relates to individuals whose inpatient care is covered under the TRICARE and CHAMPVA programs, not to Medicare beneficiaries who, though eligible for these programs, are using Medicare as the primary payer for their services. (See the Medicare Benefit Policy Manual, Pub 100-02, Chapter 16, §50.)

1008I - Compliance With Veteran's Administration (VA) Program Requirements

(Rev. 1, 05-21-04)

For the provision of inpatient hospital services pursuant to admissions occurring on or after July 1, 1987, providers must agree to be a participating provider of care to VA patients. As mandated by §1866(a)(1)(L) of the Act, providers are subject to implementing regulations governing VA program benefits under title 38, §603. The provision of inpatient hospital care to veterans is subject to the specific limitations set forth in 38 CFR 17.50(b). Hospitals must accept VA reimbursement for such services as payment in full. The Secretary has authority under §1866(b)(2) of the Act to terminate provider agreements for noncompliance. See 42 CFR 489.26.

NOTE: This requirement relates to veterans, whose inpatient care is covered under the VA program, not to Medicare beneficiaries who are also eligible for VA coverage. (See the Medicare Benefit Policy Manual, Pub 100-02, Chapter 16, §50.)

1010 - Certification Related Functions of SA

(Rev. 123, Issued: 10-03-14, Effective: 10-03-14, Implementation: 10-03-14)

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.

1012 - Explanation of Certification and Survey
(Rev. 1, 05-21-04)

1012A - Meaning of Certification
(Rev. 123, Issued: 10-03-14, Effective: 10-03-14, Implementation: 10-03-14)

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*.

1014 - Relationship of Survey Date to Date of Initial Medicare Approval
(Rev. 1, 05-21-04)

A provider or supplier cannot begin to have its services covered and reimbursed by Medicare until the date on which it is found, via the certification process, to be in compliance with all federal requirements, including compliance with **all** applicable CoPs or in substantial compliance with the requirements for SNFs and NFs, or in compliance with the CfCs if it is a supplier (42 CFR 489.13). A laboratory with a CLIA registration certificate is an exception to this rule. Other exceptions are CMHC's and FQHC's. The effective date for CMHC and FQHC participation is the date the RO signs the CMHC or FQHC agreement and determines that all medical requirements, including environmental requirements, are met. (See SOM, Chapter 2, §2004.) In most cases, it usually is impossible to schedule and complete a survey, i.e., ascertain actual compliance with all applicable requirements, on the date a new institution opens its doors. The institution generally must operate for a short initial period without Medicare payment for its services.

1016 - Approval and Correction of Deficiencies
(Rev. 1, 05-21-04)

The Medicare CoPs, Requirements for SNFs and NFs, and CfCs are sets of requirements for acceptable quality in the operation of health care entities. There is a set of Conditions, or Requirements for SNFs and NFs, for each type of provider or supplier subject to SA certification. In addition to each Condition, or Requirement for SNFs and NFs, there is a group of related quality standards, with the Condition or Requirement expressed in a summary lead sentence or paragraph characterizing the quality or result of operations to which all the subsidiary standards are directed. The SA ascertains, by a survey conducted by qualified health professionals, whether and how each standard is met. While an institution may fail to comply with one or more of the subsidiary standards during any given survey, it cannot participate in Medicare unless it meets each and every Condition or attains substantial compliance with requirements for SNFs and NFs.

NOTE: CMHCs have no conditions of participation or coverage to meet. CMHCs do have to meet certain core public health service requirements prior to Medicare approval. FQHCs do have conditions of coverage to meet, as found at 42 CFR 491. However, FQHCs attest to meeting the CfCs, rather than undergo a survey.

Many Condition or Requirement summaries are identical to statements of the statute. The essence of what the SA certifies to CMS is a finding of whether an institution meets each of the CoPs or substantially meets each requirement for SNFs and NFs applicable to it, and whether each supplier of services meets each CfC applicable to it.

The SA prepares its certification for the RO, sends the institution a "Statement of Deficiencies," Form CMS-2567. The institution is given 10 calendar days in which to respond with a Plan of Correction (PoC) for each cited deficiency, and enters this response on the form containing the statement of deficiencies. This form, with written deficiencies and acceptable PoC, is available for public inspection at the SA office and the nearest RO, and can be requested through the Freedom of Information Act (FOIA).

If the institution has not come into compliance with all Conditions or Requirements for SNFs and NFs within the time period accepted as reasonable, the SA certifies noncompliance notwithstanding a PoC.

The SA's finding constitutes a final determination (except in the case of a State-operated Medicaid-only NF or a NF subject to a validation survey or a review by CMS when CMS' decision is binding), when a Medicaid-only facility is noncompliant. The SMA must undertake either an action to terminate the non-complying facility's Medicaid participation or, if a NF, apply one or more of the remedies specified in §1919(h) of the Act, or it may do both.

