

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