

civil money penalty or assessment, constitutes—

(a) Collection of the unpaid claim or unpaid civil money penalty or assessment (to the extent the Surety's payment on the bond covers such unpaid claim, civil money penalty, or assessment); and

(b) A basis for termination of the HHA's provider agreement under § 489.53(a)(1).

§ 489.71 Surety's standing to appeal Medicare determinations.

A Surety has standing to appeal any matter that the HHA could appeal, provided the Surety satisfies all jurisdictional and procedural requirements that would otherwise have applied to the HHA, and provided the HHA is not, itself, actively pursuing its appeal rights under this chapter, and provided further that, with respect to unpaid claims, the Surety has paid CMS all amounts owed to CMS by the HHA on such unpaid claims, up to the amount of the bond.

[63 FR 29656, June 1, 1998]

§ 489.72 Effect of review reversing determination.

In the event a Surety has paid CMS on the basis of liability incurred under a bond obtained by an HHA under this subpart F, and to the extent the HHA that obtained such bond (or the Surety under § 489.71) is subsequently successful in appealing the determination that was the basis of the unpaid claim or unpaid civil money penalty or assessment that caused the Surety to pay CMS under the bond, CMS will refund to the Surety the amount the Surety paid to CMS to the extent such amount relates to the matter that was successfully appealed by the HHA (or by the Surety), provided all review, including judicial review, has been completed on such matter. Any additional amounts owing as a result of the appeal will be paid to the HHA.

§ 489.73 Effect of conditions of payment.

If a Surety has paid an amount to CMS on the basis of liability incurred under a bond obtained by an HHA under this subpart F, and CMS subsequently collects from the HHA, in

whole or in part, on such unpaid claim, civil money penalty, or assessment that was the basis for the Surety's liability, CMS reimburses the Surety such amount as CMS collected from the HHA, up to the amount paid by the Surety to CMS, provided the Surety has no other liability to CMS under the bond.

(Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh)).

[63 FR 29656, June 1, 1998]

§ 489.74 Incorporation into existing provider agreements.

The requirements of this subpart F are deemed to be incorporated into existing HHA provider agreements effective January 1, 1998.

[63 FR 315, Jan. 5, 1998. Redesignated at 63 FR 29656, June 1, 1998]

Subparts G–H [Reserved]

Subpart I—Advance Directives

SOURCE: 57 FR 8203, Mar. 6, 1992, unless otherwise noted.

§ 489.100 Definition.

For purposes of this part, *advance directive* means a written instruction, such as a living will or durable power of attorney for health care, recognized under State law (whether statutory or as recognized by the courts of the State), relating to the provision of health care when the individual is incapacitated.

§ 489.102 Requirements for providers.

(a) Hospitals, critical access hospitals, skilled nursing facilities, nursing facilities, home health agencies, providers of home health care (and for Medicaid purposes, providers of personal care services), hospices, and religious nonmedical health care institutions must maintain written policies and procedures concerning advance directives with respect to all adult individuals receiving medical care, or patient care in the case of a patient in a religious nonmedical health care institution, by or through the provider and are required to:

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(1) Provide written information to such individuals concerning—

(i) An individual's rights under State law (whether statutory or recognized by the courts of the State) to make decisions concerning such medical care, including the right to accept or refuse medical or surgical treatment and the right to formulate, at the individual's option, advance directives. Providers are permitted to contract with other entities to furnish this information but are still legally responsible for ensuring that the requirements of this section are met. Providers are to update and disseminate amended information as soon as possible, but no later than 90 days from the effective date of the changes to State law; and

(ii) The written policies of the provider or organization respecting the implementation of such rights, including a clear and precise statement of limitation if the provider cannot implement an advance directive on the basis of conscience. At a minimum, a provider's statement of limitation should:

(A) Clarify any differences between institution-wide conscience objections and those that may be raised by individual physicians;

(B) Identify the state legal authority permitting such objection; and

(C) Describe the range of medical conditions or procedures affected by the conscience objection.

(2) Document in a prominent part of the individual's current medical record, or patient care record in the case of an individual in a religious non-medical health care institution, whether or not the individual has executed an advance directive;

(3) Not condition the provision of care or otherwise discriminate against an individual based on whether or not the individual has executed an advance directive;

(4) Ensure compliance with requirements of State law (whether statutory or recognized by the courts of the State) regarding advance directives. The provider must inform individuals that complaints concerning the advance directive requirements may be filed with the State survey and certification agency;

(5) Provide for education of staff concerning its policies and procedures on advance directives; and

(6) Provide for community education regarding issues concerning advance directives that may include material required in paragraph (a)(1) of this section, either directly or in concert with other providers and organizations. Separate community education materials may be developed and used, at the discretion of providers. The same written materials do not have to be provided in all settings, but the material should define what constitutes an advance directive, emphasizing that an advance directive is designed to enhance an incapacitated individual's control over medical treatment, and describe applicable State law concerning advance directives. A provider must be able to document its community education efforts.

