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.