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

procedures are explained in section II.D of this preamble.

B. Medicaid Provisions

Section 1902 of the Act sets forth State plan requirements for medical assistance that must be submitted to the Secretary for approval. Section 4751 of OBRA '90 amended section 1902 of the Act relating to requirements for State plans by adding provisions concerning advance directives similar to the Medicare provisions in section 4206 of OBRA '90. Specifically, section 4751 of OBRA '90 amended section 1902 of the Act by adding new paragraph (57) to subsection (a) and a new subsection (w). Section 1902(a)(57) of the Act mandates, as a State Medicaid plan requirement, compliance with section 1902(w), which requires all hospitals, nursing facilities, providers of home health care and personal care services, hospices, or health maintenance organizations (as defined in section 1903(m)(1)(A) of the Act) that are receiving funds under a State plan to maintain written policies and procedures to inform, educate, and distribute written information on advance directives to all adult individuals receiving medical care by or through the provider or organization, in the manner described in the law.

Section 4751(a) also amended section 1902 of the Act by adding a new paragraph (58) to subsection (a) to require that States, acting through a State agency, association, or other private non-profit entity, develop a written description of the State law concerning advance directives for distribution to Medicaid providers and coordinated care plans.

Section 4751(b) made conforming amendments to sections 1903(m)(1)(A) and 1919(c)(2) of the Act. These requirements are to be enforced under applicable State plan provisions.

C. Public Education Requirements

Section 4751(d) of OBRA '90 requires the Secretary to conduct a public education campaign on advance directives. HCFA, primarily through our Office of Beneficiary Services, has worked in concert with State and local agencies and consumer groups to carry out this requirement. Examples of public awareness activities include:

- *Information Kit and Press Package.* An information kit was forwarded to major beneficiary organizations and the national news media. We also have issued a press package that includes a bibliography of related publications, as well as a list of organizations that have addressed the statutory requirements concerning advance directives.
- *Medicare Hotline:* 1–800–638–6833. Information concerning advance directives is available through the Medicare hotline. Staff members provide basic information from the information kit, answer questions, and forward booklets concerning advance directives upon request.
- *Articles.* A kit containing standard articles concerning advance directives was sent to all suburban daily and weekly papers. This material generated 244 articles in 25 States with a readership of an estimated 4 million persons. We also sent materials to national and local broadcast organizations, including articles and scripts and/or slides for radio and television public service announcements. The radio material is known to have been used on 258 radio stations that cumulatively reach 4.8 million homes servicing 15 million listeners. The TV material is known to have appeared on 32 stations in 23 States, cumulatively reaching 37.3 million homes.
- *Other Publications.* The following is a brief list of other publications concerning advance directives:

* *Medicare Handbook.* The Medicare Handbook now includes information regarding advance directives. We routinely send this publication, available in both English and Spanish, to each new Medicare enrollee (about 200,000 individuals per month) and more than 1 million other copies have been distributed to current beneficiaries through HCFA publication distribution channels.

* *Medicare and Advance Directives Leaflet.* Approximately 500,000 copies of this leaflet have been distributed to hospitals, beneficiary groups, agencies on aging and similar offices, as well as to some supermarkets with a high concentration of elderly clients.

* *Cartoon Booklet.* HCFA has distributed approximately 10,000 copies of an easy-to-read cartoon booklet on advance directives that is designed for audiences with low literacy levels.

In addition to these activities, we are continuing to plan and carry out further initiatives related to our public service responsibilities that are designed to further educate the public concerning advance directives.

We note that the Office of the Inspector General (OIG) conducted an early implementation study in December, 1992, to determine compliance with the advance directive provision and facility and patient responses (OEI–06–91–01130 and OEI–06–91–01131). This study found that at that time, two-thirds of the patients in the facilities studied had some understanding of advance directives. We believe that this finding indicates that HCFA, in concert with other members of the health care industry, has made significant strides towards educating the public on advance directives.

D. Enforcement Procedures

For hospitals and hospices, compliance with the advance directives requirements is considered part of the provider agreement with HCFA. The provider agreement obligates a provider to comply with the applicable requirements of title XVIII of the Act and includes some specific provisions, such as the advance directives requirements. The Secretary may refuse to enter into a provider agreement or may refuse to renew or may terminate an agreement after the Secretary: (1) Determines that the provider fails to comply substantially with the provisions of the agreement or with the provisions of title XVIII and the implementing regulations; (2) determines that the provider fails substantially to meet the applicable provisions of section 1861 of the Act (definition of services, institutions, etc.); or (3) has excluded the provider from participation under sections 1128 or 1128A of the Act (exclusion and civil monetary penalty provisions).

On-site surveys of providers are performed by State agency or Federal surveyors to determine compliance with the advance directive requirements or the conditions of participation. However, providers are assumed to be in compliance with the general requirements of the provider agreement as set forth in title XVIII. HCFA does not routinely seek information to confirm that the provider is complying with specific requirements of the provider agreement. If information concerning a provider's compliance with the agreement of the provisions of title XVIII is needed, it may be obtained in several ways, including the performance of an on-site survey.

Each hospital and hospice provider has been informed of its obligation to comply with the advance directive provisions and that these provisions are required as a part of its provider agreement with HCFA. Compliance with these provisions is necessary for continued participation in the Medicare and Medicaid programs. These providers were required to inform HCFA, in writing, of the date they achieve compliance.

Our regional offices recently completed random surveys to determine the percentage of providers who have complied with the advance directive

requirements. Based on results from 8 regions, reported compliance rates range between 97 and 100 percent. (We anticipate similar findings for the other two regions).

For hospices, and hospitals not accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or the American Osteopathic Association (AOA), compliance is verified as part of the routine survey process.

Periodic Federal recertification surveys are not conducted in hospitals that are accredited by JCAHO and/or AOA because such hospitals are ''deemed'' to meet Medicare's certification requirements. However, since the advance directive requirements for hospitals and hospices are part of the provider agreement requirement, we will investigate complaints and conduct surveys at these hospitals as needed. We will verify compliance with the advance directive provisions at accredited hospitals in response to complaints and at the time of these surveys.

For skilled nursing facilities (SNFs), nursing facilities (NFs) and home health agencies (HHAs), enforcement procedures employ the Federal on-site survey process. State agency or Federal surveyors are responsible for evaluating compliance with the Medicare and Medicaid requirements for SNFs and NFs or conditions of participation for HHAs. Therefore, State agency or Federal surveyors are able to evaluate on-site compliance with the advance directive requirements through the use of the survey protocol for SNFs, NFs and HHAs. Also, JCAHO and Community Health Accreditation Program, Inc. (CHAP) standards address for long-term care facilities and HHAs advance directive issues, which should enhance compliance with these rules by educating these entities concerning advance directives and suggesting methods of complying with statutory and regulatory advance directive requirements.

A facility that does not comply with the provisions of its provider agreement may be terminated by HCFA. HCFA must give the provider notice of termination at least 15 days before the effective date of termination of the provider agreement. This notice must state the reasons for, and effective date of termination and explain the extent to which services may continue after that date. A provider may appeal the termination of its provider agreement in accordance with 42 CFR part 498.

Under Medicaid, a provider must enter into an agreement with the State Medicaid agency. State agency surveyors or Federal surveyors (during a validation or ''look-behind'' survey) perform a function similar to that under Medicare. However, the State Medicaid agency is responsible for assuring compliance with the Medicaid provider agreement and the advance directive requirements contained therein.

For eligible or prepaid health care organizations, initial approval of a Medicare contract under sections 1833 and 1876 of the Act requires compliance with the advance directives requirements. The organization's continued adherence to these requirements is reviewed by HCFA during routine monitoring activities which include site visits, and examination of marketing materials and provider contracts. Failure to comply with the advance directives requirements may result in termination of the organization's contract with HCFA.

E. Effective Dates

The amendments made by sections 4206(a) and (d) of OBRA '90 pertaining to Medicare providers are effective with respect to services furnished on or after December 1, 1991.

The amendments made by section 4206(b) of OBRA '90 pertaining to prepaid and eligible organizations participating in the Medicare program (that is, contracts with HMOs and CMPs under section 1876(b), and Medicare payments to HCPPs under section 1833(a)(1)(A) of the Act) are effective December 1, 1991.

The amendments made by section 4751 of OBRA '90 pertaining to the Medicaid program are effective with respect to services furnished on or after December 1, 1991.

III. Provisions of the March 6, 1992 Interim Final Rule

On March 6, 1992, we published an interim final rule with comment period that set forth in regulations the new advance directive provisions (57 FR 8194). The March 6, 1992 interim final rule implemented the provisions of sections 4206 and 4751 of OBRA '90 by requiring that all hospitals, skilled nursing facilities, nursing facilities, providers of home health care or personal care services, hospices, and prepaid health plans provide written information to each adult individual receiving medical care through the provider or organization concerning his or her 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.

General Requirements

Under these regulations, the term ''advance directive'' is defined 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 the individual is incapacitated. These regulations do not require an individual to execute an advance directive prior to the provision of treatment and services. Furthermore, we note that these requirements do not apply to providers of outpatient hospital services.

The provider must inform the individual, in writing, of State laws regarding advance directives; inform the individual, in writing, of the policies of the provider regarding the implementation of advance directives, including if permitted under State law, a clear and precise explanation of any objection a provider (or any agent of such provider) may have, on the basis of conscience, to honoring an individual's directive; document in the individual's medical record whether or not the individual has executed an advance directive; educate staff on issues concerning advance directives; and provide for community education on issues concerning advance directives. In accordance with OBRA'90, the interim final rule required providers to communicate information to individuals about their right to accept or refuse medical treatment and the right to formulate an advance directive by furnishing written descriptions of State law and provider policies and practices regarding the implementation of such rights. However, with the exception of these general notification requirements, the law has a narrow and explicit focus solely on the handling of written directives for medical care made by persons who later become incapacitated. Therefore, the interim final rule did not address other related issues such as informed consent to medical care, determination of mental capacity, provision of medical care to minors, wills leaving property, or organ donation.

Content and Format of Written Information

The interim final rule also did not prescribe the content and format of the written information to be provided to each adult individual. However, in connection with our technical assistance responsibilities to States in meeting the Medicaid requirements of the law, HCFA's Administrator sent a letter to each State Medicaid Director to which was attached a sample public

information document for use in informing adult individuals about advance directives.

Note: The materials contained in the HCFA Administrator's information package, including the sample public information document, were published as Appendix I to the preamble of the interim final rule. These materials are not being republished in this final rule.

This sample public information document is suggestive of what we believe an acceptable document should include. As stated in the interim final rule, it would be consistent with the statute to develop a considerably shorter discussion than that contained in the sample document. It would also be possible to use a short summary notice, several paragraphs rather than pages long, that notified the patient that a longer and more specific document was available upon request. However, the summary notice would have to cover the legally required elements (for example, describing the purpose and the concept of an advance directive, an individual's rights under State law to accept or refuse medical or surgical treatment, the right to formulate an advance directive, and the provider's policies concerning the implementation of those rights).

As also discussed in the March 6, 1992 document, we are aware that State law on advance directives is not always clear or comprehensive. Nonetheless, Congress has mandated that, as of December 1, 1991, providers and organizations participating in Medicare or Medicaid must distribute the required materials that inform an individual of his or her right under State law to accept or refuse medical treatment and the right to formulate advance directives. This requirement relates to current State law. Therefore, changes in State law, by statute or court case, must be incorporated into subsequent provider information packages. We specifically sought public comments on what would be a reasonable period of time within which such changes should be made.

Timing for Dissemination of Written Information

Written information on advance directives must be provided to an individual upon each admission to a medical facility and each time an individual comes under the care of an HHA, personal care provider, or hospice. For example, if a person is admitted first as an inpatient to a hospital and then to a nursing home, both the hospital and the nursing home would be required to provide information on advance directives to the individual. We suggested that if an individual is being transferred from a hospital to a nursing home, the hospital discharge planner may provide the information (including the nursing home's policies regarding the implementation of advance directives) on behalf of the nursing home in the course of coordinating the smooth transfer of the patient. However, we reemphasize that the nursing home is still responsible for inquiring about the existence of an advance directive and documenting in the individual's medical record whether or not the individual has executed an advance directive.

If a patient is incapacitated at the time of admission and is unable to receive information (due to the incapacitating condition or a mental disorder) or articulate whether or not he or she has executed an advance directive, the facility should give advance directive information to the patient's family or surrogate to the extent that it issues other materials about policies and procedures to the family of the incapacitated patient or to a surrogate or other concerned persons in accordance with State law. This does not, however, relieve the facility of its obligation to provide this information to the patient once he or she is no longer incapacitated or unable to receive such information.

Description of State Laws Concerning Advance Directives

As a part of the Medicaid requirements contained in section 4751 of OBRA '90, we also required in the interim final rule that each State, acting through a State agency, association, or other private nonprofit entity, develop a written description of the State law (that is, statutory or otherwise recognized in the courts) concerning advance directives for distribution by providers. Given the requirements in the Federal law, we noted that States have a wide range of options in describing State law and in prescribing informational materials for use by providers. For example, the State materials describing an individual's rights to accept or refuse medical or surgical treatment and the right to formulate an advance directive may include lengthy or extended requirements for executing an advance directive, or they may be a short, simple statement expressing the individual's rights concerning advance directives.

The interim final rule also included some discussion of possible approaches that States and providers may take in providing the required information and that we believed would produce results consistent with the statutory requirements. In accordance with the requirements of section 4751 of OBRA '90, States may require that Medicaid providers use the State-developed description of State law only. Alternatively, States may allow providers to incorporate the general information contained in the State-developed description of State law into the providers' own package of materials that include the providers' written policies regarding the implementation of an individual's rights. Although the statute does not specifically require that Medicare providers use the State-developed description of State law, we encouraged States and providers, and organizations to work together to ensure that a complete and accurate description of State law is distributed consistently to all adult patients or residents.

Sources of Information and Technical Assistance

As mentioned earlier, HCFA provided technical assistance to the States, including the technical assistance information package released by HCFA's Administrator in September 1991. At that time, HCFA also released a State Medicaid Manual issuance (HCFA-Pub. 45–2, Transmittal #73) concerning advance directive requirements to inform the States of their responsibilities in this area. Copies can be obtained by the general public by contacting the National Technical Information Service (NTIS), ORDER #PB88–952399. You may call to order at (703) 487–4630 or send a request to NTIS Subscription Department, 5285 Port Royal Road, Springfield, VA 22161.

Finally, we note that a number of other private entities have prepared pertinent documents that States may find helpful. HCFA's Administrator issued a press package that included a bibliography of these publications, as well as a list of organizations that have addressed the statutory requirement that providers disseminate information to individuals regarding their rights under State law to accept or refuse medical treatment and the right to formulate advance directives. These materials were printed as Appendix II to the preamble of the interim final rule and are not being reprinted in this final rule.

Methods of Complying With Advance Directive Requirements

The law requires that the existence of an advance directive be documented in an individual's medical record. We recognize, particularly in the case of prepaid health care organizations, that such documentation will occur when the medical record is created. Although the statute does not specifically require

providers or organizations to have direct dialogue with each adult individual to ascertain whether he or she has executed an advance directive, we believe that this type of interaction is an acceptable method for obtaining this information.

Although it is acceptable that the patient be asked and respond to a specific question, we recognized that these procedures are not the only appropriate methods for obtaining the information needed to document medical records. It is also acceptable for providers to include in preadmission materials a form, to be completed by the patient, that sets forth whether or not the patient has executed an advance directive. Such form, when completed and returned by the patient at the time of admission, would supply the provider the information needed to document the medical record, or the form itself could be attached to such record. There are, however, issues with respect to whether these methods may impose too great a burden on the patient or may not result in eliciting the desired information from a sufficient number of patients. Therefore, we requested comments on these and other methods of obtaining the information needed to document the medical record.

As discussed in the interim final rule, there are also several options available to accomplish the requirement that a provider or organization provide for community education. The educational materials must inform the public of their rights under State law to make decisions concerning the receipt of medical care by or through the provider or organization; the right to formulate advance directives; and the provider's or organization's implementation policies concerning an individual's advance directive.

Under the interim final regulations, the provider or organization cannot condition the provision of care or discriminate against an individual based on whether or not the individual has executed an advance directive. For example, all patients are generally entitled to the medically necessary care ordered by a physician which a provider, under normal procedures, would be required to furnish and cannot delay or withhold because the individual has not executed an advance directive or the provider is waiting for an advance directive to be executed. However, once it is documented that an advance directive has been executed, then the directive takes precedence over the facility's normal procedures, to the extent required by State law.

As specified in the statute, we also required prepaid or eligible health care organizations to provide information on advance directives to enrollees at the time of enrollment. Organizations must give enrollees the advance directive material prior to the effective date of coverage. However, we encouraged organizations to give enrollees the material as early as possible after the application for enrollment is received.

We recognize that an organization may have contracts with a variety of providers (in order to assure widespread access to care), and that some of these providers may have policies with respect to advance directives that are more limited than others (for example, a hospital exercising an objection on the basis of conscience that is consistent with State law). In such cases, the organization could adopt a policy that embraces the variety of practices of its providers, and disseminate the information regarding those various practices to its enrollees as prescribed by the interim final rule. This information would be provided along with the written description of State law. On the other hand, the organization could simply note, in the material regarding State law and provider practices, that its providers have, in accordance with State law, varying practices regarding the implementation of an individual's advance directive. In this case, such varying practices must be made available to each adult individual selecting or receiving care from such providers.

For a description of the specific changes to the regulations text that were necessary to implement the above statutory provisions, see the March 6, 1992 interim final rule, 57 FR 8198.

IV. Discussion of Public Comments

In response to the March 6, 1992 interim final rule with comment period, we received 85 timely items of correspondence. We have summarized the comments and are presenting them below along with our responses.

Section IV.A contains our response to general comments. In responding to comments, the term ''provider'' generally encompasses hospitals, skilled nursing facilities (SNFs), nursing facilities (NFs), hospices, and home health agencies (HHAs). When the comments and responses deal with a specific provider type, the appropriate term is used.

Section IV.B responds to comments that deal specifically with what the statute refers to as ''prepaid or eligible organizations'' (that is, HMOs, CMPs, and HCPPs). In responding to comments, we generally use the term ''managed care plans'' to refer to these types of organizations. (We note that on July 15, 1993, we published a final rule (57 FR 38072) that replaced the term ''prepaid or eligible organization'' with the term ''HMOs and CMPs'' throughout 42 CFR part 417. Thus, all references in the regulation text now use the term HMOs and CMPs.)

In addition, we received some comments concerning Appendices I and II to the interim final rule. These documents were included in the interim final rule as a source of technical assistance only and are not being republished in this final rule; however, a discussion of these comments is contained in section IV.C.

A. General

Scope of Regulations

Comment: Two commenters asserted that these regulations are inconsistent with the requirement in sections 1866(f)(1)(A)(i) and 1902(w)(1)(A)(i) of the Act that providers give patients written information 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 advance directives. Specifically, the commenters objected to the following statements in the preamble of the interim final rule:

> ''Nothing in either the statute or this interim final rule addresses patient or provider rights or decisions regarding medical or non-medical care, except when the patient has left written instructions which become effective only after the individual becomes incapacitated''. For example, this regulation neither creates nor affects requirements with respect to informed consent to medical care * * * These and many other significant subjects are not addressed under OBRA '90. The law has a narrow and explicit focus concerning the handling of written directives for medical care made by persons who later become incapacitated. (57 FR 8196)

The commenters asserted that to be more consistent with the statute these regulations should require providers to disseminate information concerning: (1) The right to accept or refuse treatment both ''contemporaneously and in advance, the latter via advance directives;'' (2) informed consent; and (3) the fact that the effective dates of advance directives may vary in accordance with applicable State law.