(b) The information specified in paragraph (a) of this section is furnished:

(1) In the case of a hospital, at the time of the individual's admission as an inpatient.

(2) In the case of a skilled nursing facility at the time of the individual's admission as a resident.

(3)(i) In the case of a home health agency, in advance of the individual coming under the care of the agency. The HHA may furnish advance directives information to a patient at the time of the first home visit, as long as the information is furnished before care is provided.

(ii) In the case of personal care services, in advance of the individual coming under the care of the personal care services provider. The personal care provider may furnish advance directives information to a patient at the time of the first home visit, as long as the information is furnished before care is provided.

(4) In the case of a hospice program, at the time of initial receipt of hospice care by the individual from the program.

(c) The providers listed in paragraph (a) of this section—

(1) Are not required to provide care that conflicts with an advance directive.

(2) Are not required to implement an advance directive if, as a matter of

conscience, the provider cannot implement an advance directive and State law allows any health care provider or any agent of such provider to conscientiously object.

(d) Prepaid or eligible organizations (as specified in sections 1833(a)(1)(A) and 1876(b) of the Act) must meet the requirements specified in § 417.436 of this chapter.

(e) If an adult individual is incapacitated at the time of admission or at the start of care and is unable to receive information (due to the incapacitating conditions or a mental disorder) or articulate whether or not he or she has executed an advance directive, then the provider may give advance directive information to the individual's family or surrogate in the same manner that it issues other materials about policies and procedures to the family of the incapacitated individual or to a surrogate or other concerned persons in accordance with State law. The provider is not relieved of its obligation to provide this information to the individual once he or she is no longer incapacitated or unable to receive such information. Follow-up procedures must be in place to provide the information to the individual directly at the appropriate time.

[57 FR 8203, Mar. 6, 1992, as amended at 59 FR 45403, Sept. 1, 1994; 60 FR 33294, June 27, 1995; 62 FR 46037, Aug. 29, 1997; 64 FR 67052, Nov. 30, 1999; 68 FR 66720, Nov. 28, 2003]

§ 489.104 Effective dates.

These provisions apply to services furnished on or after December 1, 1991 payments made under section 1833(a)(1)(A) of the Act on or after December 1, 1991, and contracts effective on or after December 1, 1991.

PART 491—CERTIFICATION OF CERTAIN HEALTH FACILITIES

Subpart A—Rural Health Clinics: Conditions for Certification; and FQHCs Conditions for Coverage

Sec.

- 491.1 Purpose and scope.
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- 491.3 RHC procedures.
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- 491.11 Quality assessment and performance improvement.

AUTHORITY: Sec. 1102 of the Social Security Act (42 U.S.C. 1302); and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

EDITORIAL NOTE: Nomenclature changes to part 491 appear at 61 FR 14658, Apr. 3, 1996.

Subpart A—Rural Health Clinics: Conditions for Certification; and FQHCs Conditions for Coverage

§ 491.1 Purpose and scope.

This subpart sets forth the conditions that rural health clinics or FQHCs must meet in order to qualify for reimbursement under Medicare (title XVIII of the Social Security Act) and that rural health clinics must meet in order to qualify for reimbursement under Medicaid (title XIX of the Act).

[57 FR 24982, June 12, 1992]

§ 491.2 Definition of shortage area for RHC purposes.

Shortage area means a geographic area that meets one of the following criteria. It is—

- (a) Designated by the Secretary as an area with shortage of personal health services under section 330(b)(3) of the Public Health Service Act;
- (b) Designated by the Secretary as a health professional shortage area under section 332(a)(1)(A) of the public Health Service Act because of its shortage of primary medical care professionals;
- (c) Determined by the Secretary to contain a population group that has a health professional shortage under section 332(a)(1)(B) of that Act; or
- (d) Designated by the chief executive officer of the State and certified by the Secretary as an area with a shortage of personal health services.

[68 FR 74816, Dec. 24, 2003]

§ 491.3 RHC procedures.

- (a) *General.* (1) CMS processes Medicare participation matters for RHCs as