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