

# Definitions

## **DEFINITIONS - CONTRARY**

### **SECTION 160.202**

#### **As Contained in the HHS Final HIPAA Privacy Rules**

#### **HHS Regulations**

#### **Definitions - Contrary - § 160.202**

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 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 or section 264 of Pub. L. 104-191, as applicable.

#### **HHS Description**

#### **Definitions - Contrary**

None

#### **HHS Response to Comments Received**

#### **Definitions - Contrary**

*Comment:* Some commenters asserted that term “contrary” as defined at § 160.202 was overly broad and that its application would be time-consuming and confusing for states. These commenters argued that, under the proposed definition, a state would be required to examine all of its laws relating to health information privacy in order to determine whether or not its law were contrary to the requirements proposed. It was also suggested that the definition contain examples of how it would work in practical terms.

A few commenters, however, argued that the definition of “contrary” as proposed was too narrow. One commenter argued that the Secretary erred in her assessment of the case law analyzing what is known as “conflict preemption” and which is set forth in shorthand in the tests set out at § 160.202.

*Response:* We believe that the definition proposed represents a policy that is as clear as is feasible and which can be applied nationally and uniformly. As was noted in the preamble to

the proposed rules (at 64 FR 59997), the tests in the proposed definition of “contrary” are adopted from the jurisprudence of “conflict preemption.” Since preemption is a judicially developed doctrine, it is reasonable to interpret this term as indicating that the statutory analysis should

tie in to the analytical formulations employed by the courts. Also, while the court-developed tests may not be as clear as commenters would like, they represent a long-term, thoughtful consideration of the problem of defining when a state/federal conflict exists. They will also, we assume, generally be employed by the courts when conflict issues arise under the rules below. We thus see no practical alternative to the proposed definition and have retained it unchanged. With respect to various suggestions for shorthand versions of the proposed tests, such as the arguably broader term “inconsistent with,” we see no operational advantages to such terms.

*Comment:* One comment asked that the Department clarify that if state law is not preempted, then the federal law would not also apply.

*Response:* This comment raises two issues, both of which deserve discussion. First, a state law may not be preempted because there is no conflict with the analogous federal requirement; in such a situation, both laws can, and must, be complied with. We thus do not accept this suggestion, to the extent that it suggests that the federal law would give way in this situation. Second, a state law may also not be preempted because it comes within section 1178(a)(2)(B), section 1178(b), or section 1178(c); in this situation, a contrary federal law would give way.

*Comment:* One comment urged the Department to take the position that where state law exists and no analogous federal requirement exists, the state requirement would not be “contrary to” the federal requirement and would therefore not trigger preemption.

*Response:* We agree with this comment.

*Comment:* One commenter criticized the definition as unhelpful in the multi-state transaction context. For example, it was asked whether the issue of whether a state law was “contrary to” should be determined by the law of the state where the treatment is provided, where the claim processor is located, where the payment is issued, or the data maintained, assuming all are in different states.

*Response:* This is a choice of law issue, and, as is discussed more fully below, is a determination that is routinely made today in connection with multi-state transactions. See discussion below under Exception Determinations (Criteria for Exception Determinations).

## **DEFINITIONS - MORE STRINGENT**

### **SECTION 160.202**

#### **As Contained in the HHS Final HIPAA Privacy Rules**

#### **Proposed Revisions to HHS Regulations**

#### **Definitions - More Stringent - § 160.202**

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 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.

## **HHS Regulations**

### **Definitions - More Stringent - § 160.202**

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 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 of access to or amendment of individually identifiable health information, permits greater rights of access or amendment, as applicable; provided that, nothing in this subchapter may be construed to preempt any State law to the extent that it authorizes or prohibits disclosure of protected health information about a minor to a parent, guardian, or person acting in loco parentis of such minor.
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 or substance of an authorization or consent 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 authorization or consent, 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.