Response: Sections 1866(f)(3) and 1902(w)(4) of the Act make clear that the term ''advance directive'' relates to the provision of health care when an individual is incapacitated. We agree that the statute also requires providers to furnish individuals with written information about their rights under State law to direct their medical

treatment before incapacitation (that is, the right to accept or refuse medical or surgical treatment). However, we do not believe that the statute authorizes us to broaden the scope of these regulations as suggested by the commenter nor do we believe that the law intends that hospitals provide patients with an exhaustive briefing about medical decision making under State law. States and providers are free to provide additional information that might further educate patients about additional rights regarding medical decision-making that exist under State law.

Comment: Two commenters requested that HCFA limit the scope of the law so that providers and organizations need to provide only Medicare and Medicaid patients with information on advance directives.

Response: Sections 1866(f)(1) and 1902(w)(1) of the Act specify that information on advance directives be provided to all adult individuals. Narrowing the scope of the requirement to Medicare and Medicaid patients would not be consistent with the explicit language of the law and could not be done without a statutory change.

Comment: Two commenters opposed the statutory definition of an advance directive because it includes only written instructions recognized under State law. The commenter believes this definition is too narrow and precludes the recognition of other types of instructions, such as oral instructions given by competent patients, which are already commonly used in many States.

Response: Sections 1866(f)(3) and 1902(w)(4) of the Act clearly specify that the term ''advance directive'' applies only to ''written instructions''; legislative action would be necessary to amend this definition. It is important to note, however, that in describing an individual's right to make decisions concerning medical care, sections 1866(f)(1)(A)(i) and 1902(w)(1)(A)(i) of the Act recognize both the ''right to accept or refuse medical or surgical treatment'' and ''the right to formulate advance directives''. Thus, we believe that the statute does not preclude an individual from making oral instructions or a provider from executing such instructions, consistent with State law.

Comment: Several commenters requested that we define certain terms for purposes of these rules, such as ''admission,'' ''adult,'' ''incapacitation,'' ''incompetence,'' ''mental disorder,'' and others. The commenters offered many examples of applicable State definitions, particularly with regard to the meaning of ''incapacitation'' for decision-making purposes. Another commenter suggested that we should require States to furnish their Medicaid providers with a written description of all applicable State laws that determine the circumstances under which an individual under 18 is entitled to make his or her own decisions concerning advance directives and other medical care issues under the purview of this regulation.

Response: We recognize that many of these terms have already been given varying definitions under State law. In that the statute is silent on defining these terms, we believe that Congress intended to defer to State law. Therefore, we are not defining these terms in the regulations. Section 1902(a)(58) of the Act already requires that the State, acting through a State agency, association, or other private nonprofit entity, develop a written description of the law of the State (whether statutory or as recognized by the courts of the State) concerning advance directives that would be distributed by providers or organizations. Sections 1866(f)(1)(a) and 1902(w)(1) of the Act require that providers furnish written information to each individual concerning an individual's rights under State law to accept or refuse medical or surgical treatment and to formulate an advance directive. If there were a State law in effect that addressed the rights of individuals under the age of 18 to formulate an advance directive and make medical treatment decisions, a description of this law should be furnished to all Medicaid providers. As stated above, terms such as adult individual are defined in accordance with applicable State law.

Comment: Two commenters questioned the effectiveness of oral instructions, especially those given before the enactment of the advance directive provisions. The commenters know of some long-term care residents who are unable to execute an advance directive, but have already given oral instructions to their physicians (for example, no tubes, no cardiopulmonary resuscitation), and this has been clearly documented in the medical record. Also, a commenter noted that some physicians and attorneys believe that if there is no written advance directive, then the patient has lost his or her right to choice and these patients are therefore subject to the physician's decision based on accepted medical standards.

Response: Sections 1866(f)(3) and 1902(w)(4) of the Act define an advance directive as a written instruction recognized by the State and relating to the provision of health care when an individual is incapacitated. The advance directives provisions apply to patients admitted after December 1, 1991. As we have repeatedly noted, however, this statute in no way abridges any rights a patient may have under Federal or State law to specify or refuse medical treatment. The statute simply establishes requirements with respect to the dissemination of specific information about individuals' rights regarding medical treatment, including an individual's right to accept or refuse medical or surgical treatment and the right to formulate an advance directive. Individuals are not required to execute an advance directive. In fact, providers are specifically prohibited from conditioning the provision of care on whether or not an individual has executed an advance directive. Moreover, the provider must disseminate copies of its written policies respecting the implementation of such rights.

These regulations in no way contravene any existing instructions concerning an individual's medical treatment. Therefore, previous instructions remain in effect, unless amended or altered by subsequent instructions submitted in accordance with State law. Generally, such subsequent instructions can be in the form of the patient's oral instructions or the discovery of new instructions contained in or authorized by a new advance directive, subject to applicable State law.

Comment: Several commenters asserted that the statutory requirements concerning advance directives are derived from the more fundamental right of the competent individual to accept or refuse any suggested medical intervention. These commenters believe that to require notification of the derivative right to formulate an advance directive without explanation of the underlying right is likely to result in an incomplete and potentially misleading statement of patients' rights.

The commenters further asserted that our suggestion that the statute applies only to circumstances in which the individual has left written instructions that become effective only after the individual becomes incapacitated construes the definition of advance directive too narrowly. They believe that the statutory language is intentionally general and should not be interpreted as a specific limitation on the date an advance directive becomes effective. In some States, a durable power of attorney for health care may be effective when signed, rather than effective only upon the determination of

incapacity. Although the instrument may be effective immediately, the individual still maintains the power to control health care decisions while competent; so, as a practical matter, the instrument may not be used until the principal loses capacity. Nevertheless, legally the instrument is effective when signed. Since the statute is not intended to change substantive State law or limit the kinds of advance directives recognized by the States, the limiting language in the preamble of the interim final rule should be avoided.

Other commenters argued that the regulations should emphasize that providers and organizations must give equal weight to the right to accept or refuse treatment, the right to sign or not sign a directive, and the right to sign a legal directive other than the form drawn up by the State so long as that directive comports with State law.

Response: We recognize that every individual has an underlying right to accept or refuse any suggested medical intervention. These regulations are not intended to place limitations on this right. We agree with the commenters that there is nothing in the law or these regulations that diminishes an existing right to make or execute a directive (or to request or to refuse medical treatment) under current State or Federal law. We did not intend to give the impression that this was the case in the preamble to the March 6, 1992 interim final rule. In this final rule, we emphasize in several responses to comments that an individual's right to accept or refuse medical treatment is not limited by these advance directive provisions, and we have been very careful to ensure that our regulations do not extend a broader reach to these provisions than the law allows. In fact, sections 1866(f) and 1902(w) of the Act and §§ 417.436(d)(1)(i) and 489.102(a)(1)(i) of the regulations specifically require that the written instructions disseminated to adult individuals must include information about an individual's rights under State law to accept or refuse medical and surgical treatment and the right to formulate advance directives.

As noted above, sections 1866(f) and 1902(w) of the Act define an advance directive as ''Written instructions, 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) and relating to the provision of such care when the individual is incapacitated.''

Thus, we continue to believe that the focus of these regulations is two-fold: to ensure the dissemination of information about an individual's right to accept or refuse medical or surgical treatment and about an individual's right to formulate an advance directive.

Comment: A commenter suggested that we clarify the statement in the preamble to the March 6, 1992 interim final rule that ''care cannot be delayed or withheld because the individual has not executed an advance directive or the provider is waiting for an advance directive'' (57 FR 8198). Another commenter suggested that we make it clear that the restriction against delaying care applies only to treatment decisions made by providers. If the patient requests that care be delayed because he or she is waiting for an advance directive to be executed (or for any other reason), the provider must, by law, respect the patient's wishes.

Response: Under sections 1866(f)(1)(c) and 1902(w)(1)(c) of the Act, providers may not condition the provision of care or otherwise discriminate against an individual based on whether or not the individual has executed an advance directive. Thus, in general, a patient is entitled to receive the necessary care ordered by a physician that a provider under normal procedures must furnish. In addition, a provider cannot delay or deny care while waiting for an advance directive to be executed, unless otherwise instructed by the patient in accordance with applicable State law. However, the last sentence of both section 1866(f)(1) and 1902(w) of the Act makes clear that a provider cannot be required to furnish care that conflicts with an advance directive. Therefore, once the provider learns that an advance directive has been executed that stipulates refusal of care, that directive takes precedence over any physician orders or normal provider procedures, unless there is a State law that permits a provider, or any agent of such provider, to conscientiously object to implementing an advance directive.

We agree that the patient always has the option to refuse treatment, and the advance directive regulations do not impede an individual from exercising that option. Thus, as long as a patient is capable of communicating his or her wishes regarding treatment, the contents of an advance directive may not be controlling. By definition, implementation of an advance directive takes place at the time the individual is incapable of communicating his or her preference to accept or refuse medical or surgical treatment.

Written Information Provided to Individuals

Comment: Several commenters suggested that we permit the use of as many health care disciplines as possible to distribute and obtain information on advance directives from patients. Another commenter suggested that only qualified healthcare professionals (for example, nurses, physicians, social workers, etc.) be used. This would preclude admission clerks, nursing assistants, and other support personnel from disseminating and collecting information on advance directives.

Response: Sections 1866(f)(1)(A) and 1902(w)(1)(A) of the Act require the dissemination of written information concerning both State law and provider policies. However, these sections do not identify any particular disciplines or persons to disseminate this information, and we do not believe that any particular training is required to disseminate written materials or obtain information from patients regarding whether or not they have executed an advance directive. Therefore, we do not believe it is appropriate to restrict providers and other eligible organizations in terms of the type of personnel they decide to use to meet these requirements. We recognize that many providers may wish to accompany advance directives materials with an explanation and direct personal contact. However, an accompanying explanation and direct personal contact are not required by the statute, but are left to the provider's discretion and to applicable State law.

Comment: One commenter suggested that we require individuals to discuss their wishes regarding future medical care with their physician. In addition, the commenter believes that these regulations should require that physicians be responsible for documenting this discussion in detail in the patient's medical record. In accordance with State law, this document would serve as an advance directive if no actual written document is drawn up and executed.

Response: Sections 1866(f)(1)(A) and 1902(w)(1)(A) of the Act clearly place the obligation to provide information and document the existence of an advance directive on certain specific health care providers, with which the Medicare and Medicaid programs have agreements. We believe it would be inconsistent with the statute to implement a requirement as broad as that suggested by the commenter.

Comment: One commenter asserted that, when disseminating information about advance directives, a provider's staff should not be required or expected to give detailed explanations of State law, regulation or judicial decisions or to assist the client to develop an advance directive. The commenter

believes that most agencies and facilities do not have the legal expertise necessary to perform these activities. In addition, the commenter suggests that HCFA's interpretive guidelines should address an individual's right to refuse to discuss the subject of advance directives (for example, when an individual's religious or personal beliefs preclude discussion).

Response: Sections 1866(f)(1)(A) and 1902(w)(1)(A) of the Act require providers to provide written information concerning an individual's rights under State law (whether statutory or as recognized by the courts of the State) concerning the right to accept or refuse medical or surgical treatment and to formulate an advance directive. These sections do not require detailed explanations of State law concerning such rights. We believe that the exact content and complexity of laws concerning these rights vary from State to State and thus it may be burdensome for some States to provide detailed explanations of State law. As we stated in the interim final rule, we believe that it would be consistent with the statute to use a summary notice that covered the legally-required elements (that is, describing the purpose and the concept of an advance directive and the individuals' rights under State law to accept or refuse medical or surgical treatment under State law, and describe the provider's policy and procedures). However, we do not wish to discourage providers from voluntarily training staff to assist patients in developing an advance directive, in any way permissible by State law. We do not believe it is necessary to state explicitly in our guidelines that an individual may refuse to discuss advance directives. We expect that providers or other eligible organizations will address this sort of situation merely by documenting in the medical record that the individual was provided written information concerning advance directives and chose not to discuss his or her rights in this area.

Comment: One commenter suggested that a hospital should not be required to distribute exact copies of its policies and procedures to patients upon admission to the hospital. Instead, the commenter suggested that it should be sufficient to supply a statement that the hospital follows the State law and a statement concerning the availability of the hospital's policy and procedures. Other commenters expressed concern that the provision of exact copies of policies and procedures to individuals would mean that they would receive voluminous materials that they would probably find somewhat meaningless, confusing and much less useful than they would find prepared summaries written more for their understanding. Several commenters believe that furnishing patients with written policies with respect to implementation of advance directives can be time-consuming because existing medical policy documents would have to be converted into more easily understood summaries. Yet, these more easily understood summaries may inordinately simplify a complex decision-making process.

Response: We agree that exact copies of medical staff policy documents need not be provided to patients. Sections 1866(f)(1)(A) and 1902(w)(1)(A) of the Act require that the individual receive certain basic information concerning an individual's rights under State law, including the right to accept or refuse medical and surgical treatment, the right to formulate advance directives, and the policy of the hospital or other provider with respect to implementing such rights under the law. While we recognize that preparing this material may be a challenge, the law requires that it be done, and providers must take the necessary steps to ensure the written information is understandable to the patients. We provided a detailed bibliography of published materials on this matter in the March 6, 1992 interim final rule (57 FR 8200), and a number of national groups have continued to work to provide materials that will assist hospitals and other providers in this task. Although we do not intend to prescribe the content and format of the written information, it must clearly convey to individuals the required basic information about the individual's rights under State law to accept or refuse medical or surgical treatment, the right to formulate advance directives and the provider's written policies respecting the implementation of such rights. Further explanation of an individual's rights pertaining to advance directives should be made available upon request.

Comment: One commenter believes that good patient/physician decision-making practices may be hampered since other disciplines such as nurses actually may be disseminating advance directive material to the patient, as well as answering any questions the patient may have concerning advance directives. To avoid misunderstandings and potential trauma to patients, the commenter suggested that physicians or State health officials distribute this information to a patient before admission to a hospital.

Response: We believe that a clear understanding of an individual's rights in this area should improve the quality of patient/physician decision-making, regardless of who disseminates the information. We agree that the optimum time for the individual to receive this sort of information is before entering the hospital and presume that the community education programs will accomplish this over time. As noted above, we have no statutory authority to designate specific disciplines to present this information to individuals and, in the absence of State law, we believe that this matter should be left to the discretion of the provider.

Comment: One commenter opposed the statement in the interim final rule that when a patient is being transferred from a hospital to a nursing home, the hospital discharge planner may provide the information (including the nursing home's policies regarding the implementation of advance directives) on behalf of the nursing home in the course of coordinating the smooth transfer of the patient (57 FR 8197). The commenter believes that such coordination promotes the possibility that some patients may not receive the information. In addition, the commenter expressed concern that these arrangements may result in disputes between hospitals and nursing facilities concerning responsibility for errors in disseminating required information.

Response: While we recognize that coordination between hospitals and nursing homes with respect to advance directives should be carefully planned and implemented, we do not believe that these arrangements should be prohibited. However, providers and organizations are by no means relieved of their responsibility for meeting all advance directive requirements when they enter into a coordinated arrangement such as the one discussed above between a hospital and a nursing home. Any deficiencies found on the part of a hospital or nursing home in complying with the advance directive requirements will be subject to the enforcement procedures described above in section II.D. We note that the illustration of a hospital providing a nursing facility's information about rights under State law on behalf of the nursing facility was an example of permissible coordinating efforts and not a requirement. We have revised §§ 489.102(a)(1)(i) and 483.10(b)(8) to state that providers are permitted to contract with other entities to furnish this information but are still legally responsible for ensuring that the advance directive requirements are met.

Comment: One commenter suggested that there is a potential conflict between the implementation of an advance

directive executed by a client of a home health agency (HHA) and the requirements for a physician order under 42 CFR 484.18. Those regulations require that HHAs administer drugs and treatment only under the orders of a physician. A conflict may occur if the patient's physician refuses to provide orders to enable the HHA to implement the patient's advance directive. To resolve this potential conflict, the commenter suggests that documentation of contact with the physician and of the physician's orders or refusal of orders to implement the client's directive be recognized as sufficient to comply with the advance directive requirements.

Response: The potential conflict identified by the commenter can be addressed in the written information regarding the HHA's policies. This information should alert the patient to the HHA's reliance on physician orders to effectuate an advance directive or otherwise respond to a patient's request to accept or refuse treatment. It also would explain how its employees would routinely follow those orders or whether an objection on the basis of conscience (by the physician or the HHA) would prevent it. Therefore, if a patient is informed that the HHA would rely on the physician's orders to effectuate the advance directive, a patient should, prior to beginning to receive care, discuss his or her advance directive with the physician. If the patient is informed that the physician, due to an objection on the basis of conscience, would not implement the advance directive, then the patient may request either treatment from another physician who would honor the advance directive or transfer to another HHA.

A related issue involves HHA compliance with the advance directive requirements. Compliance with the advance directive provisions is a condition of participation. If an HHA fails to honor an advance directive and it has not informed the patient of a reservation of conscience permitted by State law, the HHA would be in violation of a standard under the HHA patient rights condition of participation (see § 484.10(c)(2)(ii)). If it failed to correct the deficiency, the HHA would be subject to termination of the provider agreement under § 489.53.

Comment: One commenter stated that there should be a hospital billing code for counseling the patient regarding rights to have an advance directive.

Response: The advance directive provisions do not include authority to modify the current hospital payment system in order to assist providers in complying with the advance directives requirements. Therefore, we have not included provisions relating to payment (or billing codes) in this regulation. However, hospitals as well as other providers reimbursed under the cost reimbursement system can receive reimbursement for the incurred administrative costs associated with the advance directive requirements. No separate billing code is necessary.

Comment: One commenter suggested that we revise the regulations to require that a hospital disseminate information on organ donation at the same time it disseminates information on advance directives.

Response: Section 1138(a)(1) of the Act requires hospitals to have organ procurement protocols, including procedures for approaching appropriate donors or their families. We have carefully considered requiring that hospitals disseminate information on both subjects at the same time. However, unlike section 1866(f)(2)(A) of the Act, section 1138 of the Act does not require that a hospital disseminate organ donation information upon admission. Consequently, we believe that organ donation information should be disseminated when it is deemed most appropriate by the provider.

Documenting the Medical Record

Comment: Two commenters suggested that any information documented in an individual's medical record concerning the execution of an advance directive be kept confidential to protect each individual's privacy interests.

Response: Information about advance directives that is documented in an individual's medical record would be subject to the same confidentiality protection as other information in the medical record. For example, under the ''Medical record services'' hospital condition of participation, § 482.24(b)(3) specifies that hospitals must ensure the confidentiality of patient medical records and that information from or copies of records may be released only to authorized individuals. Hospitals are also required to ensure that unauthorized individuals cannot gain access to or alter patient records. These requirements apply to information entered into the medical record as a result of the advance directive requirement. Similar confidentiality protections are set forth in the regulations governing other providers.

Comment: We received a number of comments concerning access to the advance directive. One commenter questioned the logistics of how a provider will gain access to an individual's advance directive. The commenter suggested that the regulations should establish a mechanism through which the contents of a person's advance directive document are communicated to the health care provider. Two commenters suggested that we require that providers collect a copy of the individual's advance directive or information as to where the advance directive can be located. One commenter recommended that we require providers to document any known changes to or rescissions of previous advance directives.

