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