DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 417, 430, 431, 434, 483, 484, and 489

[BPD–718–F]

RIN 0938–AF50

Medicare and Medicaid Programs; Advance Directives

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule.

SUMMARY: This final rule responds to public comments on the March 6, 1992 interim final rule with comment period that amended the Medicare and Medicaid regulations governing provider agreements and contracts to establish requirements for States, hospitals, nursing facilities, skilled nursing facilities, providers of home health care or personal care services, hospice programs and managed care plans concerning advance directives. An advance directive is a written instruction, such as a living will or durable power of attorney for health care, recognized under State law, relating to the provision of health care when an individual's condition makes him or her unable to express his or her wishes. The intent of the advance directives provisions is to enhance an adult individual's control over medical treatment decisions. This rule confirms the interim final rule with several minor changes based on our review and consideration of public comments.

DATES: *Effective date:* This final rule is effective on July 27, 1995.

FOR FURTHER INFORMATION CONTACT: Julie Stankivic, (410) 966–5725.

SUPPLEMENTARY INFORMATION:

I. Background

Advance directives are written instructions recognized under State law relating to the provision of health care when adult individuals are unable to communicate their wishes regarding medical treatment.

Note: For purposes of this final rule, the terms ''individual,'' ''patient,'' or ''resident'' refer only to adults as defined by State law.

The advance directive may be a written document authorizing another person, such as a relative or close friend, to make decisions on an individual's behalf (a durable power of attorney for health care), a written statement (a living will), or some other form of instruction recognized under State law specifically addressing the provisions of health care. The various legal devices that exist serve to enhance the ability of individuals to have their desires carried out in the event that they become unable to make their own medical treatment decisions.

Most States have enacted legislation defining an individual's right to make decisions regarding medical care, including the right to accept or refuse medical or surgical treatment and the right to formulate advance directives. However, prior to the enactment on November 5, 1990, of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90), Public Law 101–508, there were no requirements relating to advance directives under Federal Medicare or Medicaid laws.

II. Legislative Amendments

A. Medicare Provisions

Section 1866 of the Social Security Act (the Act) requires that providers of services under Medicare enter into an agreement (that is, provider agreements) with the Secretary and comply with the requirements specified in that section. Section 4206(a) of OBRA '90 amended section 1866(a)(1) of the Act relating to Medicare provider agreements by adding a new subparagraph (Q), which specifies that to participate in the Medicare program, hospitals, skilled nursing facilities, home health agencies, and hospice programs must file an agreement with the Secretary to comply with the statutory requirements in new subsection 1866(f) of the Act concerning advance directives. Section 1866(f)(3) of the Act defines an advance directive as a written instruction, such as a living will or durable power of attorney for health care, recognized under State law, relating to the provision of health care when an individual is incapacitated. The State law may either be established by statute or as recognized by the courts of the State.

Section 1866(f)(1) of the Act specifies that a provider of services or prepaid or eligible organization (that is, a health maintenance organization (HMO), competitive medical plan (CMP) as defined in section 1876(b) of the Act, or a health care prepayment plan (HCPP) as defined in section 1833(a)(1)(A) of the Act) must maintain written policies and procedures on advance directives with respect to all adult individuals receiving medical care through the provider or organization. The provider or organization must provide written information to each individual concerning an individual's rights under State law to make decisions concerning 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. The provider or organization must also furnish each individual with the written policies of the provider or organization with respect to the implementation of advance directives.

Section 1866(f)(2) of the Act requires that this written information must be provided at the time an individual is admitted as an inpatient to a hospital, at the time of admission to a skilled nursing facility, before an individual comes under the care of a home health agency, at the time of initial receipt of hospice care, or at the time of enrollment of the individual with an eligible prepaid health care organization or HCPP.

Section 1866(f)(1) of the Act also contains provisions that require the provider or organization to document in the individual's medical record whether or not the individual has executed an advance directive, not to discriminate against individuals based on whether or not they have executed an advance directive, to ensure compliance with State law, and to provide for education of staff and community on issues concerning advance directives.

Section 4206(b)(1) of OBRA '90 amended section 1876(c) of the Act by adding a new paragraph (8), which provides that the contract between the Secretary and an eligible organization must provide that the organization meets the advance directives requirements specified in section 1866(f) of the Act.

Section 4206(b)(2) of OBRA '90 also amended section 1833 of the Act by adding a new subsection (r), which specifies that the Secretary may not provide for payment under the Medicare program to an organization unless the organization provides assurances satisfactory to the Secretary that the organization meets the requirements relating to the maintenance of written policies and procedures regarding advance directives in section 1866(f) of the Act.

Section 4206(c) of OBRA '90 provides that sections 4206(a) and (b) do not prohibit the application of a State law that allows for an objection on the basis of conscience for any health care provider or any agent of such provider which, as a matter of conscience, cannot implement an advance directive.

Section 4206(d) made conforming amendments to sections 1819(c)(1) and 1891(a) of the Act, requiring that skilled nursing facilities and home health agencies, respectively, comply with the advance directives requirements in section 1866(f) of the Act. Enforcement