1018 - Exceptions to SA Certification
(Rev. 1, 05-21-04)

1018A - Federal and Indian Health Institutions
(Rev. 1, 05-21-04)

Because of questions of intergovernmental jurisdiction, the survey and certification of a hospital or SNF that is either owned or operated by the Indian Health Service, and therefore considered to be a Federal provider of services, is handled by the RO. The SA is responsible, however, for determining whether the facility meets Medicaid certification requirements. The SA may accept Medicare certification as sufficient evidence of meeting Medicaid requirements, or the SA may conduct a survey. Since Indian health tribal facilities may or may not be under Federal jurisdiction the RO determines whether the RO or the SA has jurisdiction.

1018B - Religious Nonmedical Health Care Institutions (RNHCIs)
(Rev. 1, 05-21-04)

Section 1861(e) of the Act includes in the definition of "hospital" a religious nonmedical health care institution that is operated or listed and certified by the First Church of Christ, Scientist, in Boston, Massachusetts, with respect to certain items and hospital services

furnished to inpatients. Section 1861(y) includes sanatoria with respect to items and services furnished to inpatients in a long-term care setting. All approvals are handled by the Boston RO. No SA certifications are necessary. The State may also include these services under the State plan for Medicaid.

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

(Rev. 123, Issued: 10-03-14, Effective: 10-03-14, Implementation: 10-03-14)

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 - Deemed CLIA Laboratories

(Rev. 123, Issued: 10-03-14, Effective: 10-03-14, Implementation: 10-03-14)

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/.*

1018I - Exemption of Laboratories Licensed by States
(Rev. 1, 05-21-04)

CLIA will exempt laboratories in States that have been determined to have laws and regulations in effect that are equal to, or more stringent than, CLIA requirements. Exempt laboratories must hold a valid State license within the exempt State. Oregon and Washington States have been granted complete exemption. New York State has been granted a partial exemption. Refer to Chapter 6 for additional information on CLIA exempt laboratories organizations.

1018J - Eligibility for Medicaid Facilities
(Rev. 1, 05-21-04)

A facility's eligibility for Medicaid participation can be established through Medicare deemed status for providers and suppliers that are not required under Medicaid regulations to comply with any requirements other than Medicare participation requirements for that provider or supplier type. See 42 CFR 488.6.

1020 - Effect of Accreditation, Licensure, and Other Approval Programs on Medicare Standards
(Rev. 1, 05-21-04)

Certification builds upon State and national accreditation programs. Certification requirements, State licensure codes for health facilities, programs for professional licensure and accreditation, and medical assistance standards are all related; therefore, certification activities must be coordinated with other programs. It is important that there be an interchange of information about program standards and institutions that participate in these programs between the certifying agency, accrediting organizations, State licensure programs, and State medical assistance programs.

1022 - CMS and AO Information Exchange Regarding Deemed Providers/Suppliers (Excluding CLIA)
(Rev. 123, Issued: 10-03-14, Effective: 10-03-14, Implementation: 10-03-14)

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

(Rev. 123, Issued: 10-03-14, Effective: 10-03-14, Implementation: 10-03-14)

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		
Monthly Adverse Action Report	*X*	
Notices		
Accreditation Status of Facilities Recommended for Deemed Status (includes both initial and re-accreditation surveys) • *Full Accreditation* • *Conditional Accreditation* • *Provisional Accreditation* • *Denial of Accreditation*	*X*	*X*
Termination/Withdrawals includes • *Involuntary (AO-initiated) – as a result of CoP/CfC deficiencies, AO standard deficiencies, AO non-payment, closure or other AO policies.* • *Voluntary (Facility-Initiated) – change to State Agency or other AO merger, acquisition, or closure.* *Include reason for involuntary and voluntary terminations/withdrawals and last deemed*	*X*	*X*

Types of Documents	*Central Office Email Box*	*Regional Office Email Box*
survey date		
Other Issues *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*	*X*	*X*

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

(Rev. 123, Issued: 10-03-14, Effective: 10-03-14, Implementation: 10-03-14)

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

(Rev. 123, Issued: 10-03-14, Effective: 10-03-14, Implementation: 10-03-14)

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.

Transmittals Issued for this Chapter

Rev #	Issue Date	Subject	Impl Date	CR#
R123SOM	10/03/2014	Revisions to State Operations Manual (SOM) Chapters 1, 2 and 3	10/03/2014	N/A
R93SOM	11/29/2013	State Operations Manual (SOM) Chapter 1 revisions for Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID)	11/29/2013	N/A
R01SOM	05/21/2004	Initial Issuance of Pub 100-07	N/A	N/A