(b) *Protection of record information.* (1) The clinic or center maintains the confidentiality of record information and provides safeguards against loss, destruction or unauthorized use.

(2) Written policies and procedures govern the use and removal of records from the clinic or center and the conditions for release of information.

(3) The patient's written consent is required for release of information not authorized to be released without such consent.

(c) *Retention of records.* The records are retained for at least 6 years from date of last entry, and longer if required by State statute.

(Secs. 1102, 1833 and 1902(a)(13), Social Security Act; 49 Stat. 647, 91 Stat. 1485 (42 U.S.C. 1302, 13951 and 1396a(a)(13)))

[43 FR 30529, July 14, 1978. Redesignated at 50 FR 33034, Aug. 16, 1985, as amended at 57 FR 24984, June 12, 1992]

§491.11 Quality assessment and performance improvement.

The RHC must develop, implement, evaluate, and maintain an effective, ongoing, data-driven quality assessment and performance improvement (QAPI) program. The self-assessment and performance improvement program must be appropriate for the complexity of the RHC's organization and services and focus on maximizing outcomes by improving patient safety, quality of care, and patient satisfaction.

(a) *Standard: Components of a QAPI program.* The RHC's QAPI program must include, but not be limited to, the use of objective measures to evaluate the following:

(1) Organizational processes, functions, and services.

(2) Utilization of clinic services, including at least the number of patients served and the volume of services.

(b) *Standard: Program activities.* (1) For each of the areas listed in paragraph (a)(1) of this section, the RHC must do the following:

(i) Adopt or develop performance measures that reflect processes of care and RHC operation and is shown to be predictive of desired patient outcomes or be the outcomes themselves.

(ii) Use the measures to analyze and track its performance.

(2) The RHC must set priorities for performance improvement, considering either high-volume, high-risk services, the care of acute and chronic conditions, patient safety, coordination of care, convenience and timeliness of available services, or grievances and complaints.

(3) The RHC must conduct distinct improvement projects; the number and frequency of distinct improvement projects conducted by the RHC must reflect the scope and complexity of the clinic's services and available resources.

(4) The RHC must maintain records on its QAPI program and quality improvement projects.

(5) An RHC may undertake a program to develop and implement an information technology system explicitly designed to improve patient safety and quality of care. This activity will be considered to fulfill the requirement for a project under this section.

(c) *Standard: Program responsibilities.* The RHC's professional staff, administrative officials, and governing body (if applicable) are responsible for the following:

(1) Ensuring that quality assessment and performance improvement efforts effectively address identified priorities.

(2) Identifying or approving those priorities and for the development, implementation, and evaluation of improvement actions.

[68 FR 74817, Dec. 24, 2003]

PART 493—LABORATORY REQUIREMENTS

Subpart A—General Provisions

Sec.

Subpart I—Proficiency Testing Programs for Nonwaived Testing

PROFICIENCY TESTING PROGRAMS BY SPECIALTY AND SUBSPECIALTY

Subpart J—Facility Administration for Nonwaived Testing

Subpart K—Quality System for Nonwaived Testing

GENERAL LABORATORY SYSTEMS

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Subpart L [Reserved]

Subpart M—Personnel for Nonwaived Testing

Subparts N–P [Reserved]

Subpart Q—Inspection

AUTHORITY: Sec. 353 of the Public Health Service Act, secs. 1102, 1861(e), the sentence following sections 1861(s)(11) through 1861(s)(16) of the Social Security Act (42 U.S.C. 263a, 1302, 1395x(e), the sentence following 1395x(s)(11) through 1395x(s)(16)).

SOURCE: 55 FR 9576, Mar. 14, 1990, unless otherwise noted.

Subpart A—General Provisions

SOURCE: 57 FR 7139, Feb. 28, 1992, unless otherwise noted.

§493.1 Basis and scope.

This part sets forth the conditions that all laboratories must meet to be certified to perform testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). It implements sections 1861 (e) and (j), the sentence following section 1861(s)(13), and 1902(a)(9) of the Social Security Act, and section 353 of the Public Health Service Act. This part applies to all laboratories as defined under "laboratory" in §493.2 of this part. This part also applies to laboratories seeking payment under the Medicare and Medicaid programs. The requirements are the same for Medicare approval as for CLIA certification.

§493.2 Definitions.

As used in this part, unless the context indicates otherwise—

Accredited institution means a school or program which—

(a) Admits as regular student only persons having a certificate of graduation from a school providing secondary education, or the recognized equivalent of such certificate;

(b) Is legally authorized within the State to provide a program of education beyond secondary education;

(c) Provides an educational program for which it awards a bachelor's degree or provides not less than a 2-year program which is acceptable toward such a degree, or provides an educational program for which it awards a master's or doctoral degree;

(d) Is accredited by a nationally recognized accrediting agency or association.

This definition includes any foreign institution of higher education that HHS or its designee determines meets substantially equivalent requirements.

Accredited laboratory means a laboratory that has voluntarily applied for and been accredited by a private, nonprofit accreditation organization approved by CMS in accordance with this part;

Adverse action means the imposition of a principal or alternative sanction by CMS.

ALJ stands for Administrative Law Judge.