§ 160.104 Modifications.

- (a) Except as provided in paragraph (b) of this section, the Secretary may adopt a modification to a standard or implementation specification adopted under this subchapter no more frequently than once every 12 months.
- (b) The Secretary may adopt a modification at any time during the first year after the standard or implementation specification is initially adopted, if the Secretary determines that the modification is necessary to permit compliance with the standard or implementation specification.
- (c) The Secretary will establish the compliance date for any standard or implementation specification modified under this section.
- (1) The compliance date for a modification is no earlier than 180 days after the effective date of the final rule in which the Secretary adopts the modification.
- (2) The Secretary may consider the extent of the modification and the time needed to comply with the modification in determining the compliance date for the modification.
- (3) The Secretary may extend the compliance date for small health plans, as the Secretary determines is appropriate.

 $[65\ {\rm FR}\ 82798,\ {\rm Dec.}\ 28,\ 2000,\ {\rm as}\ {\rm amended}\ {\rm at}\ 67\ {\rm FR}\ 38019,\ {\rm May}\ 31,\ 2002]$

§ 160.105 Compliance dates for implementation of new or modified standards and implementation specifications.

Except as otherwise provided, with respect to rules that adopt new standards and implementation specifications or modifications to standards and implementation specifications in this subchapter in accordance with §160.104 that become effective after January 25, 2013, covered entities and business associates must comply with the applicable new standards and implementation specifications, or modifications to standards and implementation specifications, no later than 180 days from the effective date of any such standards or implementation specifications.

[78 FR 5689, Jan. 25, 2013]

Subpart B—Preemption of State Law

§160.201 Statutory basis.

The provisions of this subpart implement section 1178 of the Act, section 262 of Public Law 104–191, section 264(c) of Public Law 104–191, and section 13421(a) of Public Law 111–5.

[78 FR 5689, Jan. 25, 2013]

§ 160.202 Definitions.

For purposes of this subpart, the following terms have the following meanings:

Contrary, when used to compare a provision of State law to a standard, requirement, or implementation specification adopted under this subchapter, means:

- (1) A covered entity or business associate would find it impossible to comply with both the State and Federal requirements; or
- (2) The provision of State law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of part C of title XI of the Act, section 264 of Public Law 104–191, or sections 13400–13424 of Public Law 111–5, as applicable.

More stringent means, in the context of a comparison of a provision of State law and a standard, requirement, or implementation specification adopted under subpart E of part 164 of this subchapter, a State law that meets one or more of the following criteria:

- (1) With respect to a use or disclosure, the law prohibits or restricts a use or disclosure in circumstances under which such use or disclosure otherwise would be permitted under this subchapter, except if the disclosure is:
- (i) Required by the Secretary in connection with determining whether a covered entity or business associate is in compliance with this subchapter; or
- (ii) To the individual who is the subject of the individually identifiable health information.
- (2) With respect to the rights of an individual, who is the subject of the individually identifiable health information, regarding access to or amendment of individually identifiable health information, permits greater rights of access or amendment, as applicable.