

# State Operations Manual

## Chapter 1 - Program Background and Responsibilities

(Rev. 1, 05-21-04)

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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. 1, 05-21-04)**

Medicaid is a State program that provides medical services to clients of the State public assistance program and, at the State's option, other needy individuals, as well as augments hospital and nursing facility (NF) services that are mandated under Medicaid. States may decide on the amount, duration, and scope of additional services, except that care in institutions primarily for the care and treatment of mental disease may not be included for persons over age 21 and under age 65. When services are furnished through institutions that must be certified for Medicare, the institutional standards must be met for Medicaid as well. In general, the only types of institutions participating solely in Medicaid are NFs, Psychiatric Residential Treatment Facilities (PRTF), and Intermediate Care Facilities for the Mentally Retarded (ICFs/MR). Medicaid requires NFs to meet

virtually the same requirements that SNFs participating in Medicare must meet. ICFs/MR must comply with special Medicaid standards. Section [1902 \(a\)\(23\)](#) of the Act provides Medicaid recipients a free choice of providers if the provider undertakes to provide the recipients with medical services. However, such freedom may be restricted under [§1932\(a\)](#) of the Act if the State determines that an individual must receive his or her medical assistance from a managed care organization.

## **1000C - Clinical Laboratory Improvement Amendments (CLIA)**

**(Rev. 1, 05-21-04)**

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.

## **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. 1, 05-21-04)**

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/MR are the responsibility of the States [See [42 CFR 483.470\(j\)\(2\)\(A\)](#)].



## **1008E - Look-Behind Authority**

**(Rev. 1, 05-21-04)**

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 and ICFs/MR, 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/MR. The CMS' decision to cancel the approval or terminate an ICFs/MR 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 facility 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 100-2, [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 100-2, [Chapter 16](#), §50.)

## **1010 - Certification Related Functions of SA**

**(Rev. 1, 05-21-04)**

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 CoPs or requirements.
- 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 and Conditions for Coverage (CfCs) requirements.

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 Accredited Entities** - These surveys are intended to furnish DHHS and Congress a monitoring of the validity of "deeming" that accredited entities meet the CoPs. Validation surveys include 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 accredited and non-accredited surveys, follow-up visits, and complaint investigations into CMS data systems, for example (ODIE, ASPEN, 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.

Ensure that providers/suppliers have enrolled with the FI or carrier, as appropriate, prior to conducting an initial survey.

## **1012 - Explanation of Certification and Survey**

**(Rev. 1, 05-21-04)**

### **1012A - Meaning of Certification**

**(Rev. 1, 05-21-04)**

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 health care entities to participate in Medicare and CLIA. Recertifications are performed periodically by the SAs.

Regardless of whether the finding is for Medicare, Medicaid, or CLIA purposes, the SA surveys an institution in exactly the same way to ascertain whether it meets the Federal health and safety requirements for participation. Except for nursing homes that participate in both Medicare and Medicaid, 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. The law provides Federal funding for these surveys. SAs survey many institutions simultaneously for Medicare, Medicaid, and State licensure, and sometimes for other inspection programs, so the costs are equitably allocated between the sharing programs.

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 neither a mere building inspection nor a "white glove inspection" which, on no more than an annual basis, would be pointless. Its more realistic focus is ascertaining that the responsible provider officials and key personnel are effectively doing **all they** must do to protect health and safety.

Many aspects of the survey are accomplished by scrutinizing the provider's records to show that professional staff members have been properly noting and evaluating the progress of patients' care or managing provider operations with continuing vigilance. Surveys of SNFs, NFs, HHAs, and ICFs/MR are conducted in accordance with outcome-oriented survey protocols, which were designed to concentrate on patient/resident/client outcomes of care in determining the provider's compliance with the Federal requirements rather than focusing on "process-oriented" requirements. A provider's certification is not questioned merely on grounds that the institution has moved a short distance or slightly modified the scope of its services. [See 42 CFR 488.26 and 488.330.](#)

## **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 - Accredited Hospitals**

**(Rev. 1, 05-21-04)**

Sections [1861\(e\)](#) and [1865\(a\)](#) of the Act allow institutions accredited as hospitals by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or by the American Osteopathic Association (AOA) to be deemed to meet the CoPs, with the exception of the following:

- The utilization review (UR) condition;

- A standard promulgated by the Secretary which is a higher-than-accreditation requirement;
- The two special Conditions for psychiatric hospitals; and
- Any higher-than-national standards approved by the Secretary.

### **1018D - Accredited/Deemed HHAs**

**(Rev. 1, 05-21-04)**

HHAs accredited by national accreditation bodies under CMS approved programs are deemed to meet Medicare CoPs. These providers are referred to as deemed status providers for participation. HHAs accredited by the Community Health Accreditation Program (CHAP) as of August 28, 1992, and JCAHO as of September 28, 1993, are deemed to meet the CoPs, and are Medicare participating HHAs.

**NOTE:** Some HHAs may be accredited by the above mentioned accrediting bodies, but may not have deemed status. The accrediting body's letter approving accreditation will specify whether it has Medicare deemed status.

### **1018E - Accredited/Deemed Hospices**

**(Rev. 1, 05-21-04)**

Hospices accredited by national accreditation bodies under CMS approved programs are deemed to meet Medicare CoPs. These providers are referred to as deemed status providers for participation. Hospices accredited by JCAHO as of June 18, 1999, and CHAP as of April 20, 1999, are deemed to meet the CoPs and are Medicare participating Hospices.

**NOTE:** Some Hospices may be accredited by the above mentioned accrediting bodies, but may not have deemed status. The accrediting body's letter approving accreditation will specify whether it has Medicare deemed status.

### **1018F - Accredited/Deemed Ambulatory Surgical Centers (ASCs)**

**(Rev. 1, 05-21-04)**

ASCs accredited by national accreditation bodies under CMS approved programs are deemed to meet Medicare CfCs. These suppliers are referred to as deemed status suppliers. ASCs accredited by the Accreditation Association for Ambulatory Health Care (AAAHC) and JCAHO as of December 19, 1996, are deemed to meet the CfCs and are Medicare participating ASCs. The ASCs accredited by the American Association for Accreditation for Ambulatory Surgery Facilities, Inc (AAAASF) as December 2, 1998,



and AOA as of January 30, 2003, are deemed to meet the CfCs and are Medicare participating ASCs.

**NOTE:** Some ASCs may be accredited by the above mentioned accrediting bodies, but may not have deemed status. The accrediting body's letter approving accreditation will specify whether it has Medicare deemed status.

## **1018G - Accredited/Deemed CAHs**

**(Rev. 1, 05-21-04)**

CAHs accredited for deemed status by national accreditation bodies under CMS approved programs are deemed to meet Medicare CoPs. These providers are referred to as deemed status providers for participation. CAHs accredited by AOA as of December 27, 2002, and JCAHO as of November 21, 2002, are deemed to meet the CoPs and are Medicare participating CAHs.

**NOTE:** Some CAHs may be accredited by the above mentioned accrediting body, but may not have deemed status. The accrediting body's letter approving accreditation will specify whether it has Medicare deemed status.

## **1018H - Accredited CLIA Laboratories**

**(Rev. 1, 05-21-04)**

Because each accrediting organization that has received deeming authority 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 accrediting organizations. Each of the following organizations are approved for distinct specialties or subspecialties:

- American Association of Blood Banks;
- American Osteopathy Association;
- American Society of Histocompatibility and Immunogenetics;
- Joint Commission on Accreditation of Healthcare Organizations;
- College of American Pathologists; and
- Commission on Office Laboratory Accreditation.

## **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.