**HHS Description**  
**Definitions - More Stringent**

None

**HHS Response to Comments Received**  
**Definitions - More Stringent**

*Comment:* Many commenters supported the policy in the proposed definition of “individual” at proposed § 164.502, which would have permitted unemancipated minors to exercise, on their own behalf, rights granted to individuals in cases where they consented to the underlying health care. Commenters stated, however, that the proposed preemption provision would leave in place state laws authorizing or prohibiting disclosure to parents of the protected health information of their minor children and would negate the proposed policy for the treatment of minors under the rule. The comments stated that such state laws should be treated like other state laws, and preempted to the extent that they are less protective of the privacy of minors.

Other commenters supported the proposed preemption provision--not to preempt a state law to the extent it authorizes or prohibits disclosure of protected health information regarding a minor to a parent.

*Response:* Laws regarding access to health care for minors and confidentiality of their medical records vary widely; this regulation recognizes and respects the current diversity of state law in this area. Where states have considered the balance involved in protecting the confidentiality of minors’ health information and have explicitly acted, for example, to authorize disclosure, defer the decision to disclose to the discretion of the health care provider, or prohibit disclosure of minor’s protected health information to a parent, the rule defers to these decisions to the extent that they regulate such disclosures.

*Comment:* The proposed definition of “more stringent” was criticized as affording too much latitude to for granting exceptions for state laws that are not protective of privacy. It was suggested that the test should be “most protective of the individual’s privacy.”

*Response:* We considered adopting this test. However, for the reasons set out at 64 FR 59997, we concluded that this test would not provide sufficient guidance. The comments did not address the concerns we raised in this regard in the preamble to the proposed rules, and we continue to believe that they are valid.

*Comment:* A drug company expressed concern with what it saw as the expansive definition of this term, arguing that state governments may have less experience with the special needs of researchers than federal agencies and may unknowingly adopt laws that have a deleterious effect

on research. A provider group expressed concern that allowing stronger state laws to prevail could result in diminished ability to get enough patients to complete high quality clinical trials.

*Response:* These concerns are fundamentally addressed to the “federal floor” approach of the statute, not to the definition proposed: even if the definition of “more stringent” were narrowed, these concerns would still exist. As discussed above, since the “federal floor” approach is statutory, it is not within the Secretary’s authority to change the dynamics that are of concern.

*Comment:* One comment stated that the proposed rule seemed to indicate that the “more stringent” and “contrary to” definitions implied that these standards would apply to ERISA plans as well as to non-ERISA plans.

*Response:* The concern underlying this comment is that ERISA plans, which are not now subject to certain state laws because of the “field” preemption provision of ERISA but which are subject to the rules below, will become subject to state privacy laws that are “more stringent” than the federal requirements, due to the operation of section 1178(a)(2)(B), together with section 264(c)(2). We disagree that this is the case. While the courts will have the final say on these questions, it is our view that these sections simply leave in place more stringent state laws that would otherwise apply; to the extent that such state laws do not apply to ERISA plans because they are preempted by ERISA, we do not think that section 264(c)(2) overcomes the preemption effected by section 514(a) of ERISA. For more discussion of this point, see 64 FR 60001.

*Comment:* The Lieutenant Governor’s Office of the State of Hawaii requested a blanket exemption for Hawaii from the federal rules, on the ground that its recently enacted comprehensive health privacy law is, as a whole, more stringent than the proposed federal standards. It was suggested that, for example, special weight should be given to the severity of Hawaii’s penalties. It was suggested that a new definition (“comprehensive”) be added, and that “more stringent” be defined in that context as whether the state act or code as a whole provides greater protection.

An advocacy group in Vermont argued that the Vermont legislature was poised to enact stronger and more comprehensive privacy laws and stated that the group would resent a federal prohibition on that.

*Response:* The premise of these comments appears to be that the provision-by-provision approach of Subpart B, which is expressed in the definition of the term “contrary”, is wrong. As we explained in the preamble to the proposed rules (at 64 FR 59995), however, the statute dictates a provision-by-provision comparison of state and federal requirements, not the overall comparison suggested by these comments. We also note that the approach suggested would be practically and analytically problematic, in that it would be extremely difficult, if not impossible, to determine what is a legitimate stopping point for the provisions to be weighed on either the state side or the federal side of the scale in determining which set of laws was the “more stringent.” We accordingly do not accept the approach suggested by these comments.