Response: These comments suggest that HCFA should specify procedures and requirements that are beyond the scope of this legislation. The statute does not address the issue of how a provider will locate or gain access to an advance directive. Sections 1866(f)(1)(B) and 1902(w)(1)(B) of the Act require only that the provider document in the medical record whether or not an individual has executed an advance directive. The statute does not require the collection of copies of an advance directive or the collection of information about the location of an advance directive, nor does it require a provider to document known changes or rescissions to prior advance directives. However, section 1866(f)(1)(D) of the Act does specify that providers must maintain policies and procedures that ensure compliance with requirements of State law. Thus, providers must comply with State laws that may require the documentation of information concerning the location of and access to advance directives, and copies of advance directives would need to be located and possibly held by the provider when the State law requires this result.

In summary, we believe that the document will be provided by the patient when asked or will be located when its use becomes necessary. Moreover, the statute intended to defer to State law the questions about the creation and preservation of advance directives. Providers should look to State statutory and case law for guidance on access to advance directives. We encourage providers to incorporate State statutory and case law into their written policies.

Comment: One commenter stated that our suggestions in the preamble to the interim final rule (57 FR 8197) on possible methods for ascertaining whether or not an individual has executed an advance directive, for example, the use of direct dialogue and preadmission forms, would, if made mandatory, place an unfair burden upon providers. Another commenter suggested that in order to prevent an administrative burden and potential

liability issue, the final regulations require that providers make reasonable efforts to acquire information as to whether or not an individual has an advance directive and document this information in the medical record. The commenter requests clarification regarding a provider's liability if it could not determine if an individual has executed an advance directive and later learns that one does exist. The commenter requests more information about the provider's responsibility for any treatment decisions that may have been taken that may run counter to the advance directive.

Response: We recognize that there are many possible methods by which providers may determine the existence of an advance directive. The interim final rule did not mandate any method but suggested several alternatives. We agree that a provider should have to make only a reasonable effort to determine if an adult individual has an advance directive. Except when an individual is incapacitated at the time of admission, a reasonable effort can be defined as simply giving out the information and documenting in the medical record whether or not the individual has executed an advance directive. If the patient is incapacitated at the time of admission, then the provider should have follow-up procedures to determine if the patient has an advance directive or when the patient may be given the information directly. (This issue is further discussed below under the heading ''Individuals Incapacitated at Admission.'')

For Federal compliance and enforcement purposes, we would not hold a provider responsible for failing to ensure compliance with an advance directive if the patient never furnished it to the provider or responded negatively when the inquiry was made about having an advance directive. However, in accordance with State law, the provider may be liable for treatment decisions made after learning that an advance directive exists, that may run counter to the advance directive. Also, we note, that if State law holds providers to a higher standard, State law would prevail.

Comment: Two commenters asserted that the requirement in § 489.102(a)(2) that providers ''document in the individual's medical record whether or not the individual has executed the implementation of such rights'' was unclear. The commenters suggested that the phrase ''implementation of such rights'' be replaced with ''an advance directive in accordance with State law.'' The commenters believe that the requirement as written could be broadly interpreted to include documenting all acceptances and refusals of treatment, thus resulting in an increased burden on providers and a waste of direct care nursing time, as well as increasing costs associated with these requirements.

Response: We agree that § 489.102(a)(2) is unclear and are revising it to state that providers must ''Document in the individual's medical record whether or not the individual has executed an advance directive.''

Comment: Three commenters suggested that the final regulations require that providers ask patients if they have executed an advance directive.

Response: The statute does not specifically require that direct dialogue be the method for obtaining the information. Although we believe that this is frequently the most effective way to obtain the information, we are also aware of situations in which other methods may be appropriate. For example, some health maintenance organizations deal with new enrollees primarily by mail, including providing and obtaining information concerning advance directives by mail. Thus, we do not believe that the regulations should prohibit the use of methods other than direct dialogue to discover whether or not an individual has executed an advance directive.

Comment: Several commenters supported our suggestion in the interim final rule that providers could use the preadmission process to obtain the information necessary to document in the medical record the existence of an advance directive. One of these commenters suggested that another method to obtain information regarding the existence of an advance directive is at the time of preadmission testing. Another commenter suggested that more guidance be issued concerning other possible methods of obtaining this information.

One commenter suggested that if a provider chooses to obtain information about whether individuals have advance directives through its preadmission process, HCFA should not specify the type of form to be used. The commenter recommended that we leave this decision to the discretion of the provider.

Response: We agree that information concerning whether or not an individual has executed an advance directive may be obtained at the time of preadmission testing. In addition, we agree that there are many ways to determine whether or not an individual has executed an advance directive. However, we have not required any particular method in order to enhance provider flexibility in this area.

Although we suggested in the interim final rule that providers may use forms to obtain advance directive information, we do not intend to specify any form for the provider's use.

Information Collection Estimate

Comment: We estimated in the interim final rule that the information collection burden associated with the requirement that providers document in the medical record whether an advanced directive exists would be approximately 3 minutes per medical record. Many commenters stated that the 3-minute estimate appears to account only for making notation in the medical record and does not include the time needed to help individuals understand their rights, consult with other disciplines, for example, doctors, nurses, social workers, pastoral care clergy, etc. Others believe our estimate should include time spent in responding to phone calls and written inquiries by affected individuals. Some commenters suggested that it would take at least 15 to 30 minutes to explain the characteristics of advance directives, obtain the required signatures and follow up to assure compliance. Another commenter asserted that it will take an immeasurable amount of time to accomplish this documentation; therefore, it is an unfair burden to enforce this requirement, especially without separate reimbursement.

Response: The 3-minute estimate only takes into account the amount of time required to document in the medical record whether an advance directive exists. The Paperwork Reduction Act is concerned only with the burden of recordkeeping under this requirement as a result of these regulations. This estimate is not based on the time necessary to develop policies and procedures, printing costs and assembling of the material for the information packets for adult individuals. This estimate does not include the time spent explaining an individual's rights under Federal and State laws, nor any consultation with other disciplines to help the individual execute an advance directive that the provider or organization may choose to provide. The statute merely requires the dissemination of information, obtaining information as to whether the individual has executed an advance directive and the documentation of this information in the individual's medical record. Therefore, we believe that the estimated burden of 3 minutes per medical record is accurate.

Comment: In light of the requirement placed upon nursing facilities by the Omnibus Budget Reconciliation Act of 1987 (OBRA '87) that rights must be explained to residents in a manner that they can understand, a commenter asserted that the 3-minute information estimate is inaccurate for nursing facilities. The commenter believes that the burden imposed on these facilities is at least 30 minutes to explain the advance directives requirement in a manner the resident can understand.

Response: The commenter is correct that, in accordance with resident rights provisions of OBRA '87, § 483.10(b) requires facilities to inform residents both orally and in writing in a language that the resident understands of his or her rights, including the advance directive provision. However, as explained above, the information collection estimate does not include time to explain the advance directives requirements. Therefore, the burden to which the commenter refers is not appropriately part of the advance directives estimate.

Comment: One commenter misinterpreted the estimate of 15 million individuals used in the calculation of the information collection burden as representing the number of individuals who have executed advance directives.

Response: Fifteen million did not represent the number of persons who have executed advance directives, rather it represented the projected number of Medicare beneficiaries and Medicaid recipients who were expected to receive services from providers and organizations subject to these regulations. In other words, in the interim final rule, we projected that in FY 1992 providers and eligible organizations would be required to meet the advance directive requirements, including proper documentation of the medical record, for at least 15 million Medicare and Medicaid beneficiaries/recipients.

Discrimination Based on Advance Directive

Comment: Although opposed to the statutory requirements concerning advance directives because they appear to place the Federal government in the role of advancing euthanasia in the United States, one commenter urged HCFA to promulgate regulations that ensure that providers and organizations are prohibited from exerting any form of coercion, or undue influence to make an individual feel that he or she must execute an advance directive. In addition, the commenter believes we should make it clear that States are not obligated by these regulations to pass laws addressing advance directives.

Response: Sections 1866(f)(1)(C) and 1902(w)(1)(C) of the Act, as well as our implementing regulations, clearly prohibit any type of discrimination against individuals based on whether or not an individual has executed an advance directive. Thus, we agree with the commenter that providers and organizations are not permitted to coerce or pressure any individual into executing an advance directive. As stated in the sample public information document published in the interim final rule (57 FR 8199), the law does not require an individual to execute an advance directive. Similarly, we agree with the commenter that these rules do not require States to enact legislation to address advance directive requirements.

Comment: Two commenters recommended that we make it clear that discriminating against an individual because he or she has an advance directive is strictly prohibited. One commenter believes there is a real danger that an advance directive may deprive patients of the normal care that they would receive if there were no advance directive.

Response: Again, sections 1866(f)(1)(C) and 1902(w)(1)(C) of the Act and the regulations both prohibit any discrimination based on whether or not the individual has an advance directive. In addition, in the event that problems are encountered, individuals have the right to submit a complaint to the State agency or regional office for investigation.

Provider Responsibilities To Ensure Compliance With the Requirements of State Law Concerning Advance Directives

Comment: A commenter suggested that the regulations require that a facility's policies for objections on the basis of conscience be reviewed annually for compliance with State law. In addition, the commenter suggested that the facility's advance directive informational packages should contain a statement that its policies have been reviewed and found in compliance with State law and should cite the State law authority.

Response: Under sections 1866(f)(1) and 1902(w)(1) of the Act, providers have been required since December 1, 1991 to maintain and distribute written policies and procedures concerning an individual's rights under State law to accept or refuse medical or surgical treatment and to formulate advance directives, and the providers' policies for ensuring compliance with such rights. Section 489.102(a)(1)(ii) specifies that providers must provide written information to all adult individuals concerning its written policies 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. As discussed in further detail below, we are revising § 489.102(a)(1)(i) to require that providers must 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. Therefore, we do not believe it is necessary to require a separate annual review of compliance with State laws concerning objections on the basis of conscience. HCFA has various mechanisms, such as certification surveys, for assessing provider compliance with rules and regulations. We do not believe it is necessary for a provider's documents to contain a statement addressing approval findings of compliance surveys. In general, we will rely upon the State (for example, during its licensure inspections) to determine if its advance directives laws are being enforced properly.

Comment: Two commenters suggested that the regulations address the extent of the provider's responsibility to determine the validity of an advance directive. They believe that the advance directive is valid if it appears to meet the formal requirements of applicable State law, unless the provider knows, or has reason to know, otherwise. Also, the commenters suggested that a provider's written policy should explain the extent to which advance directives that are prepared in other jurisdictions will be honored if they meet the formal requirements of applicable State law. One commenter suggested that we clarify that the most recently executed advance directive should be the one the provider relies upon in making determinations relating to health care delivery.

Response: The statute does not address the issues raised by these commenters. As a practical matter, State laws typically govern the procedures for determining the validity of advance directives and how such documents from other jurisdictions will be honored. In general, we would expect that providers will comply with the advance directives of individuals from other States, unless the directive conflicts with State law or the provider conscientiously objects, in accordance with State law. In addition, although not required by the statute, we believe it is appropriate for providers to confirm with individuals the contents of their advance directive to ensure that the

provider is relying upon the most recently executed advance directive.

Comment: One commenter argued that it is inappropriate to require providers to ensure compliance with State law because the commenter believes that a provider is prohibited from practicing law and interpreting the meaning of statutes and case law. The commenter suggested that the requirement of § 489.102(a)(4) that providers ''ensure compliance with requirements of State law'' be revised to read ''Review the advance directive to ascertain whether or not there are advance directive requirements in the execution of the document that have not been met.''

Response: Sections 1866(f)(1)(D) and 1902(w)(1)(D) of the Act specify that providers are required to ensure compliance with the requirements of State law. Thus, the regulations implementing these provisions are not discretionary. Moreover, we do not agree with the commenter that this requirement involves the unauthorized practice of law by providers. It has been a long-standing policy of the Medicare and Medicaid programs to hold participating providers responsible for compliance with applicable State and Federal laws related to the overall health and safety of patients. For example, § 482.11 establishes compliance with Federal, State and local laws as a condition of Medicare participation for hospitals.

Comment: One commenter suggested amending § 489.102(a)(4) to clarify that interference with a physician's conduct toward his or her patient is prohibited. The commenter believes that this provision may be interpreted as constituting the practice of medicine by the hospital and would, therefore, be illegal under State laws prohibiting the ''corporate practice of medicine.'' Another commenter asserted that since we are not giving guidance to providers on what is meant by the phrase ''ensure compliance with requirements of State law regarding advance directives'', we need to acknowledge that providers cannot control the medical judgement of physicians in individual cases.

Response: We do not agree that existing language at § 489.102(a)(4) is illegal under State laws prohibiting the ''corporate practice of medicine''. While it may be true that a hospital or other provider may not direct the specific actions of an individual physician in a case, a provider may determine who may or may not be a member of its medical staff and may set conditions for membership. We believe that it may be prudent for a provider's advance directives policy to be developed with input from its medical staff and that, during the process of granting admitting privileges to physicians, it would be reasonable to require physicians to comply with provider policies and State law on the matter of advance directives. Therefore, because most hospitals include compliance with advance directives requirements as a condition of membership for physicians, we do not believe it is necessary to issue regulations regarding this issue.

Comment: One commenter requested we amend § 489.102(a) by adding new language to require that a documented advance directive would ''take precedence over the facility's normal procedures, to the extent required by State law''.

Response: We agree that an advance directive should take precedence over a facility's normal procedures to the extent authorized by State law. However, we believe existing regulations at §§ 489.102(c) and 417.436(d)(2)(i), which state that providers and organizations are not required to provide care that conflicts with an advance directive, already establish that advance directives take precedence over a facility's normal procedures.

Comment: Some commenters had questions concerning our discussion in the interim final rule (57 FR 8197) of situations in which State law on advance directives is not clear or where there is no State law addressing advance directives. Two commenters asserted that in the absence of State law on the subject, it is imperative that the regulations be flexible enough to include common law and institutional practices. Two other commenters questioned our suggestion to rely on ''institutional practice'' in lieu of a State statute. The commenters believe that few institutions or organizations have had enough direct experience to dictate the best way to accomplish statutory requirements concerning advance directives. These commenters noted that the American Bar Association has stated that many providers have interpreted State laws concerning advance directives in an overly restrictive manner. The commenters believe that, as a result, many providers have failed to develop a full range of effective patient-oriented decision-making practices. The commenters suggested that providers be encouraged to interpret statutory silence as an invitation to develop ''best practice'' procedures based on emerging notions of good clinical practice and professional standards.

Response: Sections 1866(f)(1)(D) and 1902(w)(1(D) of the Act specify that providers are to ensure compliance with requirements of State law (whether statutory or as recognized by the courts of the State). We agree that common law and institutional practices can be of assistance when the law is unclear or there is no State law regarding advance directives and believe that these regulations are flexible enough to include common law and institutional practices along with statutory law.

Also, we encourage providers to develop ''best practice'' procedures based on emerging notions of good clinical practice and professional standards. We also encourage the American Bar Association and other professional organizations to continue working with providers and State legislatures to ensure that State laws are clearly written, revised and updated where necessary, and to ensure that the Federal advance directives requirements are implemented in accordance with applicable State law.

Community Education

Comment: Two commenters asserted that the interim final rule lacks guidance on what constitutes minimally sufficient educational efforts. The commenters suggested that the final rule should require that the provider's written community education plan include at a minimum: (1) its intended target audiences, (2) the frequency of its educational efforts, and (3) the expected penetration of the target population to be attained by the educational efforts.

Response: We believe that the intent of the community education requirement is to educate as large a number of individuals as would be reasonable for that provider. However, as noted by the commenters, the interim final rule did not specify a minimum level of activity for the community education effort. In an effort to determine if further guidance was needed in this area, our regional offices recently conducted a survey of a small sample of providers to determine the level of community education efforts among providers. For sample purposes, the regional offices accepted copies of any document generated to publicize and conduct community education efforts. The results indicated that providers are using a variety of methods, for example, workshops, seminars, public meetings, health fairs, civic affairs, and the media.

Our review of the many methods and types of community education documentation maintained by providers leads us to believe that providers are reaching targeted audiences, are conducting frequent campaigns, and raising the advance directive issue

before new audiences. Therefore, most of the commenter's suggestions are currently being achieved by providers without explicit guidance.

Based on the survey, we do not feel it is necessary to establish the type of prescriptive requirements suggested by the commenters. Instead, we are revising the regulations at §§ 417.436(d)(1)(B)(vii) and 489.102(a)(6) to require that providers must be able to document their community education efforts. Although we are not limiting provider flexibility in meeting this requirement, one possible method for a provider to document its efforts would be to maintain copies of any materials used as part of its community education programs. We believe that the maintenance of community education documentation will strengthen our ability to enforce the community education requirement without limiting provider flexibility in this area.

While we believe that the requirement that providers maintain documentation will assist us in evaluating the level of community education efforts achieved by providers, we considered whether it would be an added burden to require the maintenance of such documentation. However, in all likelihood, providers will maintain copies of the materials used as part of their community education efforts for their own purposes, and we are not limiting the type of documentation that would be acceptable. Thus, we do not believe that this requirement constitutes an added burden.

Comment: One commenter suggests that physicians be targeted for much of the national educational campaigns conducted by Federal and State governments. The commenter believes that a national educational campaign for physicians would ensure that terms such as medical and surgical treatment are explicitly defined and consistently applied. The commenter believes that this is necessary, particularly in nursing facilities, because physicians are the critical link in implementing an individual's advance directives. The commenter believes that a national educational campaign would ensure that all parties (physicians, residents, surrogate decision-makers) are knowledgeable concerning the advance directives requirements.

Response: National educational campaigns are being addressed separately from these rules. However, in accordance with sections 1866(f)(1)(E) and 1902(w)(1)(E), providers are responsible for the education of physicians who are provider staff members or under contract concerning advance directives. Also, we note that medical schools and professional associations are providing training and education to physicians on issues concerning advance directives and patient's rights. With respect to what constitutes medical or surgical treatment, State laws typically govern the definition of these terms.

Comment: One commenter suggested that for any written or oral presentation concerning State law, a provider be required to: (1) Obtain approval by the State; (2) use State material or; (3) conduct joint presentations with State-recognized experts in the field.

Response: Individual States have the latitude to stipulate the use of specific documents but may also permit providers, at their discretion, to use other methods of informing patients. Also, we do not believe it would be appropriate to require State approval of presentations or to mandate the use of State-recognized experts in this field. We believe adopting the commenter's suggestions would place an unfair burden on both the State and providers. Therefore, we have left this matter up to the discretion of the individual States.

Comment: One commenter asserted that enforcement of the community education requirements would violate a provider's First Amendment rights to freedom of religion. Therefore, the commenter recommended that providers be allowed to exempt themselves from any community education activities based on conscience.

Response: The statute does not permit providers to exempt themselves from the community education requirement. However, both sections 4206(c) of OBRA '90 and 1902(w)(3) of the Act permit a provider, in accordance with State law, to object to implementing an advance directive on the basis of conscience. Accordingly, we believe it would be appropriate for a provider to register that objection as it conducts its community education requirement. That is, the provider must meet its obligation to conduct community education on advance directives, but may inform the community that the State law offers a choice that, because of a conscientious objection, it would not honor. We believe that this information is valuable for community members to have since it may affect their choice of a provider. Therefore, we are not adopting the suggestion that providers be allowed exemptions from the community education requirements.

