

## § 160.104

### § 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 FR 82798, Dec. 28, 2000, as amended at 67 FR 38019, 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]

## 45 CFR Subtitle A (10–1–20 Edition)

### 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.

(3) With respect to information to be provided to an individual who is the subject of the individually identifiable health information about a use, a disclosure, rights, and remedies, provides the greater amount of information.

(4) With respect to the form, substance, or the need for express legal permission from an individual, who is the subject of the individually identifiable health information, for use or disclosure of individually identifiable health information, provides requirements that narrow the scope or duration, increase the privacy protections afforded (such as by expanding the criteria for), or reduce the coercive effect of the circumstances surrounding the express legal permission, as applicable.

(5) With respect to recordkeeping or requirements relating to accounting of disclosures, provides for the retention or reporting of more detailed information or for a longer duration.

(6) With respect to any other matter, provides greater privacy protection for the individual who is the subject of the individually identifiable health information.

*Relates to the privacy of individually identifiable health information* means, with respect to a State law, that the State law has the specific purpose of protecting the privacy of health information or affects the privacy of health information in a direct, clear, and substantial way.

*State law* means a constitution, statute, regulation, rule, common law, or other State action having the force and effect of law.

[65 FR 82798, Dec. 28, 2000, as amended at 67 FR 53266, Aug. 14, 2002; 74 FR 42767, Aug. 24, 2009; 78 FR 5689, Jan. 25, 2013]

#### § 160.203 General rule and exceptions.

A standard, requirement, or implementation specification adopted under this subchapter that is contrary to a provision of State law preempts the provision of State law. This general rule applies, except if one or more of the following conditions is met:

(a) A determination is made by the Secretary under § 160.204 that the provision of State law:

- (1) Is necessary:

- (i) To prevent fraud and abuse related to the provision of or payment for health care;

- (ii) To ensure appropriate State regulation of insurance and health plans to the extent expressly authorized by statute or regulation;

- (iii) For State reporting on health care delivery or costs; or

- (iv) For purposes of serving a compelling need related to public health, safety, or welfare, and, if a standard, requirement, or implementation specification under part 164 of this subchapter is at issue, if the Secretary determines that the intrusion into privacy is warranted when balanced against the need to be served; or

(2) Has as its principal purpose the regulation of the manufacture, registration, distribution, dispensing, or other control of any controlled substances (as defined in 21 U.S.C. 802), or that is deemed a controlled substance by State law.

(b) The provision of State law relates to the privacy of individually identifiable health information and is more stringent than a standard, requirement, or implementation specification adopted under subpart E of part 164 of this subchapter.

(c) The provision of State law, including State procedures established under such law, as applicable, provides for the reporting of disease or injury, child abuse, birth, or death, or for the conduct of public health surveillance, investigation, or intervention.

(d) The provision of State law requires a health plan to report, or to provide access to, information for the purpose of management audits, financial audits, program monitoring and evaluation, or the licensure or certification of facilities or individuals.

[65 FR 82798, Dec. 28, 2000, as amended at 67 FR 53266, Aug. 14, 2002]

#### § 160.204 Process for requesting exception determinations.

(a) A request to except a provision of State law from preemption under § 160.203(a) may be submitted to the Secretary. A request by a State must be submitted through its chief elected official, or his or her designee. The request must be in writing and include the following information: