Comment: In light of the requirement placed upon nursing facilities by the Omnibus Budget Reconciliation Act of 1987 (OBRA '87) that rights must be explained to residents in a manner that they can understand, a commenter asserted that the 3-minute information estimate is inaccurate for nursing facilities. The commenter believes that the burden imposed on these facilities is at least 30 minutes to explain the advance directives requirement in a manner the resident can understand.

Response: The commenter is correct that, in accordance with resident rights provisions of OBRA '87, § 483.10(b) requires facilities to inform residents both orally and in writing in a language that the resident understands of his or her rights, including the advance directive provision. However, as explained above, the information collection estimate does not include time to explain the advance directives requirements. Therefore, the burden to which the commenter refers is not appropriately part of the advance directives estimate.

Comment: One commenter misinterpreted the estimate of 15 million individuals used in the calculation of the information collection burden as representing the number of individuals who have executed advance directives.

Response: Fifteen million did not represent the number of persons who have executed advance directives, rather it represented the projected number of Medicare beneficiaries and Medicaid recipients who were expected to receive services from providers and organizations subject to these regulations. In other words, in the interim final rule, we projected that in FY 1992 providers and eligible organizations would be required to meet the advance directive requirements, including proper documentation of the medical record, for at least 15 million Medicare and Medicaid beneficiaries/recipients.

Discrimination Based on Advance Directive

Comment: Although opposed to the statutory requirements concerning advance directives because they appear to place the Federal government in the role of advancing euthanasia in the United States, one commenter urged HCFA to promulgate regulations that ensure that providers and organizations are prohibited from exerting any form of coercion, or undue influence to make an individual feel that he or she must execute an advance directive. In addition, the commenter believes we should make it clear that States are not obligated by these regulations to pass laws addressing advance directives.

Response: Sections 1866(f)(1)(C) and 1902(w)(1)(C) of the Act, as well as our implementing regulations, clearly prohibit any type of discrimination against individuals based on whether or not an individual has executed an advance directive. Thus, we agree with the commenter that providers and organizations are not permitted to coerce or pressure any individual into executing an advance directive. As stated in the sample public information document published in the interim final rule (57 FR 8199), the law does not require an individual to execute an advance directive. Similarly, we agree with the commenter that these rules do not require States to enact legislation to address advance directive requirements.

Comment: Two commenters recommended that we make it clear that discriminating against an individual because he or she has an advance directive is strictly prohibited. One commenter believes there is a real danger that an advance directive may deprive patients of the normal care that they would receive if there were no advance directive.

Response: Again, sections 1866(f)(1)(C) and 1902(w)(1)(C) of the Act and the regulations both prohibit any discrimination based on whether or not the individual has an advance directive. In addition, in the event that problems are encountered, individuals have the right to submit a complaint to the State agency or regional office for investigation.

Provider Responsibilities To Ensure Compliance With the Requirements of State Law Concerning Advance Directives

Comment: A commenter suggested that the regulations require that a facility's policies for objections on the basis of conscience be reviewed annually for compliance with State law. In addition, the commenter suggested that the facility's advance directive informational packages should contain a statement that its policies have been reviewed and found in compliance with State law and should cite the State law authority.

Response: Under sections 1866(f)(1) and 1902(w)(1) of the Act, providers have been required since December 1, 1991 to maintain and distribute written policies and procedures concerning an individual's rights under State law to accept or refuse medical or surgical treatment and to formulate advance directives, and the providers' policies for ensuring compliance with such rights. Section 489.102(a)(1)(ii) specifies that providers must provide written information to all adult individuals concerning its written policies respecting the implementation of such rights, including a clear and precise statement of limitation if the provider cannot implement an advance directive on the basis of conscience. As discussed in further detail below, we are revising § 489.102(a)(1)(i) to require that providers must update and disseminate amended information as soon as possible, but no later than 90 days from the effective date of the changes to State law. Therefore, we do not believe it is necessary to require a separate annual review of compliance with State laws concerning objections on the basis of conscience. HCFA has various mechanisms, such as certification surveys, for assessing provider compliance with rules and regulations. We do not believe it is necessary for a provider's documents to contain a statement addressing approval findings of compliance surveys. In general, we will rely upon the State (for example, during its licensure inspections) to determine if its advance directives laws are being enforced properly.

Comment: Two commenters suggested that the regulations address the extent of the provider's responsibility to determine the validity of an advance directive. They believe that the advance directive is valid if it appears to meet the formal requirements of applicable State law, unless the provider knows, or has reason to know, otherwise. Also, the commenters suggested that a provider's written policy should explain the extent to which advance directives that are prepared in other jurisdictions will be honored if they meet the formal requirements of applicable State law. One commenter suggested that we clarify that the most recently executed advance directive should be the one the provider relies upon in making determinations relating to health care delivery.

Response: The statute does not address the issues raised by these commenters. As a practical matter, State laws typically govern the procedures for determining the validity of advance directives and how such documents from other jurisdictions will be honored. In general, we would expect that providers will comply with the advance directives of individuals from other States, unless the directive conflicts with State law or the provider conscientiously objects, in accordance with State law. In addition, although not required by the statute, we believe it is appropriate for providers to confirm with individuals the contents of their advance directive to ensure that the