Comment: One commenter believes that the community education requirement is duplicative, inefficient, and does not provide any further information to consumers concerning advance directives. Therefore, the commenter suggested this requirement should be eliminated. Another commenter suggested that this requirement is an undue burden on hospitals and believes the responsibility to educate the community should be borne only by Federal and State governments. Another commenter objected to the requirement that facilities engage in community education presentations or outreach efforts as a condition of participation in Medicare. Rather, the commenter believes that surveyors should find a facility in compliance with this requirement if it produces evidence that it provides written materials to individuals who come to the facility to investigate admission or to visit family members.

Response: Section 1866(a)(1)(A) of the Act requires that in order to participate in Medicare, any provider of services must meet the advance directives requirements set forth in section 1866(f) of the Act. Section 1902(a)(57) of the Act establishes a similar requirement for Medicaid participation. Thus, the elimination of the community education portion of the advance directive requirement would require statutory changes. As to the scope of community education activities, we do not believe it is appropriate to restrict this to individuals expressing interest in admission, since many individuals in the community who ultimately may require admission would profit from the chance to learn about State laws on advance directives.

Comment: Several commenters requested clarification of the statement in the preamble to the March 6, 1992 interim final rule (57 FR 8197) that ''whatever method is used, it must be in writing and subject to survey review for compliance with Federal requirements.'' The commenters believe that many readers would presume ''in writing'' to refer to a provider's description of activities with respect to community education, rather than the educational materials to be distributed. Finally, some facilities believe that distributing copies of their policies to the general public may be viewed as a form of unwanted advertising by those individuals who are not interested in particular facilities.

Another commenter objected to our suggestion that written information distributed could be similar to what is required to be disseminated to individuals upon admission. The commenter asserted that Congressional intent is simply to foster discussion about advance directives instead of

actively encouraging individuals to execute an advanced directive.

Response: As discussed above, we have revised §§ 417.436(d)(1)(B)(vii) and 489.102(a)(6) to require that providers must be able to document their community education efforts. The community education itself may be carried out through a variety of methods or formats, at the discretion of the provider. We are not requiring the distribution of any particular written material as part of a provider's community education efforts, although we recognize that many providers may choose to distribute written descriptions of their policies.

While we recognize that some individuals may view these programs as a form of unwanted advertising, we note that community education is a requirement under sections 1866(f)(1)(E) and 1902(w)(1)(E) of the Act and thus, we have no discretion to permit exceptions to these provisions.

We agree Congress intended to foster discussion about advanced directives, but we do not believe that community education constitutes encouraging individuals to execute advance directives. Again, community education concerning advance directives should involve not only a discussion of an individual's right to execute an advance directive, but also of a patient's broader right to accept or refuse medical or surgical treatment.

Comment: One commenter asserted that when community education is done in concert with other providers and organizations, it would be inappropriate for the attendees to receive written information detailing policies and procedures specific to each provider participating in community education efforts. Also, some commenters believe that creativity among providers and organizations, such as the use of lectures, seminars, videotaped programs and health fairs, will be discouraged if they are required to use the same material distributed to patients upon admission. Therefore, the commenter suggested that we modify § 489.102(a)(6), which requires that community education materials regarding advance directives include a provider's written policies regarding an individual's rights under State law and a provider's policies concerning the implementation of those rights. The commenter believes that we should instead require a provider to make the information about its policies on the implementation of the advance directives provisions available to attendees only upon request.

Response: We agree with the commenter that, for community education purposes, it may not be appropriate for a provider to distribute the same documents as are used by the provider to meet its internal advance directive obligations, especially when community education presentations are conducted by several different providers or provider types. The interim final rule merely presented several acceptable options aimed at assuring providers that they would not necessarily need to develop separate materials for both advance directive and community education purposes. Clearly, separate materials could be developed for each purpose, at the discretion of providers, and they would not need to use the same written materials in all contexts. We have amended §§ 489.102(a)(6) and 417.436(d)(1)(vii) to clarify that separate materials may be developed for both the advance directive and community education requirements.

Comment: One commenter, although in support of the community education requirement, was concerned that some health care providers, particularly small rural hospitals and other isolated or financially struggling institutions, may have problems meeting this requirement. Therefore, the commenter suggested that HCFA provide funding support for the educational initiatives.

Response: The advance directive provisions do not include authority to modify the current hospital payment system in order to assist providers in complying with the advance directives requirements. Therefore, we have not included provisions relating to payment in this regulation. However, hospitals as well as other providers reimbursed under the cost reimbursement system can receive reimbursement for incurred administrative costs, associated with the advance directive requirements.

Comment: One commenter believes that the use of the public relations offices to educate the community would preclude providers from obtaining State and Federal funding for advertisement campaigns. Another commenter believes the regulations should be revised to specify that the use of Federal and State funds is permitted for reimbursement of advance directive community education activities. The commenter believes that the cost of advance directive activities should be considered an allowable cost.

Response: Medicare policy has long provided that a provider's costs of advertising to the general public are not allowable if the advertising seeks to increase utilization of the provider's services. However, advertising costs incurred in connection with a provider's public relations activities are allowable if they are directly or indirectly related to patient care. (See section 2136 of the Provider Reimbursement Manual.) Thus, our suggestion in the interim final rule that public relations offices be used to inform the community about advance directives was not intended to suggest that we believe the associated costs should be disallowed. To the contrary, we believe public relations activities to inform the community on advance directives should be common and accepted activities in the provider community and that their costs generally would be related to patient care. In summary, we agree with the commenter that for Medicare providers that are paid on the basis of cost, the cost of advance directives activities could be considered an allowable cost related to patient care.

For Medicaid purposes, Federal financial participation at the 50 percent matching rate is available for expenses paid for by the State for administrative costs the State incurs for implementing the Medicaid requirements of this section. To the extent that States make additional payments to providers for their costs of advance directives activities, Federal financial participation is available at the Federal Medicaid Assistance Percentage.

Comment: Two commenters requested that the final rule explicitly define the size and parameters of the community for purposes of defining a provider's obligation to participate in community education efforts. The commenters suggested that, for nursing homes, these regulations limit the facility's community education program responsibilities to residents, their family members, resident and family councils (if any) and staff. Another commenter believes that education of the public at large should be solely the responsibility of the Secretary of the Department of Health and Human Services (HHS).

Response: In general, we believe that Congress intended that the concept of community encompass members of the general population that could potentially be served by a provider, rather than the much narrower interpretation suggested by the commenters. We believe that the concept of ''community'' as embodied in the law relates to the catchment area of the individual provider, which means that an HMO and a hospital, for example, would likely have community areas very different in scope. However, we do not intend to define the size and parameters of a community for each facility subject to this final rule because it would be cumbersome and overly prescriptive.

We note that the location, size, and other characteristics of the population served by different providers are some

of the factors that would impact on the manner in which a provider defines its community for purposes of the community education requirement. The various possible combinations of these factors make developing a fair, equitable definition of community difficult. For example, the use of geographical distances might place an unfair financial burden on rural, isolated hospitals while it might not further educate the public in urban areas where there are frequently multiple facilities in closer proximity who may possibly serve some of the same patients.

Moreover, as noted above, we believe that our survey of community education efforts by providers indicates that establishing more prescriptive requirements in this area is not necessary. Providers are already utilizing many different formats, working jointly to minimize the financial costs associated with community education and have done an excellent job without explicit guidance. Therefore, except with regard to managed care plans, we do not intend to define the term ''community'' for the purposes of this regulation but instead will afford providers the flexibility to define their own ''community''. As noted below in section IV, community has been defined as ''service area'' for managed care plans.

With regard to the suggestion that community education should be solely the responsibility of the Secretary of HHS, we believe that Congressional intent is clear on this subject. Sections 1866(f)(1)(E) and 1902(w)(1)(E) of the Act require that providers conduct community education activities, and section 4751(d) of Public Law 101–508 directs the Secretary to conduct a national campaign addressing public and medical and legal professions. The Secretary's public education responsibilities clearly are separate and distinct from provider responsibilities in this area. We note that providers, for example would bear the responsibility for informing the public about applicable State law requirements, which would be impossible to address in a national public education campaign.

Comment: One commenter suggested that the final rule require nursing facilities to conduct community education activities in the context of the resident rights requirements that were established under the nursing home reform provisions of OBRA '87. The commenter believes that community education programs should include diverse points of view on the issue of advance directives, including the right not to make an advance directive, and that providers should not limit a patient's options or influence patients as to the specific content of their advance directive. In addition, providers should ensure that all material presented is consistent with State law.

Response: Each nursing facility has the discretion to develop and conduct education programs that best suit their targeted population, and we encourage providers to coordinate their efforts to educate their residents and the community. When Congress enacted the advance directives provisions, it also amended the resident rights provisions of the statute (1819(c)(1)(E) of the Act) to effectuate the advance directives requirement for nursing homes. Therefore, it is expected that nursing facilities will incorporate advance directive information into their policies for informing residents of their rights. We note that § 483.10(b)(8) already specifies that facilities must ''inform and provide written information to all adult residents concerning the right to accept or refuse medical or surgical treatment and, at the individual's option, formulate an advance directive.'' In addition, § 483.10(b)(8) requires that facilities include ''a written description of the facility's policies to implement advance directives and applicable State law.''

Comment: Two commenters noted that the outpatient setting is the optimal forum for initial discussion of advance directives, rather than at the time of acute illness. Accordingly, one commenter suggested that we stress the need for providers to distribute information regarding patients' rights under State law to the widest audience possible, including outpatients and minors who have the capacity to be involved in decision-making.

Response: Sections 1866(f)(1)(E) and 1902(w)(1)(E) specify that a provider of services or eligible organization must provide (individually or with others) for education for staff and the community on issues concerning advance directives. As the commenter suggests, we believe that the clear intent of these provisions is that information concerning advance directives be made available to the widest possible audience. We have not provided more explicit guidelines on this matter because we believe that there must be sufficient flexibility to accommodate a variety of community and provider responses to this requirement.

As discussed above, sections 1866(f)(2) and 1902(w)(2) of the Act specify that hospitals, SNFs, and NFs must provide written information concerning an individual's rights under State law to accept or refuse medical or surgical treatment, including the right to formulate an advance directive to all adult individuals upon admission. However, we agree with the commenter that it would be beneficial to hospital patients and nursing home residents if information concerning advance directives were available before admission. Again, we believe that this eventually will be achieved through the providers' community education activities and the Secretary's national education campaign.

Comment: Although generally supportive of the need for the community education requirement, three commenters objected to permitting providers to use community education activities to fulfill their requirement to document the medical record concerning whether or not an individual had executed an advance directive. In particular, the commenters disagreed with our suggestion in the interim final rule that providers may ask attendees if they have executed an advance directive and then later document this information in the medical record (57 FR 8197). The commenters generally believe that these campaigns are primarily oral presentations to community groups and any attendee may or may not be subsequently admitted to the facility represented by the speaker. Thus, there would be great logistical problems as well as confidentiality problems in implementing our suggestion. Also, the commenter notes that providers do not have record systems to accommodate information regarding individuals who are not patients.

Response: We believe that the commenter raises several valid points. Therefore, in this final rule, we have omitted any suggestion that providers consider using the community education forum to obtain information as to whether or not an individual has executed an advance directive. We note that information about advance directives that is documented in an individual's medical record would be subject to the same confidentiality protection as other information in the medical record. For example, the regulations setting forth conditions for hospital participation in Medicare, § 482.24(b)(3) specify that hospitals must ensure the confidentiality of patient medical records and that information from or copies of records may be released only to authorized individuals. Hospitals are also required to ensure that unauthorized individuals cannot gain access to or alter patient records. These requirements apply to information entered into the medical

record as a result of the advance directive requirement.

Comment: Three commenters were concerned that the regulations neither require nor encourage providers to address the level of literacy for written English, the use of non-technical language in developing informational materials, etc., to ensure that the materials disseminated would be easily understood by the recipients. Many of the recipients of this information may not speak English or may speak English as a second language. Therefore, the commenter suggested that the regulations require that basic patient information materials be developed in other languages where the community composition warrants it. In addition, the commenter recommended that language barriers be anticipated, understood and handled appropriately with the assistance of interpreters.

Response: We believe that the statute and regulations require that providers distribute material that is clear and understandable to each patient. Sections 1866(f) and 1902(w) of the Act, and implementing regulations, specifically require that providers develop and disseminate to adult individuals written information about an individual's rights under State law to accept or refuse medical and surgical treatment and the right to formulate advance directives. Providers must also describe and distribute their written policies respecting the implementation of such rights. To meet the intent of the law (that is, to educate individuals concerning such rights), the written information must be clear and understandable. Therefore, we believe that it is inherent in the distribution requirement that the information be communicated in a language that the patient understands.

If the patient's knowledge of English or the predominate language of the facility is inadequate for comprehension, a means to communicate the information concerning patient rights and providers responsibility and practices must be available and implemented. For foreign languages commonly encountered in a provider locale, the provider should have written translations of its description of State law and its statement of procedures, and should, when necessary, make the services of an interpreter available. In the case of less commonly encountered foreign languages, providers may rely on the patient's representative to attest that he or she has explained the material to the patient.

Comment: Three commenters believe these regulations should consider differences in patients' cultural backgrounds. They stated that patients in today's American health system have diverse cultural and religious backgrounds and that, for some patients, discussions of even the possibility of death, whether imminent or remote, are a violation of their own cultural mores. The commenters view these regulations as an imposition on personal beliefs and values and believe that patients should be exempted on this basis; otherwise, clergy or other relevant staff members need appropriate experience or training in dealing with individuals on these sensitive issues.

Response: Although the law does not deal with these issues, we would expect a provider to be sensitive to the cultural differences in its community. We do not, however, believe the law provides for an exception to the requirement that all adult individuals receiving care be informed about their rights to accept or refuse medical or surgical treatment or to formulate an advance directive. We note that disseminating information and inquiring about the existence of an advance directive does not necessarily require that an individual discuss issues related to death. Instead, the focus should be on offering individuals information about their rights to enhance their control over medical treatment.

Comment: One commenter acknowledged that area hospitals, with or without outside help, have endeavored to instruct the public about advance directive requirements in order to avoid undue concerns when the patient is hospitalized. The commenter requested that HCFA distribute, or make available, publications that describe how hospitals have successfully instructed the community about this topic.

Response: In Appendix II to the preamble of the interim final rule, we identified a sampling of organizations and publications that could provide technical assistance on advance directive issues. While the statute does not require HCFA to become a ''depository'' for publications developed under this requirement, HCFA does maintain numerous materials concerning advance directives, as summarized in the preamble. Some materials may be obtained through the Medicare Hotline and others are disseminated to new Medicare enrollees. In addition to the resources that we have, we strongly encourage area providers and organizations to share experience and expertise in order to help one another develop the best informational packages possible for any given community.

Dissemination of Information

Comment: Several commenters requested clarification as to whether the requirement that hospitals provide information about an individual's right to accept or refuse medical or surgical treatment and to formulate advance directives to individuals upon admission also applied to ''providers of outpatient hospital services.'' Among the areas of concern were applicability to ''in-and-out'' surgical suites, dialysis facilities, and any patients undergoing general anesthesia, regardless of setting. Another commenter believes that emergency medical technicians or paramedics performing emergency services and ambulance transports should be subject to this regulation. The commenter argued that it is grossly unfair for the patient to receive CPR in the ambulance so that he can be ''allowed to die'' at the hospital.

Response: Sections 1866(f)(2)(A) and 1902(w)(2) of the Act specify that written information concerning an individual's rights to accept or refuse medical or surgical treatment and to formulate advance directives should be provided to an adult individual, in the case of a hospital, at the time of admission as an inpatient. We agree with the commenters that there are other health care situations in which it might be appropriate for a patient to be advised about advance directives; however, the statute is very specific concerning the settings to which these requirements apply. We note that these regulations do not preclude a State from requiring or a provider from voluntarily providing this information in any case where it believed it to be appropriate.

Section 1866(f) and 1902(w) do not require information to be provided in any outpatient settings except for home health, hospice, and personal care services. Thus, the statute does not require emergency medical technicians and paramedics to implement the advance directives requirements, although there is nothing in it that would prevent the operators of these services from giving individuals this information.

Comment: One commenter suggested that, for certain types of patients, a hospital be permitted to modify its procedures in order to implement this rule logically. For example, the commenter believes that it is inappropriate to disseminate advance directive information to hospital patients being admitted for labor/delivery, or to repeatedly disseminate information to multiple admissions patients. If these procedures are not modified, multiple admission patients

may find themselves collecting large numbers of the same brochure on advance directives. The commenter also recommended that we not require hospitals to disseminate advance directives information to individuals undergoing same-day outpatient surgery or emergency room treatment.

Response: Sections 1866(f)(2)(A) and 1902(w)(2)(A) of the Act explicitly require that hospitals disseminate advance directive information to individuals at the time of their admission as inpatients. Neither the statute nor the regulations require the dissemination of this information to outpatients or emergency room patients unless they are admitted to the hospital. When a patient is admitted, however, we have no discretion to permit exceptions to this requirement. We note that hospitals repeat many admission procedures as part of every separate admission, often in accordance with applicable State and Federal laws. Even in multiple admission cases, the dissemination of information and inquiry about the existence of an advance directive should not impose a significant burden on hospitals and helps ensure that the patient is knowledgeable about his or her rights, along with verifying that the hospital has the most recent copy of an individual's advance directive. Patients are always free to return the brochure or refuse the information if they have already received it.

Comment: Some commenters suggested that the final rule address the tendency of individuals, once presented with this written information, to desire to execute advance directives upon admission or ''on the spot.'' The commenters believe that the time of admission may not always be the best time to complete and execute advance directives because of the tension, anxiety and depression often experienced by individuals about to be admitted. The commenters added that advance directives should be executed only after prudent reflection.

Response: The commenter has raised several valuable points. A hospital could address the commenter's concerns by providing advance directives information on a preadmission basis (for elective admissions) and also through its efforts to educate the community as to the advance directives options available under State law. Although these regulations do not prevent a provider from assisting a patient in completing an advance directive if the patient so desires and the hospital is willing, the provider should ensure that there are no State laws that may preclude this activity. We would stress that the law and this regulation contain a limited range of requirements relating to advance directives. We do not believe it is appropriate to extend the requirements of this final rule beyond the confines of law. Instead, we believe it is appropriate that providers retain the flexibility to continue to refine their application of the advance directive provisions based on their experience.

Comment: Two commenters strongly suggested that the final rule expressly direct providers not to disseminate or execute advance directive forms routinely at the point of admission, but only upon request. Another commenter suggested that if copies of advance directives forms are given out, that a representative sample be given, or be made available upon request, so that the patient can be fully aware of the various kinds available. Finally, a few commenters argued that while it may be legally permissible for providers to disseminate advance directive forms, actively assisting an individual in the preparation of a will, a durable power of attorney, or other documents of legal import would constitute the practice of law. Therefore, the commenters recommended that the final rule should explicitly forbid the provider from drafting, interpreting, advising and assisting individuals in the execution of such documents by persons who are not licensed to do so under State law.

Response: This final rule neither requires providers to disseminate advance directives forms upon admission nor does it prohibit them from doing so. We know that different groups of hospitals have adopted different policies as to the appropriateness of this practice, and we also believe that State laws may bear on this activity. Again, the statute and this rule focus on ensuring that individuals are informed of their rights with regard to the advance directives, not on prescribing procedures for executing directives.

We decided not to adopt the suggestion that we require providers to supply a representative sample of forms since we have no statutory authority to do so. Also, this final rule does not address the issue of whether assisting an individual in preparing a living will, a durable power of attorney or other documents of legal import would constitute an unauthorized practice of law. Providers should look to State laws that may address the legality of these actions.

