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