Response: Sections 1866(f)(1)(A) and 1902(w)(1)(A) of the Act require that providers and organizations furnish individuals receiving medical care with written information concerning an individual's rights under State law and the provider's policies concerning the implementation of these rights. Also, section 4206(c) of OBRA '90 and section 1902(w)(3) of the Act provide that the statutory advance directive requirements do not prohibit the application of a State law that allows for an objection on the basis of conscience for any provider (or its agent) that, as a matter of conscience, cannot implement an advance directive. As the commenter noted, implementing regulations at § 417.436(d)(1)(i)(B) and 489.102(a)(1)(iii) require that this information include a statement of limitation if a provider cannot implement an advance directive on the basis of conscience. We agree that the written information may mirror State-developed descriptions of State law concerning advance directives. However, we do not believe that requiring a provider to supply copies of applicable State law is necessary, because the statute requires the dissemination of descriptions of State laws. We believe that Congress imposed this requirement because many State statutes may be written in technical terms that may be misunderstood. We have reviewed the six suggested requirements for statements of limitation. We believe that the commenters have highlighted some important minimum points of information that should be given to all affected individuals, but we also believe some of the suggestions go beyond the intent of this law. As a result, we have decided to implement the first, third and fourth of the commenters' suggested requirements.

We have several reasons for not adopting the second, fifth and sixth suggested requirements. We have not adopted the second suggestion because the basis for the objection is not necessarily material as long as the objection raised is permitted by State law. A provider may wish to explain an institutional policy; however, an individual physician or practitioner may not wish to do so, and neither of them is required by this law to do so. We have not adopted the commenter's fifth suggestion concerning transfers for a similar reason. The law does not require this level of information. We note that if an individual is given information regarding the provider's conscientious objection, and he or she does not request a transfer, the provider is not obligated to implement any elements of an individual's advance directive that conflict with the provider's conscientious objection. However, it is reasonable to expect that assistance would be provided for a transfer at the patient's request. We did not accept the commenter's last recommendation because we do not believe it would be reasonable to require that a provider speculate on what, if any, burden would be placed on patients or surrogate decision-makers to help effectuate the implementation of an advance directive. Therefore, we are revising the regulations at §§ 417.436(d)(1)(i)(B) and 489.102(A)(1)(ii) to include only the first, third, and fourth points.

Finally, when a entire facility opts to object on the basis of conscience, assuming the objection is permitted under State law and the facility complies with all other provisions of the statute and regulations, neither Medicare nor Medicaid reimbursement will be interrupted.

Comment: One commenter requested that we clarify that a provider is not required to implement an advance directive to which the provider objects on the basis of conscience when the State law is silent or does not specifically prohibit such objection.

Response: The advance directives legislation does not give us authority to make such a clarification. We believe that, unless State law allows a provider to object to implementing an advance directive as a matter of conscience, the provider is required to honor the advance directive as written. As discussed in the preceding response, we have revised §§ 417.436(d)(1)(i)(B)(3) and 489.102(a)(1)(ii)(C) to specify that a provider's statement of limitation must identify the ''State legal authority'' permitting an objection on the basis of conscience.

We note that State statutory law may be silent on a particular issue, such as whether a provider may decline to follow a directive to which it objects on the basis of conscience. As we suggested in the interim final rule, in the absence of statutory law, providers should look to common law or case law for guidance (57 FR 8197).

Comment: One commenter asserted that religiously-sponsored facilities have the right to exercise an objection on the basis of conscience to the requirement that facilities conduct community education. Otherwise, enforcement of the community education requirement would violate provider's First Amendment rights to adhere to their religious beliefs.

Response: Section 1902(w)(3) of the Act and section 4206(c) of OBRA '90 specifically refer to the application of State laws regarding conscientious objections. These statutory provisions permit exceptions to implementing advance directives based on a conscientious objection as prescribed under applicable State law. No provision is made for an exception to sections 1866(f)(1)(E) and 1902(w)(1)(E) of the Act concerning community education efforts. Thus, the provider must meet the requirements relating to community education; that is, the provider must furnish information to the community concerning State law regarding the right to accept or refuse medical or surgical treatment and to formulate an advance directive, even if the provider simultaneously informs the community that it is exercising a conscience objection that would permit it to refuse to honor an advance directive.

Comment: One commenter believes that it would be difficult if not impossible for many providers, especially Roman Catholic facilities, to provide a precise statement of limitation if a provider cannot implement an advance directive on the basis of conscience. According to the commenter, there are various ethical, religious and moral restrictions on whether or not a particular advance directive can be implemented at a Catholic facility. Another commenter believes that providers may not always be able to write clear and precise statements of limitation when objecting on the basis of conscience and requested that the regulations permit alterations to the written policy based upon case-by-case determinations of issues not previously considered by the facility.

Response: As discussed above, we have revised the regulations at §§ 417.436(d)(i)(B) and 489.102(a)(1)(ii) to provide further clarification on the content of the statement of limitation. Regardless of their religious affiliation, facilities may comply with the law by providing patients with written materials containing the minimum points of information required by these regulations. These revisions describe the minimum amount of information that should be included in the statement of limitation. For the most part, we believe that the statement of limitation can be written to accommodate or reflect the case-by-case approach. Although we cannot readily envision a situation in which the required information, if properly provided, would not adequately inform the patient, we agree that such a situation would permit an individualized notice.