Comment: Several commenters suggested that the widest latitude be offered for providers to disseminate information to patients about their advance directives rights under State law and the provider's policies concerning the implementation of those rights. One commenter specifically suggested that the timing for dissemination of materials be adjusted by the nursing facility according to its admissions practices. For example, one facility's ''admission process'' may not involve the level of personnel who would have the education and training to provide advance directive information in a manner most helpful to patients. Yet, another facility's ''admission process'' may include the use of qualified staff, such as a nurse, and may involve an initial nursing/comprehensive assessment that is usually completed within 6 hours of admission. Another commenter suggested that these regulations be applied in conjunction with other nursing home requirements, for example, the free choice provision under the resident rights requirement (§ 483.10(d)) or the scope of services provisions under the plan of care requirement (§ 483.20(d)(1)), which would provide the additional time needed to disseminate information regarding advance directives. The commenters further suggested that the advance directive documentation should be done as part of the care plan and revisited at the quarterly care planning meetings. Finally, the commenters suggested that, for home health agencies and personal care providers, the required information should be disseminated during the first visit but before actual delivery of care, in the same manner as other patient rights information.

Response: We have attempted to address these concerns in this final rule within the confines of the statute. Hospitals and nursing facilities must follow the explicit language of sections 1866(f)(2) and 1902(w)(2) of the Act, which require that information concerning advance directives be provided ''at the time of admission.'' We do not believe that the statute affords us the discretion to implement any of the commenters' suggestions for revising the meaning of ''at the time of admission'' as it applies to nursing homes.

For HHAs, sections 1866(f)(2) and 1902(w)(2) of the Act require that the information be provided ''in advance of the individual coming under the care of the agency,'' without specifying a particular time. We believe it is reasonable to permit this function to be performed at the time of the first home visit, as long as the information is given before care is provided. This visit traditionally encompasses patient assessment and the administrative details necessary for the start of home

care, and we believe it would be appropriate to comply with the advance directive requirements at this time. Therefore, we have amended regulations at §§ 484.10(c)(2)(ii) and 489.102(b)(3)(i) to clarify that an HHA may furnish advance directive information to a patient at the time of the first home visit, as long as the information is furnished before care is provided.

A similar requirement has been adopted with regard to personal care providers. We have amended regulations at §§ 489.102(b)(3)(ii) to clarify that they may furnish advance directive information to a patient at the time of the first home visit, as long as the information is furnished before care is provided. (For further discussion of the timing issue as it concerns HMOs and CMPs, see Section II.B of this preamble below).

Comment: One commenter asserted that some nursing home patients are unable to receive this information immediately upon admission and noted that, in accordance with OBRA '87, nursing homes have an added requirement to advise these individuals in a way that they will understand. The commenter believes that the best method to achieve this is through some sort of discussion. Some patients have experienced emotional breakdowns upon being informed of their rights with regards to advance directives because they think they are about to die. The commenter suggested that for SNF and NF residents who appear likely to be threatened by this conversation at the time of admission, these regulations permit the dissemination of information and discussion to occur at some time between entry to the facility and completion of the initial minimum data set (or resident assessment). Therefore, the commenter suggested that we define ''at the time of admission'' to mean that the information must be given promptly upon (but no later than 14 days after the date of admission), which is in accordance with the meaning of ''upon admission'' under section 1819(b)(3)(C)(i) of the Act.

Response: We do not believe that it is appropriate to permit information routinely to be delayed simply because it is of a sensitive nature. However, some residents may well be incapacitated by virtue of a physical or mental disorder, in which case the information could be provided at a later time, if feasible. We believe this is a medical decision to be made by the facility after considering the patient's medical condition and the likelihood of any negative effect upon the patient. This determination should be made on a case-by-case basis by the facility in accordance with State law. This issue also is discussed below under the heading ''Individuals Incapacitated at Admission''.

Sections 1819(b)(3)(C)(i) and 1919(b)(3)(C)(i) of the Act specify that a SNF and NF must conduct a comprehensive resident assessment for each individual promptly upon admission, but not later than 14 days after the date of admission. In general, nursing homes use registered nurses or other trained personnel to conduct resident assessments, and depending on the medical condition of the resident, this assessment may become a lengthy process. In contrast, sections 1866(f)(1) and 1902(w)(1) of the Act do not specify any particular health care discipline or trained personnel to disseminate information on advance directives or to document in the resident's medical record whether or not the individual has executed an advance directive. Therefore, we believe that it is not necessary or consistent with the advance directives statute to revise the regulations to routinely allow up to 14 days to disseminate this information as the commenter suggests.

Individuals Incapacitated at Admission

Great concern was voiced by commenters concerning the provision of advance directive information to psychiatric patients, and to patients suffering from Alzheimer's disease or other diseases affecting an individual's decision-making capacity. In particular, commenters suggested that the advance directive information may exacerbate the symptoms of mental illness and hamper psychiatric treatment, especially for suicidal patients. The commenters offered the following suggestions to address the overall issue of individuals incapacitated at the time of admission and other related issues.

Comment: One commenter suggested that the regulations implementing the advance directive requirements include a provision for a ''good faith exception to the Act'' for all psychiatric hospital admissions or, at a minimum, for those persons involuntarily admitted for psychiatric treatment because they have been determined to be dangerously mentally ill.

Response: Sections 1866(f)(1) and 1902(w)(1) of the Act specify that the advance directives requirements apply to all adult individuals receiving medical care. Therefore, we believe that a general ''good faith'' exception is precluded by the law. Although we recognize that certain individuals may not be able to receive information about advance directives due to incapacity, we believe that such a determination must always be made on a case-by-case basis by the facility in accordance with State law.

Comment: Two commenters noted that the interim final rule did not specify the personnel that would be responsible for determining whether or not an individual was capable of receiving information concerning advance directives. The commenters believe that further guidance is needed in this area and suggested that the final rule require that the professional judgment of a qualified healthcare professional (such as a physician, nurse or social worker) be used to determine when an individual can receive this information.

Response: Since the statute is silent on this issue, we do not believe it would be appropriate to impose on providers by regulation a requirement that only a physician or nurse is permitted to make the professional judgment concerning an individual's capacity to receive this information. Therefore, we defer to State law addressing the subject. Where there are no State laws concerning this subject, then the institution may make the decision.

Comment: Some commenters interpreted the discussion of the incapacitation issue in the interim final rule (57 FR 8197) as requiring hospitals to disseminate information concerning a patient's right to accept or refuse medical or surgical treatment and to formulate an advance directive to family members or surrogates when the individual is incapacitated upon admission. They stated that such a requirement would extend beyond the scope of the statute and suggested it be deleted. One commenter stated that, in some States, third parties (for example, family and/or surrogates) may execute advance directives or otherwise act without meaningful restriction on behalf of an incapacitated patient, in the absence of an advance directive executed by the patient. The commenter suggested that the regulations explicitly state that the advance directive requirements only apply to an individual patient's rights; thus third parties should have no further role but to receive the information on behalf of the incapacitated individual.

Response: We did not require that family members or surrogates receive advance directives information in place of incapacitated patients. We merely suggested that providing them with this information, to the extent the facility provides such individuals with other information related to the patient's care, would be appropriate and might help the provider discover the existence of an advance directive. We agree that

sections 1866(f) and 1902(w) of the Act apply only to individual patient's rights and that these statutory provisions do not create a right for third parties to receive information on advance directives or to execute advance directives on behalf of incapacitated patients. However, we are aware that some States permit third parties to execute advance directives on behalf of an incapacitated patient. We believe that defining rights of third parties as the commenter suggested would conflict with Congressional intent that issues not addressed through explicit provisions of the statute be decided under State law.

Comment: One commenter stated that there has been some confusion among facilities concerning the implementation of advance directive requirements for incapacitated patients. As a result, some facilities are requiring the appointment of a guardian over their residents for purposes of meeting these requirements. The commenter suggests we address this issue.

Response: The determination of whether or not an individual is incapacitated and unable to receive advance directives information and the role of surrogate third parties are issues that involve both the individual's medical condition and State law regarding decision-making authority in such cases. We defer to State law on these issues. The appointment of a guardian is not required by the statute but is left to the discretion of the facility in accordance with applicable State law.

Comment: One commenter suggested that the regulations clarify that no assumptions be made by third parties regarding an incapacitated resident's right to accept or refuse medical or surgical treatment in the event the resident has not executed an advance directive.

Response: The statute does not grant authority for actions on the part of the family or surrogate for the incapacitated individual. Therefore, providers should look to State laws that address responsibility for treatment decisions in those instances where an individual is incapacitated.

Comment: One commenter suggested that, in order to facilitate the development of policies concerning incapacitated individuals, we allow national organizations such as the American Psychiatric Association, the National Association of Private Psychiatric Hospitals and the American Hospital Association to develop guidelines or recommendations on how to address incapacitated patients in providers' written policies concerning advance directives.

Response: Providers and organizations should have already completed their policies and procedures on these advance directive requirements. However, particularly in light of the changes in the regulations included in this final rule concerning providing advance directives information to surrogate decision-makers, we encourage national organizations to work with providers to help them refine their policies concerning this portion of the advance directive requirements.

Comment: We received several comments on the statement in the preamble of the interim final rule that indicated that providers are obligated to track patients who are unconscious on admission in order to determine when they are able to receive information concerning advance directives (57 FR 8197). Some commenters stated that this requirement was unnecessary in cases in which hospitals provided the information upon admission to family members, or surrogates, since it is likely that the family would pass the information on to the patient when he or she regained consciousness. Other commenters supported the requirement and suggested that we require periodic reassessments of comatose patients to determine when they are able to receive the information. One commenter asserted that some patients may never regain decision-making capacity while hospitalized and are often discharged without ever having been in a condition to receive the required information. The commenter suggested we specifically address whether a facility still is obligated to provide the information under these conditions.

Response: Sections 1866(f)(1)(A) and 1902(w)(1)(A) of the Act specify that it is the patient's right to formulate an advance directive and the provider's obligation to inform the patient of that right. We do not believe that a provider can meet this obligation by providing information to surrogate decision-makers or family members. In this final rule, we have clarified this point by adding language at §§ 417.436(d)(1)(ii), 483.10(b)(8), and 489.102(e) to specify that facilities may give advance directive information to the patient's family or surrogate, but this does not relieve the facility of its obligation to provide this information to the patient once he or she is no longer incapacitated or unable to receive such information. Therefore, the provider will need to develop follow-up procedures to determine if and when the patient may be given the information directly.

We agree that it would be appropriate to conduct periodic reassessments of comatose patients; however, we believe that the timing of reassessments should be determined by the provider based on the medical condition of the individual patient. If an individual remains incapacitated throughout an entire hospital stay, we recognize that there may never be an opportunity for the advance directives information to be provided. In such cases, we would expect the provider to document in the patient's medical record its awareness of its obligation and its continuing judgment that the patient's medical condition does not permit the information to be provided.

Objections Based on Conscience

Comment: Several commenters requested additional information on our policy in situations in which a health care provider, as a matter of conscience, cannot implement an advance directive. Specifically, the commenters requested that we clarify the requirement under §§ 417.436(d)(1)(i)(B) and 489.102(a)(1)(ii) that the written policies of a provider or organization include ''a clear and precise statement of limitation if the provider cannot implement an advance directive on the basis of conscience.'' One commenter suggested that the explanation of State law concerning objections on the basis of conscience mirror either the State law or the State-developed description of the State law concerning this topic. Two other commenters suggested that, where State law permits a conscientious objection, the regulations should require that the provider's explanation: (1) Clarify any differences between institution-wide conscience objections and those that may be raised by individual physicians; (2) explain the basis for the objection (that is, whether it is based on various religious, moral, or professional grounds); (3) identify the State legal authority permitting such objection; (4) describe the range of medical conditions or procedures affected by the conscience objection; (5) describe what steps will be taken to transfer or otherwise accommodate individuals whose wishes are impeded by the institution's policy; and (6) describe what, if any, burden will be placed on the patient or the patient's surrogate decision-maker to help effectuate the implementation of the advance directive. Finally, one commenter asked whether Medicare and Medicaid payments would be terminated if an entire institution objects to implementing advance directives on the basis of conscience.

Response: Sections 1866(f)(1)(A) and 1902(w)(1)(A) of the Act require that providers and organizations furnish individuals receiving medical care with written information concerning an individual's rights under State law and the provider's policies concerning the implementation of these rights. Also, section 4206(c) of OBRA '90 and section 1902(w)(3) of the Act provide that the statutory advance directive requirements do not prohibit the application of a State law that allows for an objection on the basis of conscience for any provider (or its agent) that, as a matter of conscience, cannot implement an advance directive. As the commenter noted, implementing regulations at § 417.436(d)(1)(i)(B) and 489.102(a)(1)(iii) require that this information include a statement of limitation if a provider cannot implement an advance directive on the basis of conscience. We agree that the written information may mirror State-developed descriptions of State law concerning advance directives. However, we do not believe that requiring a provider to supply copies of applicable State law is necessary, because the statute requires the dissemination of descriptions of State laws. We believe that Congress imposed this requirement because many State statutes may be written in technical terms that may be misunderstood. We have reviewed the six suggested requirements for statements of limitation. We believe that the commenters have highlighted some important minimum points of information that should be given to all affected individuals, but we also believe some of the suggestions go beyond the intent of this law. As a result, we have decided to implement the first, third and fourth of the commenters' suggested requirements.

We have several reasons for not adopting the second, fifth and sixth suggested requirements. We have not adopted the second suggestion because the basis for the objection is not necessarily material as long as the objection raised is permitted by State law. A provider may wish to explain an institutional policy; however, an individual physician or practitioner may not wish to do so, and neither of them is required by this law to do so. We have not adopted the commenter's fifth suggestion concerning transfers for a similar reason. The law does not require this level of information. We note that if an individual is given information regarding the provider's conscientious objection, and he or she does not request a transfer, the provider is not obligated to implement any elements of an individual's advance directive that conflict with the provider's conscientious objection. However, it is reasonable to expect that assistance would be provided for a transfer at the patient's request. We did not accept the commenter's last recommendation because we do not believe it would be reasonable to require that a provider speculate on what, if any, burden would be placed on patients or surrogate decision-makers to help effectuate the implementation of an advance directive. Therefore, we are revising the regulations at §§ 417.436(d)(1)(i)(B) and 489.102(A)(1)(ii) to include only the first, third, and fourth points.

Finally, when a entire facility opts to object on the basis of conscience, assuming the objection is permitted under State law and the facility complies with all other provisions of the statute and regulations, neither Medicare nor Medicaid reimbursement will be interrupted.

Comment: One commenter requested that we clarify that a provider is not required to implement an advance directive to which the provider objects on the basis of conscience when the State law is silent or does not specifically prohibit such objection.

Response: The advance directives legislation does not give us authority to make such a clarification. We believe that, unless State law allows a provider to object to implementing an advance directive as a matter of conscience, the provider is required to honor the advance directive as written. As discussed in the preceding response, we have revised §§ 417.436(d)(1)(i)(B)(3) and 489.102(a)(1)(ii)(C) to specify that a provider's statement of limitation must identify the ''State legal authority'' permitting an objection on the basis of conscience.

We note that State statutory law may be silent on a particular issue, such as whether a provider may decline to follow a directive to which it objects on the basis of conscience. As we suggested in the interim final rule, in the absence of statutory law, providers should look to common law or case law for guidance (57 FR 8197).

Comment: One commenter asserted that religiously-sponsored facilities have the right to exercise an objection on the basis of conscience to the requirement that facilities conduct community education. Otherwise, enforcement of the community education requirement would violate provider's First Amendment rights to adhere to their religious beliefs.

Response: Section 1902(w)(3) of the Act and section 4206(c) of OBRA '90 specifically refer to the application of State laws regarding conscientious objections. These statutory provisions permit exceptions to implementing advance directives based on a conscientious objection as prescribed under applicable State law. No provision is made for an exception to sections 1866(f)(1)(E) and 1902(w)(1)(E) of the Act concerning community education efforts. Thus, the provider must meet the requirements relating to community education; that is, the provider must furnish information to the community concerning State law regarding the right to accept or refuse medical or surgical treatment and to formulate an advance directive, even if the provider simultaneously informs the community that it is exercising a conscience objection that would permit it to refuse to honor an advance directive.

Comment: One commenter believes that it would be difficult if not impossible for many providers, especially Roman Catholic facilities, to provide a precise statement of limitation if a provider cannot implement an advance directive on the basis of conscience. According to the commenter, there are various ethical, religious and moral restrictions on whether or not a particular advance directive can be implemented at a Catholic facility. Another commenter believes that providers may not always be able to write clear and precise statements of limitation when objecting on the basis of conscience and requested that the regulations permit alterations to the written policy based upon case-by-case determinations of issues not previously considered by the facility.

Response: As discussed above, we have revised the regulations at §§ 417.436(d)(i)(B) and 489.102(a)(1)(ii) to provide further clarification on the content of the statement of limitation. Regardless of their religious affiliation, facilities may comply with the law by providing patients with written materials containing the minimum points of information required by these regulations. These revisions describe the minimum amount of information that should be included in the statement of limitation. For the most part, we believe that the statement of limitation can be written to accommodate or reflect the case-by-case approach. Although we cannot readily envision a situation in which the required information, if properly provided, would not adequately inform the patient, we agree that such a situation would permit an individualized notice.

Where an individualized notice is needed, facilities may comply with the law by providing patients with written materials indicating the basis upon which decisions will be made, that each decision would be unique, and how the patient may predict the decision in his or her own case. It is not necessary that the written material distributed to patients contain enough information to permit the patients to make a definitive determination about what action the provider will take in every situation. It is only necessary for the provider to state its policy with respect to complying with the provisions of State law regarding an adult individual's right to accept or refuse medical or surgical treatment or formulate an advance directive, even if that policy is to make individual decisions based on religious rules.

Comment: Two commenters requested more guidance on how providers are to deal with individual health care professionals who object to executing an advance directive on the basis of conscience. One commenter stated that although the interim final rule did not require that lists of members of a hospital medical staff be provided to individuals, the regulation text should clarify that hospitals are not expected to provide information about the moral reservations of individual members of the medical staff. Any document describing each physician's position on advance directives would be potentially lengthy, constantly in need of updating, and of little use to patients, who typically choose their physicians before entering the hospital.

Response: We believe a provider may well have a policy under which an individual physician or its medical staff may determine (consistent with State law) whether to honor advance directives. If this is the case, the provider would need to inform the patient of this policy, so that the patient could consult with his or her physician on the subject, as necessary. It would be up to the patient, having been informed of the provider's policy, to consult with the physician.

Although a hospital with a complicated policy may need detailed documents to describe it, we do not believe that this would always be the case. In addition, as the commenter noted, many individuals choose their physicians long before admission and may already have discussed these issues with them. However, although we agree with the commenter that a document describing the positions of individual physicians concerning advance directives would be quite lengthy and of little use to patients, we do not believe it is necessary or appropriate to state in regulations that hospitals are not expected to provide information about the moral reservations of medical staff.

Comment: One commenter noted that the requirements at §§ 417.436(d)(2) and 489.102(a)(1)(ii) specify that a provider is not required to provide care that would conflict with an advance directive and is 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. The commenter believes that these requirements would permit the transfer of a patient when a provider cannot honor his or her advance directive and thus are in conflict with the ''anti-dumping'' rules, which prohibit the transfer of emergency patients except under limited conditions. The commenter suggested that the advance directive provisions be amended to prohibit patient transfers, except under the permissible circumstances in the anti-dumping rules concerning stabilizing the patient.

Response: We disagree with the commenter's assertion that the provisions of this regulation permitting a patient transfer would violate the ''anti-dumping'' statute. The anti-dumping statute (section 1867 of the Act) provides for patient-initiated transfers so long as they are properly documented and done in accordance with applicable Federal and State law. Therefore, we do not believe that a transfer that is requested by a patient after being informed by a provider that it cannot honor an advance directive on a basis of conscience (to a provider who will honor the advance directive) would violate the ''anti-dumping'' statute.

Comment: One commenter believes that physicians are not normally considered agents of health care providers, and thus providers are not responsible for the actions of their individual physicians. The commenter suggested that the final rule clearly acknowledge the need for a collaborative judgment between providers, their agents, and physicians as to when a provider or its agent chooses to exercise an objection on the basis of conscience.

Response: As noted above, section 4206(c) of OBRA '90 and section 1902(w)(3) of the Act do not prohibit the application of State laws that allow for an objection on the basis of conscience for any provider or any agent of a provider that, as a matter of conscience, cannot implement an advance directive. The meaning of the term ''agent'' varies from State to State, and Congress did not define this term in the advance directives provisions. Therefore, for purposes of this final rule, the term ''agent'' is defined by applicable State law.

Regardless of whether or not State law defines a physician as an agent of the provider, sections 1866(f)(1) and 1902(w)(1) of the Act clearly establish that it is the health care provider's responsibility to have a policy on advance directives and to assure that it is followed. Implementing regulations at §§ 417.436(d) and 489.102(a)(1)(ii) require that a provider's policies include a statement of limitation if the provider cannot implement an advance directive as a matter of conscience. To the extent that close collaboration between provider medical staff and other staff is necessary to implement the provider's advance directive policies, it is the responsibility of the provider to assure that it occurs. Ordinarily providers assure compliance through such mechanisms as medical staff by-laws, which physicians agree to observe in return for staff privileges.

Comment: One commenter stated that before a patient's admission, providers should be required to publicize their position on any advance directive they cannot fulfill. As part of this process, the commenter suggested we require providers and organizations to place this information in preadmission packages to be received by the individuals within 10 days before elective admission.

Response: As we have noted elsewhere, we do not believe that the provisions of this regulation should limit individual provider choices on such issues as when to send out pre-admission information packages. Sections 1866(f)(1)(A) and 1902(w)(1)(A) of the Act require that providers provide written information to each individual concerning an individual's rights under State law to accept or refuse medical treatment, the right to formulate an advance directive, and the written policies of the provider respecting the implementation of these rights. Sections 1866(f)(2)and 1902(w)(2) specify when this information must be furnished. These requirements are also set forth in regulations. Also, as discussed in detail above, we require that if a provider cannot implement an advance directive due to a conscientious objection, its written policies must include a clear and precise statement of limitation, as described under §§ 417.436(d)(1)(i)(B) and 489.102(a)(1)(ii).

We believe that these requirements are sufficient to ensure that there is a

timely exchange of information between providers and patients with respect to advance directives, without unnecessarily limiting provider flexibility. Thus, although we encourage providers to include any statement of limitation in pre-admission materials, we do not believe it would be appropriate to impose requirements concerning pre-admission materials.

Descriptions of State Law

Comment: One commenter suggested that we prescribe in regulations the process that States must follow when developing the written descriptions of State law concerning advance directives. At a minimum, the commenter believes that the process should include participation by providers, consumers, community advocacy groups, bar association groups and others. The commenter believes that the written description of the State's advance directive requirements should be reviewed in draft form to ensure that it can be understood by non-experts of average reading ability. Also, the description should be certified as to its accuracy by the State's Attorney General or other legal advisor with the necessary expertise in this area (for example, a commission, committee, court, judicial panel, etc.). Other commenters recommended that information distributed to patients should be subject to review by the State agency upon the receipt of any complaint that the information does not comply with the standard of strict objectivity in describing State law.

Response: The requirement that each State develop a written description of its law concerning advance directives has been in effect since December 1, 1991, and States have followed varying practices in meeting the requirements of the law. At least a few States have consulted widely while other States have issued requirements prepared by the State's Attorney General. This is in keeping with alternatives offered by the statute, and we do not believe it would be appropriate to limit State flexibility on this matter in this final rule. We note that State survey agencies would have the opportunity to review the contents of provider advance directive packages, which could include ensuring that descriptions of State law are accurate.

Comment: One commenter suggested that we request that the Attorney General in each State publish a written description of the State law concerning advance directives and update it regularly.

Response: Section 1902(a)(58) of the Act requires that each State, ''acting through a State agency, association, or other private nonprofit entity, develop a written description of the law of the State (whether statutory or as recognized by the courts of the State) concerning advance directives that would be distributed by providers or organizations under . . . [the Medicaid requirements].'' While we are not making this a requirement, a State may use its Attorney General to prepare the description of State law. In addition, we note that under the Medicaid program, we are requiring that States revise their descriptions of State law and furnish copies of revised descriptions to providers and managed care plans within 60 days from the effective date of a change in State law (see revised § 431.20(b)). Under both Medicare and Medicaid, managed care plans and all providers must provide updated written information to adult individuals within 90 days of the effective date of any new State law.

Comment: Two commenters suggested that we require Medicare providers to use the State-developed description of State law in their informational materials. The commenters believe that Congress intended to mandate the use of the State-developed description similar to the requirement for Medicaid providers and that the lack of such a requirement in section 1866(f) of the Act was a Congressional oversight. The commenters suggested we amend § 431.20(b) to implement this requirement.

Response: As the commenters point out, section 1902(a)(58) of the Act specifically mandates the use of the State-developed description for Medicaid providers, but there is no statutory provision regarding the use of the State-developed description for Medicare providers. Also, we have found no evidence in the legislative history that the Congress intended to implement this requirement for the Medicare program. Therefore, we have not mandated the use of the State-developed description for Medicare providers.

Comment: Four commenters disagreed with our suggestion in the interim final rule that States may prescribe the content of the information disseminated by Medicaid providers, including requiring ''that Medicaid providers use the State-developed descriptions of State law only'' (57 FR 8197). These commenters urged that we withdraw this suggestion in the final rule. Another commenter asserted that providers may misconstrue our suggestion to mean that they should use the State's description only, when providers should be allowed to supplement these descriptions with their own materials as needed. This commenter suggested that we avoid the use of the word ''only'' in this context. Alternatively, States could allow providers to incorporate the general information contained in the State-developed descriptions of State law into their own packages of materials that include their written policies regarding the implementation of an individual's rights under the advance directive provision.

Response: States have the authority to administer the Medicaid program under broad Federal guidelines coupled with each State's own statutory and regulatory requirements. The advance directive provisions of the statute, as well as the implementing regulations, have been designed to ensure that States maintain maximum autonomy and flexibility in this area. The discussion in the preamble to the interim final rule merely reflected possible approaches that States could take in providing the required information, and we continue to believe that the approaches are consistent with the statutory requirements. Therefore, each State's law determines if providers are restricted to using only the State-developed descriptions of State law regarding advanced directives or if providers are permitted to supplement these descriptions with their written policies concerning advanced directives.

Comment: Several commenters suggested that, to the extent that providers are allowed to develop their own descriptions of State law, the final rule should require States to have a process in place to evaluate and pre-approve the provider's particular version of the description of the State's law. The commenter believes that without such a requirement, the various descriptions being used by different providers may be inaccurate or inconsistent. To ensure uniformity, the commenter suggested that HCFA actively encourage States to use a single, uniform State description.

Response: We believe it to be beyond the intent of the statute to require that States evaluate and pre-approve the provider's versions of any description of State law. The States themselves are best equipped to determine whether or not they should evaluate and pre-approve a provider's description of State law, and we have preserved the flexibility for them to do so in this final regulation. However, it is important to note that section 1902(a)(58) of the Act requires that the State, acting through a State agency, association, or other private non-profit entity, develop a written description of the State law

concerning advance directives to be distributed to Medicaid providers and HMOs. HCFA believes that the availability of this document and the coordination among all providers will ensure that the descriptions are accurate and consistent.

Comment: Many commenters responded to our request for recommendations on what would be a reasonable time period for States and providers to incorporate descriptions of changes in State law into provider information packages and for providers to distribute this information. The recommended time periods varied widely, ranging from as soon as practicable, to 60 days, not less than 90 days, not more than 4 to 6 months, annually (requested by HMOs, in particular, to coincide with the annual schedule for reprinting and distribution of enrollment materials, also see section II.B, below), and no later than by the time of the effective date of individual State law. In addition, a number of commenters suggested a two-step time frame—a deadline on States to revise the State description of the law and issue copies to providers and organizations and a second deadline on providers to revise and disseminate their materials to adult individuals coming under their care. Two commenters suggested that we prescribe the timing requirements in the regulations.

In addition, one commenter expressed concern that providers may think they have some obligation for monitoring and interpreting changes in State law. This commenter believes that it is inappropriate to depend on providers to monitor or interpret changes in State law and that Congress would not require States to develop descriptions of their laws without the implicit intent that States would also be responsible for updating the descriptions. Unless States are required to update their own description, the commenter believes that consistency will be lost over time. The commenter suggested that HCFA clarify that it is the responsibility of States, not the providers, to update these descriptions.

Response: In general, we believe that States, as well as providers and managed care plans, will wish to revise advance directive information packages promptly in order to ensure that they disseminate the most accurate information possible concerning State law changes relating to advance directive issues. Realistically, however, we know that it will take some time to receive the information, revise their summary descriptions of State law, and print and disseminate these updated summaries. Based on our review of all recommendations, we are imposing two new independent requirements for States and providers for updating descriptions of State law. First, under the Medicaid program, we are requiring that States revise their descriptions of State law and furnish copies of revised descriptions to providers and managed care plans within 60 days from the effective date of a change in State law. Second, under both Medicare and Medicaid, managed care plans and all providers must provide updated written information to adult individuals within 90 days of the effective date of any new State law. Thus, in situations where States have an obligation under the Medicaid program to develop descriptions of State law, we are allowing providers an additional 30 days in order to permit them sufficient time to adopt language from State law or State-developed descriptions where necessary.

We are revising §§ 431.20(b) and 489.102(a)(1)(i) to reflect these two requirements. (See the discussion in section II.B below regarding timeframes for managed care plans.) States or providers that disseminate outdated materials during the grace periods established by this regulation would not be violating the Federal requirements regarding the dissemination of written information about an individual's rights under State law only. However, this grace period will not protect a provider from an action in State or Federal court resulting from any harm caused by the dissemination of outdated material. In addition, States are free to impose more restrictive requirements on the dissemination of updated materials.

Also, § 430.12(c)(1)(ii) requires that a State amend its State plan to reflect material changes in State law. Since the State is required to include a written description of its law concerning advance directives in its State plan, any changes in State law concerning advance directives must not only be furnished to providers participating in the Medicaid program, but must also be included in the State plan. To be consistent, we are revising § 430.12(c)(1)(ii) to require the amendment to be submitted as soon as possible, but no later than 60 days from the effective date of the law.

Comment: Another commenter suggested that the Secretary be given 60 days to notify State Medicaid agencies, licensure agencies and providers of changes in Federal law, and that these groups then have 60 days from the date of Federal notification to implement corresponding changes in their respective responsibilities.

Response: Changes in Federal law take effect in accordance with the effective dates established by the Congress in the statute in which they are enacted. The Secretary generally is not responsible for notifying States or providers of statutory changes; nor are the effective dates of statutory changes generally subject to the Secretary's discretion.

Comment: One commenter suggested that the determination of when State case law has changed for purposes of mandatory alteration of policies and procedures be uniformly fixed at the highest appellate court of a State, so that informational materials may be amended at a consistent time throughout affected States. However, the commenter also believes that some provision should be made for discretionary changes in the statement of State law disseminated by the State, based upon an analysis of intermediate appellate or trial court decisions.

Response: We have already outlined the timeframes for providers to incorporate descriptions of State law into their policies and procedures. With regards to revisions or amendments that may occur as a result of appellate or trial court decisions, we believe that States are best suited to respond timely to such changes. Therefore, States should be responsible, on a case-by-case basis, for determining when State law has changed and thus, when providers must revise informational materials. Medicare and Medicaid providers may have wide discretion in designing informational materials for dissemination to patients and residents, or States may institute more specific requirements under either or both programs. We do not choose to abridge State flexibility on this issue.

Provider Agreements

Comment: One commenter expressed concern that § 431.107(b)(4) of the interim final rule appears to require that the State Medicaid agency revise provider agreements to incorporate the requirement that providers comply with the advance directives requirements. The commenter believes that this requirement can be made binding upon the State Medicaid agencies and providers without the administrative burden associated with issuing new provider agreements.

Response: Section 431.107(b)(4) requires that a State plan must provide for an agreement between the Medicaid agency and each provider or organization furnishing services under the plan in which the provider or organization agrees to comply with the applicable advance directive

requirements. The changes to § 431.107(b)(4) do not require that States issue new provider agreements. States frequently use provider agreements that are general in nature but that bind the provider to adhere to the provider requirements stipulated in the State's regulations or manuals. It is not our intention to change, by this regulation, the mechanics by which States impose requirements upon their Medicaid providers.

States have flexibility to prescribe procedures for complying with additional Federal requirements relating to its provider agreement. A determination should be made by each State regarding whether revisions or new provider agreements are necessary, or whether the agreement is all-inclusive, that is, the provider agrees to comply with all additional Federal requirements, and no revisions are needed.

Enforcement Procedures

Comment: Some commenters requested further instructions on the statement in the preamble of the interim final rule that hospitals and hospices must inform HCFA in writing of the ''date they achieve compliance'' (57 FR 8195), while another believes this requirement is unnecessary. One commenter suggested that §§ 417.436(d) and 483.10 be amended to include an address and telephone number at which HCFA will receive non-compliance complaints.

Response: The process for hospitals and hospices to inform HCFA of the day they achieved compliance was set forth through instructions issued by HCFA in October, 1992. The reporting process is now complete. The purpose of this process was to provide us with evidence that hospitals and hospices were maintaining policies that would provide written information to adult individuals of their rights to accept or refuse medical or surgical treatment and to formulate an advance directive. These rights are subsequently referred to as the ''advance directive requirements''. This mechanism was designed so we would not need to conduct immediate on-site inspections of the nearly 8,000 hospitals and hospices to determine compliance with the advance directive requirements.

In addition, we note that to ensure that HHAs, SNFs and NFs are complying with the advance directives requirements, these entities will be assessed for compliance during the next routine on-site survey. The advance directive requirements are part of the resident rights requirements at § 483.10(b)(8) for SNFs and NFs and the patient rights condition of participation at § 484.10(c)(2)(ii) for HHAs.

Concerning where an individual can file a complaint for non-compliance, we have decided to follow the usual procedure and delegate the responsibility to receive complaints and initiate investigations to the State survey and certification agency under the authority of Regional Administrators. We have added new provisions at §§ 417.436(d)(3) and 489.102(a)(4) to require that providers and HMOs and CMPs must inform individuals that complaints concerning non-compliance with the advance directive requirements may be filed with the State survey and certification agency. This may be accomplished, for example, by posting a statement of an individual's rights under the advance directives requirements of the law and the name, address and telephone number of the State survey and certification agency to which the individual should file his or her complaint. In addition, we are amending § 483.10(b)(7)(iv) to require a facility to include in its written description of a resident's legal right a statement that the resident may file a complaint with the survey and certification agency concerning noncompliance with the advance directives requirements. Section 484.10(f) of the HHA patient rights condition of participation also has been amended to specify that the patient also has the right to use the home health hotline to lodge complaints concerning the implementation of the advance directive requirements. In addition, the Medicare Hotline (1–800–638–6833) is another avenue to register complaints.

Comment: One commenter asked how soon after a hospital adds a new unit or service would it have to report to HCFA regarding achieving compliance with the advance directive requirements.

Response: We are not requiring hospitals to notify HCFA concerning compliance with the advance directive requirements each time a new unit or service is added. However, any new unit or service that is added to a hospital would be expected to meet the advance directive requirements for all new admissions as soon as it began operation and would be monitored in accordance with the normal enforcement procedures, as outlined above.

Comment: One commenter suggested that we grant hospitals that are accredited by the Joint Committee on the Accreditation of Hospitals (JCAHO) deemed status for advance directive requirements now that the JCAHO has incorporated advance directives requirements into its standards. Another commenter questioned if HCFA will ask State departments of health to monitor compliance with the advance directive requirements within the context of the Medicare validation survey process.

Response: National organizations that have been granted recognition of their accrediting programs are required to provide reasonable assurance to HCFA that the providers that they accredit meet the Medicare conditions of participation. However, since the advance directives requirements are not part of the Medicare conditions of participation for hospitals, accredited hospitals are not deemed to meet this requirement based on an accreditation survey.

Instead, each hospital and hospice must comply with the advance directive requirements as part of its provider agreement with HCFA. As discussed above, each hospital (including any accredited by JCAHO or AOA) was required to inform HCFA, in writing, of the date that it achieved compliance with the advance directive requirements. As part of the compliance process, each hospital submitted an attestation statement signed and dated by its hospital administrator that informed HCFA of compliance. Compliance with the advance directive requirements is verified as part of the next routine on-site survey for hospices and non-accredited hospitals. For accredited hospitals, compliance is verified during any complaint investigation and at the time of validation surveys. This verification is a one-time event for both hospitals and hospices, unless a specific complaint is received about advance directives. All complaints about advance directives are investigated; failure to comply with the advance directives requirements is a cause for termination of a hospice's or hospital's provider agreement.

Comment: Two commenters suggested we extend the time period for the State agency to conduct an investigation to determine if a facility is in compliance with the advance directives provisions to the date when the provider agreement with HCFA is terminated. Currently, the time period for written notification of deficiencies is 15 days from the initial visit and the commenters are requesting that this be changed to 30 days. The commenters believe that 15 days is not sufficient time to permit adequate communication with all entities involved in many health care systems, particularly when providers are members of hospital chains, where information needs to be exchanged between corporate headquarters, attorneys, and the particular facility cited.

Response: Although we give providers 15 days' advance notice before termination of the provider agreement, the provider usually has 90 days to correct a deficiency, between the time of the survey and the effective date of termination. Furthermore, enforcement procedures for deficiencies in meeting the advance directives requirements are handled in the same manner as other types of deficiencies. Medicare operational guidelines establish procedures and timeframes that we believe allow a provider ample opportunity to make corrections and to exchange information related to the deficiencies before the effective date of the actual termination. The communication needs cited by the commenters are not unique to situations involving non-compliance with the advance directives provisions, and thus we do not believe that changes in our termination procedures are warranted.

Miscellaneous Issues

Comment: One commenter expressed concern with the applicability of the provider obligations contained in the advance directive requirements to independent personal care providers, as opposed to a home health agency, and the consequences of requiring individual personal care providers to comply with these requirements. The commenter asserted that independent personal care providers typically are semi-skilled workers who, in many instances, perform non-medical functions. The commenter believes that in many cases these individuals would not be able to comply with the advance directive requirements for providers. Therefore, the commenter requested that R.N. supervisors, rather than the personal care attendants, fulfill the requirements for personal care services. Furthermore, the commenter asserted that the obligations of the statute appear to apply only to providers and organizations that furnish ''medical care.'' Since independent personal care providers generally do not furnish medical care, they are not subject to the statute.

Response: Section 1902(a)(57) of the Act specifically requires that each State Medicaid program assure that all affected providers, including personal care providers, meet the requirements of section 1902(w) of the Act as well as all other Medicaid requirements. The statute does not prohibit a personal care provider from contracting with another entity to carry out the advance directive requirements, but personal care providers should enter into these contracts with the knowledge that they will still be legally responsible for ensuring that advance directive requirements are met. To clarify this point, we have revised § 489.102(b)(3)(ii) to specify that all providers, including personal care providers, are permitted to contract with another entity to furnish this information but are still legally responsible for ensuring that advance directive requirements are met.

Thus, a personal care provider may either perform the requirements of the advance directive provisions, or it may work with others to fulfill the requirements of this provision. If a personal care provider enters into a contract or other written agreement with another entity (for example, case manager, local home health agency, hospital discharge planner, or others) to satisfy the requirements of section 1902(w) of the Act, we suggest that such a written agreement specify that the person or entity is satisfying the requirements of section 1902(w) of the Act. Thus, the agreement should specify that the person or entity would (1) furnish written information (usually prepared by the State) to individuals receiving care regarding their rights under State law to make decisions concerning medical care; (2) furnish the providers written policies respecting the implementation of such rights (including any conscientious objections allowed by State law); (3) document in the individual's medical record whether or not the individual has executed an advance directive; (4) not discriminate against an individual based on whether or not the individual has executed an advance directive; (5) ensure compliance with State law; and (6) educate staff (if applicable) and community (which can be defined as the population served) on issues concerning advance directives.

Although the commenter's question centered on the applicability of the provider obligations for personal care providers, we have revised §§ 489.102(a)(1)(i), 417.436(d)(1)(i)(A) and 483.10(b)(8) to permit all providers to enter into agreements such as the one described above.

Comment: One commenter expressed confusion over what he believes to be an apparent conflict between the advance directive provisions of this regulation and the election procedures for Medicare hospice patients. Medicare-certified hospice programs are required to inform new patients at the time they elect hospice care of what types of care the hospice provides. At that point, the patient exercises a choice with respect to services that may include an acknowledgement that life sustaining treatment would be withheld.

Response: We do not believe that there is an inconsistency between the advance directives provisions of this regulation and the election procedures for Medicare hospice patients. In fact, we believe these requirements are entirely consistent with the intended exchange of views and information that takes place when an individual elects hospice care. Hospice patients may appropriately be asked if they have an advance directive even though their choice of hospice care reflects a preference for palliative rather than curative treatment. We rely upon the hospice to inform the patient fully at the time of the hospice election as to the nature of the care. The hospice, after being informed of the patient's choice, will inform the patient of its treatment plan, policies and whether the patient's advance directive may be implemented. As part of the process, the patient will be informed if the advance directive will not be honored because State law permits the facility to object to implementing an advance directive on the basis of conscience.

B. Comments Specific to Managed Care Plans

Scope

Comment: One commenter questioned whether the advance directive requirements apply to both risk-based and cost-reimbursed Medicare HMOs and CMPs.

Response: 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 concerning the right to accept or refuse medical or surgical treatment and to formulate an advance directives with respect to all adult individuals receiving medical care through the provider or organization. These requirements apply to both risk-based and cost-reimbursed Medicare HMOs and CMPs. In addition, organizations providing services to Medicaid enrollees, such as health insurance organizations, prepaid health plans and Medicaid HMOs, also must meet these requirements. The statute does not authorize exceptions for certain model types.

Advance Directives Information Provided by Managed Care Plans

Comment: Several commenters suggested that HMOs and CMPs be allowed to provide information

concerning an adult individual's right to accept or refuse medical or surgical treatment and to formulate an advance directive only to the subscriber of the plan, who would then share this information with his or her covered dependents. This would prevent multiple mailings of material to the same address.

Response: We concur with the commenter that HMOs and CMPs are permitted to provide information concerning advance directives only to the subscriber of the plan. Typically, HMOs and CMPs send enrollment packages to the subscriber who in turn shares the information with his or her dependents. All the information that a subscriber needs, including membership cards, evidence of coverage, and listings of participating providers are usually sent in this package. Sections 1866(f)(1) and 1902(w)(1) of the Act require that written materials concerning an individual's right to accept or refuse medical or surgical treatment and to formulate an advance directive be provided to all adult individuals receiving medical care by or through the provider or organization. However, since it is customary for subscribers to share membership material with adult dependents, we believe that permitting HMOs and CMPs to send advance directives material only to subscribers (who would then be instructed to share the material with adult dependents) would fulfill the statutory requirement. The membership material should indicate to subscribers that they are expected to share the advance directives information with adult dependents.

Comment: One commenter requested clarification as to what kind of documentation an HMO or CMP is required to keep to prove that written information regarding advance directives was provided to new enrollees (for example, a patient's signature acknowledging receipt).

Response: Section 1866(f)(2)(E) of the Act requires HMOs or CMPs to provide written information to adult individuals concerning their rights under State law to accept or refuse medical or surgical treatment and to formulate an advance directive to enrollees at the time of enrollment. Although we encourage recordkeeping actions such as a notation in the beneficiaries' medical record, we are not requiring that an HMO document that it has provided the material to each individual enrollee. Rather, we will verify compliance with this requirement by reviewing the materials provided to new enrollees and examining an HMO's or CMP's systems and procedures to ensure that it provides the materials timely.

Comment: A few commenters expressed concern over the meaning of ''at the time of enrollment.'' Many individuals join HMOs or CMPs through their employers. However, employers often do not relay enrollment information to health care plans until after the effective date of coverage, making the requirement impossible to meet. In addition, the requirement that information be provided at the time of enrollment could force health care plans to mail the advance directive information before other membership materials, such as membership cards and directories, creating unnecessary added costs.

Response: In accordance with section 1866(f)(1)(B) of the Act, § 417.436(d)(1)(ii) requires that an HMO or CMP provide written information concerning its policies that implement advance directives to adult individuals at the time of enrollment (57 FR 8198). In view of the comments we received on this issue, we recognize that it would be helpful to clarify how managed care plans may meet this requirement. For enrollees that join managed care plans as individuals, the meaning of ''at the time of enrollment'' is relatively straightforward, that is, as soon as possible after the application is received, but before the effective date of coverage. However, for individuals that join managed care plans through an employer group, we are clarifying that ''at the time of enrollment'' means at the time that the employer group enrolls the beneficiary into the plan. In such situations, the managed care plan may not be informed of the enrollment immediately; therefore, to implement the requirements of the statute, we believe it would be permissible for the employer group to provide, on behalf of the organization, information concerning an adult individual's right to accept or refuse medical or surgical treatment and to formulate an advance directive. In keeping with other provisions of this rule, the HMO or CMP may incorporate such information into the marketing material that the managed care plan supplies to employer groups so that the information is disseminated when the employer distributes other plan marketing materials to potential enrollees.

Comment: One commenter questioned whether ''at the time of enrollment'' referred not only to individuals' initial enrollments but also to individuals' annual re-enrollments.

Response: We believe that the intent of the legislation is to require that the written advance directives information be provided at the time of initial enrollment. Therefore, we are not requiring that written advance directives material be provided for individuals renewing their enrollments. We have revised § 417.436(d)(1)(ii) to clarify that this information needs to be provided only at the time of initial enrollment.

Comment: Several commenters requested clarification regarding whether a managed care plan's written policies on advance directives must provide detailed information regarding the advance directive policies of its contracting providers. Commenters believe that requiring a plan to disseminate information regarding the policies of its contracting providers would be overly burdensome and duplicative. These commenters believe that health care plans should be allowed to inform enrollees that each provider has its own policies and that enrollees may request more information from the individual provider.

Response: We believe that information regarding whether contracting providers will implement advance directives is an integral part of each managed care plan's advance directives policies. Without such information, enrollees will not be able to make informed decisions regarding advance directives. The interim final rule provided two options describing contracting providers' policies. The first option allows a managed care plan to develop a policy that embraces all of its providers' policies. The second option allows a managed care plan to simply note that differences among its providers policies exist, and that more information is available from the organization upon request. These options do not necessarily require detailed information regarding each provider's policies. For example, if all contracting providers implement all advance directives that meet State requirements, the plan could simply note this information. On the other hand, if one or more of the contracting providers have a more limited policy (for example, a hospital exercising a reservation of conscience), the plan may either (1) provide a written policy that states the restrictions these providers placed on advance directives or (2) note that some providers may object to implementing an advance directive, but that more information is available upon request. At a minimum, plans should have information available upon request as to which contracting institutions place limits on implementing advance directives.

Comment: One commenter believes that the discussion in the preamble to the interim final rule concerning the content and format of the written

information to be provided to each adult individual exceeded the provisions of section 1866(f) of the Act. (See 57 FR 8196.) Specifically, the commenter objected to our statement that the legally required elements of the written information would include a description of the provider's ''policies and procedures''. The commenter believes that the term ''policies and procedures'' overstates the provisions of section 1866(f) of the Act.

Response: We believe that the commenter has misinterpreted a parenthetical statement in the interim final rule that the summary notice would need to contain the legally required elements, including a description of the provider's policy and procedures. In accordance with section 1866(f) of the Act, §§ 417.436(d)(1)(i)(B) and 489.102(a)(1)(ii) specify that the written information provided to each adult individual include a description of ''the written policies'' of an organization or a provider concerning the organization's policies respecting the implementation of an individual's advance directive rights. The information provided to enrollees should be specific to the plan, and include information on the organization's written policies regarding the execution of a beneficiary's advance directive.

Comment: One commenter questioned whether the regulations require physicians that contract with HMOs to develop policies regarding advance directives or if physicians are required to comply with the HMO policy.

Response: The statute and our regulations do not address this issue. The individual physician's role and responsibilities will be determined by State law and the HMO's contracts and policy. For plans that operate in more than one State, the HMO should insure that contracting physicians follow the applicable statutes of the State or States in which they practice.

Comment: One commenter suggested that managed care plans should have to maintain written policies and procedures only for individuals for whom they provide care directly. Thus, plans that arrange for services, but do not provide them directly, would not have to develop policies.

Response: Under sections 1866(f)(1), 1902(a)(57), and 1902(w) of the Act, all managed care plans with Medicare or Medicaid contracts are required to maintain written policies concerning advance directives, with respect to all adult individuals receiving medical care by or through the organization. As noted above, the statute does not authorize exceptions for certain model types.

Comment: One commenter asserted that HMOs and CMPs should not be solely responsible for locating alternate providers if a provider will not honor an advance directive as a matter of conscience.

Response: In accordance with section 1866(f)(1)(B) of the Act, § 417.436(d)(1)(iii) requires that an HMO or CMP document in the medical record whether or not an individual has executed an advance directive. Section 417.436(d)(1)(iii) also specifies that HMOs and CMPs 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 to conscientiously object. However, neither the statute nor the regulations require an HMO or CMP to locate alternative providers when a provider chooses, as a matter of conscience, not to honor an individual's advance directive. We do not believe it is appropriate to require this. However, it is reasonable to expect that assistance would be provided for a transfer at the patient's request. We note that an HMO or CMP would be required to comply with any applicable State law to that effect.

Description of State Law

Comment: One commenter requested that we explicitly state that the requirement for managed care plans to provide information to their enrollees concerning an individual's rights under State law applies only to the law of the State in which the HMO or CMP provides services.

Response: We concur and have revised § 417.436(d)(1)(i)(A) to clarify that HMOs or CMPs are required to provide information that relates to the law of the State in which services are being provided. For plans that have multi-state provider networks, the information should reference the advance directive laws of all States in the service area.

Documentation in Individual Medical Records

Comment: Several commenters questioned who should be ultimately responsible for documenting in an enrollee's medical record whether or not the individual has executed an advance directive—the physician or physician group. Most of these commenters recommended that physicians that practice in HMOs or CMPs should be held responsible, and that the HMO or CMP should not have to ensure that these physicians document the medical record. Another commenter asserted that physicians should not be required to obtain advance directives information on behalf of HMOs or CMPs. This commenter believes that a HMO or CMP should be required to maintain its own advance directives records and relay the information to the physicians.

Response: Sections 1866(f)(1), 1902(a)(57) and 1902(w)(1) of the Act clearly specify that the advance directives requirements apply to ''providers and organizations''. Thus, we believe that an HMO or CMP is ultimately responsible for ensuring that the existence of an advance directive is documented in an enrollee's medical records. HMOs or CMPs may use any procedures they wish, consistent with State law, to ensure that this requirement is met. We do not believe it would be consistent with the intent of the statute to require any particular process. One possible process would be for the HMO or CMP to amend contracts with its physicians to require them to obtain the information. However, the HMO or CMP would still need to verify that its physicians document in the medical record whether or not an individual has executed an advance directive.

Comment: One commenter requested confirmation that HMOs or CMPs will not be out of compliance with the requirement to document the medical record if some enrollees never have a medical record because they never used medical services.

Response: We agree that if a medical record is not created, the requirement to document in the medical record whether or not an advance directive exists would not apply.

Comment: Several commenters stated that the requirement concerning the documentation of medical records should not be made applicable to individual practice associations (IPAs), network-model or group-model HMOs because these organizations characteristically do not generate or have access to patient medical records. Therefore, these organizations cannot fulfill the requirement that they document in the enrollee's medical record whether or not the individual has executed an advance directive. One commenter suggested that managed care plans, particularly IPAs, should be allowed to use a centralized recordkeeping system rather than the individual medical record to document whether or not the individual has executed an advance directive.

Response: Under sections 1866(f)(1)(B) and 1902(w)(1)(B) of the Act, all managed care organizations must document in the individual's medical record whether or not the individual has executed an advance

directive. Managed care plans may use a centralized recordkeeping system to maintain information on whether or not an individual has executed an advance directive. However, the use of a centralized recordkeeping system may not necessarily meet the requirement that managed care plans document in each enrollee's medical record whether or not the individual has executed an advance directive. If the central file is a medical record file, then the use of the centralized file would meet the requirement. If the central file is not a medical file (for example, it only contains enrollment and general policy information concerning advance directives), the managed care plan also would have to document in the medical record whether or not an individual has executed an advance directive. Again, the statute does not authorize exemptions for certain managed care plans due to their organizational structure.

Comment: Several commenters stated that clarification is needed regarding the reasonable steps a managed care plan must take to document in the member's record whether or not the member has executed an advance directive. Several commenters believed that enrollees should be responsible for notifying their health care plan as to whether they have executed an advance directive.

Response: As noted above, the statute requires that each enrollee's medical record contain documentation as to whether or not the enrollee has executed an advance directive. The interim final rule gives several examples of appropriate methods for obtaining the information needed to document medical records (57 FR 8197). For example, a managed care plan may modify its contracts with its primary care providers to require that the advance directive information be recorded when an enrollee's medical record is created. Alternatively, plans could request members to provide this information by mail. Whatever method the plan uses, it must obtain some response from the enrollee. If an enrollee refuses to disclose information regarding whether or not he or she has an advance directive, the managed care plan should record the enrollees refusal to answer.

Comment: One commenter asked if a managed care plan is required to contact patients and ask definitive questions concerning life-sustaining treatment.

Response: Section 417.436(d)(1)(iii) requires only that an HMO or CMP document in the medical record whether or not an enrollee has executed an advance directive. It does not require HMOs or CMPs to document the type of advance directive or ask specific questions regarding an enrollee's wishes for life-sustaining treatment. As we have noted earlier, an HMO or CMP would be required to comply with any applicable State law or other Federal requirement that may make it necessary to take additional steps such as those discussed by the commenter.

Comment: One commenter noted that the interim final rule is unclear as to whether or not the documentation must be done for all current enrollees as well as for all new enrollees.

Response: Section 4206(e)(2) of OBRA '90 specifies that for managed care plans, the advance directive provisions took effect on December 1, 1991. Therefore, documentation of the medical record is required only for new enrollees since that date.

Comment: One commenter expressed concern that managed care plans may face liability if enrollees change, cancel or execute new advance directives after the plan has documented the medical record, since the plan's information may not match the enrollees' wishes.

Response: Neither the statutory provisions nor the regulations concerning advance directives address the issue of liability in cases where the patient changes an advance directive. We would defer to State law for a decision on liability in this type of situation.

Sections 1866(f)(1)(B) and 1902(w)(1)(B) of the Act and implementing regulations require only that the managed care plan document whether or not the enrollee has executed an advance directive, not necessarily the contents of the advance directive. After the medical record is documented, we are not imposing further medical record documentation requirements on managed care plans in this rule. However, if an enrollee informed the plan that he or she had changed or cancelled an advance directive, we would expect a health plan to update the medical record information. In addition, the plan would be responsible for complying with applicable State and Federal requirements regarding the implementation of the new advance directive.

Time Required To Update Descriptions of State Law

Comment: Many managed care plans responded to our request for an estimate of an appropriate amount of time to update information on advance directives after changes in State law. The estimated time frames ranged from 30 days to 1 year after all approvals are obtained.

Response: We have thoroughly reviewed the many suggestions concerning timeframes for updating information on advance directives after changes in State law. Since information concerning advance directives is often included in marketing material, which is reviewed by federal or State regulators on an annual basis, we considered permitting plans to update their advance directive information on an annual basis. For some individuals, however, one of the factors that may contribute to the selection of a plan may be the individual's belief that the plan would honor its advance directive. We believe that distributing erroneous or outdated advance directive information to potential enrollees could unfairly influence their decision to enroll in a given plan. Therefore, as discussed above in section IV.A, managed care plans, like all other providers, are required to update their advance directives information as soon as possible but no later than 90 days after the effective date of a change in State law. Applying the 90-day time limit for plans to update changes in State laws will ensure that potential enrollees are provided with accurate information before enrolling in a plan while at the same time providing managed care plans with a reasonable amount of time in which to update their information. We have revised §§ 417.436(d)(1)(i)(A) and 434.28 to reflect this requirement.

We also have revised § 431.20(b) to require that revisions to the written descriptions of State law must be incorporated in such advance directive information and distributed to Medicaid providers, and HMOs and CMPs, as soon as possible, but no later than 60 days from the effective date of the change. We believe that this requirement is necessary to keep potential and existing enrollees informed about advance directive changes that could affect their care decisions. We note that, in addition to the use of marketing materials, plans may disseminate information about changes in State law concerning advance directive by using their community education programs and procedures, mailing information directly to all enrollees, or using any other method they believe may help further provide enrollees with updated information.

Ensuring Compliance With State Law

Comment: One commenter believes that organizations that contract with providers to provide health care, but do not provide health care directly, should not be required to ensure that providers comply with State law.

Response: Sections 1866(f)(1)(D) and 1902(w)(1)(D) of the Act and implementing regulations at § 417.436(d)(1)(i)(A) require that a prepaid or eligible organization maintain written policies and procedures that ensure compliance with the requirements of applicable State law regarding an adult individual's right under State law to accept or refuse medical or surgical treatment and to formulate an advance directive. As discussed above, there is no statutory basis under which we could exempt certain prepaid health care plans due to their organizational structure.

Comment: One commenter wanted general standards for managed care plans to use in ensuring compliance with State law.

Response: We note that plans have followed varying practices in complying with State law and we do not believe it is necessary or appropriate to prescribe standards to achieve this. State survey agencies would have the opportunity to ensure that plans have complied with State law concerning an adult individual's rights under State law to accept or refuse medical or surgical treatment and to formulate an advance directive.

Education of Staff and Community

Comment: One commenter requested that we define ''community'' for purposes of a managed care plan's community education responsibilities.

Response: Typically, the community served by a managed care plan is defined as the organization's service area.

Comment: One commenter suggested that HMOs and other health care providers be allowed to combine their community education programs to meet the community education requirement.

Response: In accordance with sections 1866(f)(1)(E) and 1902(w)(1)(E) of the Act, § 417.436(d)(1)(vii) specifically permits HMOs or CMPs to provide community education regarding advance directives either directly or in concert with other providers.

Comment: One commenter requested clarification on what constitutes community education in the case of managed care plans. Specifically, the commenter questioned whether including information on advance directives in the marketing brochure would be adequate.

Response: The meaning of community education is no different for managed care plans than it is for other Medicare and Medicaid providers. Plans can distribute educational materials to the public on advance directives, or they can provide seminars to the public. As mentioned earlier, the community education requirement does not need to be conducted through a community relations department, but information on advance directives must be conveyed to the community. A marketing brochure that contains the required information, and is distributed to the relevant community, may contribute to the statute's community education goals. Although we will evaluate the community education efforts of each managed care plan on an individual basis, generally we believe that activities such as seminars or direct community mailing, in combination with the distribution of marketing materials regarding advance directives, would be needed to satisfy the community education requirements. In summary, there are numerous methods for conducting community education, and we encourage creativity among the plans to reach as large a number of individuals as would be reasonable for their service area.

Comment: One commenter requested clarification regarding whether the educational materials must be approved by HCFA.

Response: Any marketing material that discusses the risk-based or cost-reimbursed HMO programs and is provided to Medicare beneficiaries must be approved by HCFA. Material that discusses advance directives, but does not discuss these programs, does not need to be approved. We do not approve marketing material for HCPPs and Medicaid organizations; however, these organizations must comply with applicable State requirements regarding approval for materials.

Comment: Two commenters questioned how HMOs and CMPs could obtain information on the existence of advance directives through the community education campaigns.

Response: The interim final rule stated that it may prove acceptable for a provider or organization to obtain information on the existence of advance directives through a community education campaign (57 FR 8197). The point of this statement was that we do not wish to limit the alternatives available to a provider or an HMO or CMP for obtaining this information. Thus, if an HMO finds it feasible to collect such information from some of its enrollees during a community education campaign, we would not object. The interim final rule discussed several other more likely methods for obtaining information about the existence of an advance directive, and we urge providers and organizations to use the approach that they find most effective.

Comment: One commenter requested clarification of the requirement for educating staff concerning advance directives.

Response: Sections 1866(f)(1)(E) and 1902(w)(1)(E) of the Act require that a provider or organization educate both staff and the community on issues concerning advance directives. In general, we would expect an organization to provide parallel educational information to its staff as it does for the community, that is, inform the public of their rights under State law to make decisions concerning the receipt of medical care by or through the provider or organization; the right to formulate advance directives; and the provider or organization's implementation policy concerning advance directives. Thus, a managed care plan is responsible for providing staff education to ensure that its advance directive policies and procedures are executed timely and correctly.

C. Comments on Appendices

Comment: Two commenters requested that in our public information document, ''Advance Directives—The Patient's Right to Decide'', which was published as Appendix I to the interim final rule, nurses should be specifically mentioned as one of the disciplines individuals may wish to talk to. Another commenter suggested that, under the question ''What Should I Do With My Advance Directive If I Choose to Have One?'', we should recommend that individuals review their advance directives at least annually and communicate any revisions to their physicians. In addition, several organizations submitted suggestions for additions to the organizations and publications listed as ''National Resources on Advance Directives'', which was published as Appendix II to the preamble of the interim final rule.

Response: We are not reprinting either of these two documents in this final rule. However, we have passed these suggestions on to HCFA's Office of Public Affairs, which is responsible for the development and distribution of this information. We note that the following organizations and publications were suggested by commenters for addition to the national resource list on advance directive issues:

''American Life League, Inc.'', P.O. Box 1350, Stafford, Virginia 22554, (703) 659–4171.

''Advance Directive Protocols and the Patient Self-Determination Act: A Resource Manual for the Development of Institutional Protocols.'' Choice in

Dying, 200 Varick Street, New York 10014.

''Patient Self-Determination Act of 1990, Implementation Issues.'' This document deals specifically with long-term care issues. American Association of Homes and Services for the Aging, 901 E. Street, N.W., Suite 500, Washington, D.C. 20004–2037.

V. Changes to Provisions of the Interim Final Rule

As discussed above in section IV of this preamble, we are making several changes to the regulations based on public comments. The specific revisions to the current advance directive regulations are as follows:

- We are revising §§ 417.436(d)(1)(i)(A), 483.10(b)(8), and 489.102(a)(1)(i) to clarify that providers and HMOs or CMPs are permitted to contract with other entities to furnish information concerning the advance directive requirements but are still legally responsible for ensuring that the statutory requirements are met.
- We are revising §§ 417.436(d)(1)(i)(A), 430.12(c)(1)(ii), 431.20(b), 434.28, and 489.102(a)(1)(i) to clarify our requirements when changes to State advance directive laws are enacted.

When changes to State laws are enacted, States are required under § 431.20(b) to provide revised copies of their descriptions of State law to Medicaid providers and HMOs and CMPs as soon as possible, but no later than 60 days from the effective date of the law. Within that same timeframe, States are required under § 430.12(c)(ii) to amend their State plan.

In turn, providers are required under § 489.102(a)(1)(i) to revise and disseminate the amended informational materials as soon as possible, but no later than 90 days from the effective date of the change in State law. Under §§ 417.436(d)(1)(i)(A)) and 434.28, HMOs and CMPs are required to revise their informational material as soon as possible, but no later than 90 days from the effective date of a change in State law.

- In §§ 417.436(d)(1)(i)(B) and 489.102(a)(1)(ii), we are adding a description of the minimum information that should be contained in a provider's, HMO's, or CMP's statement of limitation if an advance directive cannot be implemented because of an objection on the basis of conscience.
- We are revising §§ 417.436(d)(1)(ii), 483.10(b)(8), and 489.102(e) to clarify our policy on the provision of information about advance directives to family members or a surrogate when an individual is incapacitated. This change codifies in the regulations policy that was set forth in the preamble to the interim final rule.
- We are revising §§ 417.436(d)(1)(vii) and 489.102(a)(6) to clarify that a provider, HMO, or CMP is not required to disseminate during community education efforts the same material it gives to adult individuals at admission. Providers, HMOs and CMPs are not restricted to disseminating the same type of information in all settings; but at a minimum the community education materials 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. In addition, we have added the requirement that a provider, HMO, or CMP must be able to document its community education efforts.
- We have added new § 417.436(d)(3) and revised § 489.102(a)(4) to require that providers and HMOs or CMPs must inform individuals that complaints concerning non-compliance with the advance directive requirements may be filed with the State survey and certification agency. We have also revised § 484.10(f) to specify that a patient has the right to use the home health hotline to lodge complaints concerning the implementation of the advance directives requirements.
- In §§ 484.10(c)(2)(ii) and 489.102(b)(3)(i), we are specifying that an HHA may furnish advance directive information to a patient at the time of the first home visit, as long as the information is furnished before care is provided. In addition, we are revising § 489.102(b)(3)(ii) to specify that providers of personal care services may furnish advance directive information to a patient at the time of the first home visit, as long as the information is furnished before care is provided. Personal care providers are permitted to contract with another entity to furnish advance directives information but are still legally responsible for ensuring that the advance directive requirements are met.

VI. Impact Statement

For final rules such as this, we generally prepare a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612) unless the Secretary certifies that a final rule will not have a significant impact on a substantial number of small entities. For purposes of the RFA, we do not consider States or individuals to be small entities.

In our March 6, 1992 interim final rule, we set forth regulations amending the Medicare and Medicaid regulations governing provider agreements and contracts by implementing certain changes made by OBRA '90. Those regulations establish requirements concerning advance directives for States, hospitals, nursing facilities, skilled nursing facilities, providers of home health care or personal care services, hospice programs and managed care plans such as HMOs and CMPs. In our analysis of the impact of the interim final rule, we concluded that performing the functions necessary to meet the requirements of the interim final rule, as required by the statute, would not cause a consequential expenditure of time and effort. Although we received several comments regarding our estimate of the information collection burden associated with these requirements (see section IV of this preamble), commenters generally did not object to our overall conclusion that the advance directives requirements set forth in the interim final rule would not cause a consequential increase in expenditure of time and effort.

This final rule largely confirms provisions of the interim final rule with comment. This final rule makes only minor changes to the current advance directives regulations, such as clarifying our policy on incapacitated individuals. None of the changes to the interim final rule has more than a marginal effect on the overall costs or benefits of the advance directive requirements.

Section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis if a final rule will have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that has fewer than 50 beds and is located outside a Metropolitan Statistical Area.

We have determined, and the Secretary certifies, that this final rule will not have a significant economic impact on the operations of a substantial number of small entities or small rural hospitals. Therefore, we have not prepared a regulatory flexibility analysis or an analysis of the impact of this rule on small rural hospitals.

This regulation was not reviewed by the Office of Management and Budget.

VII. Collection of Information Requirements

Sections 417.436(d)(iii), 417.801(b)(5), 431.107(b)(4), 434.28, 483.10(b)(8), 484.10(c)(2)(ii), and 489.102(a)(2) of the

interim final rule imposed information collection requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). These information collections require hospitals, nursing facilities, skilled nursing facilities, providers of home health care or personal care services, hospice programs and HMOs and CMPs to document in the medical record whether or not an individual has executed an advanced directive. We received several comments on our estimates of the collection burdens involved. The comments and our responses are presented in detail in section IV.A of the preamble to this final rule. OMB has approved the information collection requirements set forth in our March 6, 1992 interim final rule through June 30, 1996 (Approval Number 0938–610).

List of Subjects

42 CFR Part 417

Administrative practice and procedure, Health maintenance organizations (HMOs), Medicare, Reporting and recordkeeping requirements.

42 CFR Part 430

Grants to States for Medical Assistance Programs.

42 CFR Part 431

Grant programs—health, Health facilities, Medicaid, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 434

Grant programs—health, Health maintenance organizations (HMO), Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 483

Grant programs—health, Health facilities, Health professions, Health records, Medicaid, Nursing homes, Nutrition, Reporting and recordkeeping requirements, Safety.

42 CFR Part 484

Administrative practice and procedure, Health facilities, Health professions, Home health agencies, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 489

Health facilities, Medicare, Reporting and recordkeeping requirements.

42 CFR chapter IV is amended as follows:

A. Part 417 is amended as set forth below:

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

1. The authority citation for part 417 continues to read as follows:

Authority: Secs. 1102, 1833(a)(1)(A), 1861(s)(2)(H), 1871, 1874, and 1876 of the Social Security Act (42 U.S.C. 1302, 13951(a)(1)(A), 1395x(s)(2)(H), 1395hh, 1395kk, and 1395mm); sec. 114(c) of Pub. L. 97–248 (42 U.S.C. 1395mm note); secs. 1301 through 1318 of the Public Health Service Act (42 U.S.C. 216 and 300e through 300e–17), unless otherwise noted.

2. In § 417.436, the introductory text of paragraph (d)(1) is republished, paragraphs (d)(1)(i), (d)(1)(ii) and (d)(1)(vii) are revised, the introductory text of paragraph (d)(2) is republished, paragraph (d)(2)(ii) is revised, and paragraph (d)(3) is added to read as follows:

§ 417.436 Rules for enrollees.

* * * * *

(d) *Advance directives.* (1) An HMO or CMP must maintain written policies and procedures concerning advance directives, as defined in § 489.100 of this chapter, with respect to all adult individuals receiving medical care by or through the HMO or CMP and are required to:

(i) Provide written information to those individuals concerning—

(A) Their rights under the law of the State in which the organization furnishes services (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. Such information must reflect changes in State law as soon as possible, but no later than 90 days after the effective date of the State law; and

(B) The HMO's or CMP's written policies respecting the implementation of those rights, including a clear and precise statement of limitation if the HMO or CMP cannot implement an advance directive as a matter of conscience. At a minimum, this statement should:

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

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

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

(ii) Provide the information specified in paragraphs (d)(1)(i) of this section to each enrollee at the time of initial enrollment. If an enrollee is incapacitated at the time of initial enrollment and is unable to receive information (due to the incapacitating condition or a mental disorder) or articulate whether or not he or she has executed an advance directive, the HMO or CMP may give advance directive information to the enrollee's family or surrogate in the same manner that it issues other materials about policies and procedures to the family of the incapacitated enrollee or to a surrogate or other concerned persons in accordance with State law. The HMO or CMP is not relieved of its obligation to provide this information to the enrollee once he or she is no longer incapacitated or unable to receive such information. Follow-up procedures must be in place to ensure that the information is given to the individual directly at the appropriate time.

* * * * *

(vii) Provide for community education regarding advance directives that may include material required in paragraph (d)(1)(i)(A) of this section, either directly or in concert with other providers or entities. Separate community education materials may be developed and used, at the discretion of the HMO or CMP. The same written materials are not required for 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. An HMO or CMP must be able to document its community education efforts.

(2) The HMO or CMP—(i) * * *

(ii) Is not required to implement an advance directive if, as a matter of conscience, the HMO or CMP cannot implement an advance directive and State law allows any health care provider or any agent of such provider to conscientiously object.

(3) The HMO or CMP must inform individuals that complaints concerning non-compliance with the advance directive requirements may be filed with the State survey and certification agency.

B. Part 430 is amended as set forth below:

PART 430—GRANTS TO STATES FOR MEDICAL ASSISTANCE PROGRAMS

1. The authority citation for part 430 continues to read as follows:

Authority: Sec. 1202 of the Social Security Act (42 U.S.C. 1302).

Subpart B—State Plans

2. In § 430.12, the introductory text of paragraph (c)(1) is republished, and paragraph (c)(1)(ii) is revised to read as follows:

§ 430.12 Submittal of State plan and plan amendments.

* * * * *

(c) *Plan amendments.* (1) The plan must provide that it will be amended whenever necessary to reflect—

* * * * *

(ii) Material changes in State law, organization, or policy, or in the State's operation of the Medicaid program. For changes related to advance directive requirements, amendments must be submitted as soon as possible, but no later than 60 days from the effective date of the change to State law concerning advance directives.

* * * * *

C. Part 431 is amended as set forth below:

PART 431—STATE ORGANIZATION AND GENERAL ADMINISTRATION

1. The authority citation for part 431 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

Subpart A—Single State Agency

2. In § 431.20, paragraph (b) is revised to read as follows:

§ 431.20 Advance directives.

* * * * *

(b) A State Plan must provide that the State, acting through a State agency, association, or other private nonprofit entity, develop a written description of the State law (whether statutory or as recognized by the courts of the State) concerning advance directives, as defined in § 489.100 of this chapter, to be distributed by Medicaid providers and health maintenance organizations (as specified in section 1903(m)(1)(A) of the Act) in accordance with the requirements under part 489, subpart I of this chapter. Revisions to the written descriptions as a result of changes in State law must be incorporated in such descriptions and distributed as soon as possible, but no later than 60 days from the effective date of the change in State law, to Medicaid providers and health maintenance organizations.

D. Part 434 is amended as set forth below:

PART 434—CONTRACTS

1. The authority citation for part 434 continues to read as follows:

Authority: 1102 of the Social Security Act (42 U.S.C. 1302).

Subpart C—Contracts with HMOs and PHPs: Contract Requirements

2. In subpart C, § 434.28 is revised to read as follows:

§ 434.28 Advance Directives.

A risk comprehensive contract with an HMO must provide for compliance with the requirements of subpart I of part 489 of this chapter relating to maintaining written policies and procedures respecting advance directives. This requirement includes provisions to inform and distribute written information to adult individuals concerning policies on advance directives, including a description of applicable State law. Such information must reflect changes in State law as soon as possible, but no later than 90 days after the effective date of the State law.

E. Part 483 is amended as set forth below:

PART 483—REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES

1. The authority citation for part 483 continues to read as follows:

Authority: Secs. 1102, 1819(a)–(d), 1861 (j) and (l), 1863, 1871, 1902(a)(28), 1905 (a),(c), and (d), and 1919(a)–(f) of the Social Security Act (U.S.C. 1302, 1395(i)(3)(a)–(f), 1395x (j) and (l), 1395z, 1395hh, 1396a(a)(28), 1396d (a),(c) and (d) and 1396r(a)–(f)), unless otherwise noted.

Subpart B—Requirements for Long-Term Care Facilities

2. In § 483.10, paragraph (b)(7) introductory text is republished, and paragraphs (b)(7)(iv) and (b)(8) are revised to read as follows:

§ 483.10 Resident rights.

* * * * *

(b) *Notice of rights and services.*

* * *

(7) The facility must furnish a written description of legal rights that includes— * * *

(iv) A statement that the resident may file a complaint with the State survey and certification agency concerning resident abuse, neglect, misappropriation of resident property in the facility, and non-compliance with the advance directives requirements.

(8) The facility must comply with the requirements specified in subpart I of part 489 of this chapter relating to maintaining written policies and procedures regarding advance directives. These requirements include provisions to inform and provide written information to all adult residents concerning the right to accept or refuse medical or surgical treatment and, at the individual's option, formulate an advance directive. This includes a written description of the facility's policies to implement advance directives and applicable State law. Facilities 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. If an adult individual is incapacitated at the time of admission and is unable to receive information (due to the incapacitating condition or a mental disorder) or articulate whether or not he or she has executed an advance directive, the facility 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 facility 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.

* * * * *

F. Part 484 is amended as set forth below:

PART 484—CONDITIONS OF PARTICIPATION: HOME HEALTH AGENCIES

1. The authority citation for part 484 continues to read as follows:

Authority: Sec. 1102, 1861, 1866(a), 1871, and 1891 of the Social Security Act (42 U.S.C. 1302, 1395x, 1395cc(a), 1395hh, and 1395bbb).

Subpart B—Administration

2. In § 484.10, paragraphs (c)(2)(ii) and (f) are revised to read as follows:

§ 484.10 Condition of participation: Patient rights.

* * * * *

(c) * * *

(2) * * *

(ii) The HHA complies with the requirements of subpart I of part 489 of this chapter relating to maintaining written policies and procedures

regarding advance directives. The HHA must inform and distribute written information to the patient, in advance, concerning its policies on advance directives, including a description of applicable State law. 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.

* * * * *

(f) *Standard: Home health hotline.* The patient has the right to be advised of the availability of the toll-free HHA hotline in the State. When the agency accepts the patient for treatment or care, the HHA must advise the patient in writing of the telephone number of the home health hotline established by the State, the hours of its operation, and that the purpose of the hotline is to receive complaints or questions about local HHAs. The patient also has the right to use this hotline to lodge complaints concerning the implementation of the advance directives requirements.

G. Part 489 is amended as set forth below:

PART 489—PROVIDER AND SUPPLIER AGREEMENTS

1. The authority citation for part 489 continues to read as follows:

Authority: Secs. 1102, 1861, 1864, 1866, 1867, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395x, 1395aa, 1395cc, 1395dd, and 1395hh) and sec. 602 (k) of Pub. L. 98–21 (42 U.S.C. 1395ww note).

Subpart I—Advance Directives

2. In § 489.102, paragraph (a) introductory text is republished, paragraphs (a)(1), (a)(2), (a)(4) and (a)(6) are revised, paragraph (b) introductory text is republished, paragraph (b)(3) is revised, paragraph (c) introductory text is republished, paragraph (c)(2) is revised, and paragraph (e) is added to read as follows:

§ 489.102 Requirements for providers.

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

(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 the individual's medical record 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;

* * * * *

(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: * * *

(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.

* * * * *

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

(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.

* * * * *

(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.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; Program No. 93.774, Medicare—Supplementary Medical Insurance Program; and Program No. 93.778, Medical Assistance Program)

Dated: May 31, 1995.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

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