With respect to the comment of the Vermont group, nothing in the rules below prohibits or

places any limits on states enacting stronger or more comprehensive privacy laws. To the extent that states enact privacy laws that are stronger or more comprehensive than contrary federal requirements, they will presumably not be preempted under section 1178(a)(2)(B). To the extent that such state laws are not contrary to the federal requirements, they will act as an overlay on the federal requirements and will have effect.

*Comment:* One comment raised the issue of whether a private right of action is a greater penalty, since the proposed federal rule has no comparable remedy.

*Response:* We have reconsidered the proposed “penalty” provision of the proposed definition of “more stringent” and have eliminated it. The HIPAA statute provides for only two types of penalties: fines and imprisonment. Both types of penalties could be imposed in addition to the same type of penalty imposed by a state law, and should not interfere with the imposition of other types of penalties that may be available under state law. Thus, we think it is unlikely that there would be a conflict between state and federal law in this respect, so that the proposed criterion is unnecessary and confusing. In addition, the fact that a state law allows an individual to file a lawsuit to protect privacy does not conflict with the HIPAA penalty provisions.

## **DEFINITIONS - RELATES TO THE PRIVACY OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION**

### **SECTION 160.202**

#### **As Contained in the HHS Final HIPAA Privacy Rules**

#### **HHS Regulations**

##### **Definitions - Relates to the Privacy of Individually Identifiable Health Information -§160.202**

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.

#### **HHS Description**

##### **Definitions - Relates to the Privacy of Individually Identifiable Health Information**

None

#### **HHS Response to Comments Received**

##### **Definitions - Relates to the Privacy of Individually Identifiable Health Information**

*Comment:* One comment criticized the definition of this term as too narrow in scope and too uncertain. The commenter argued that determining the specific purpose of a state law may be difficult and speculative, because many state laws have incomplete, inaccessible, or

non-existent legislative histories. It was suggested that the definition be revised by deleting the word “specific” before the word “purpose.” Another commenter argued that the definition of this term should be narrowed to minimize reverse preemption by more stringent state laws. One commenter generally supported the proposed definition of this term.

*Response:* We are not accepting the first comment. The purpose of a given state enactment should be ascertainable, if not from legislative history or a purpose statement, then from the statute viewed as a whole. The same should be true of state regulations or rulings. In any event, it seems appropriate to restrict the field of state laws that may potentially trump the federal standards to those that are clearly intended to establish state public policy and operate in the same area as the federal standards. To the extent that the definition in the rules below does this, we have accommodated the second comment. We note, however, that we do not agree that the definition should be further restricted to minimize “reverse preemption,” as suggested by this comment, as we believe that state laws that are more protective of privacy than contrary federal standards should remain, in order to ensure that the privacy of individuals’ health information receives the maximum legal protection available.

## **DEFINITIONS - STATE LAW**

### **SECTION 160.202**

#### **As Contained in the HHS Final HIPAA Privacy Rules**

#### **HHS Regulations**

##### **Definitions - State Law - § 160.202**

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

#### **HHS Description**

##### **Definitions - State Law**

None

#### **HHS Response to Comments Received**

##### **Definitions - State Law**

*Comment:* Comments noted that the definition of “state law” does not explicitly include common law and recommended that it be revised to do so or to clarify that the term includes evidentiary privileges recognized at state law. Guidance concerning the impact of state privileges was also requested.

*Response:* As requested, we clarify that the definition of “state law” includes common law by including the term “common law.” In our view, this phrase encompasses evidentiary privileges recognized at state law (which may also, we note, be embodied in state statutes).

*Comment:* One comment criticized this definition as unwieldy, in that locating state laws pertaining to privacy is likely to be difficult. It was noted that Florida, for example, has more than 60 statutes that address health privacy.

*Response:* To the extent that state laws currently apply to covered entities, they have presumably determined what those laws require in order to comply with them. Thus, while determining which laws are “contrary” to the federal requirements will require additional work in terms of comparing state law with the federal requirements, entities should already have acquired the knowledge of state law needed for this task in the ordinary course of doing business.

*Comment:* The New York City Department of Health noted that in many cases, provisions of New York State law are inapplicable within New York City, because the state legislature has recognized that the local code is tailored to the particular needs of the City. It urged that the New York City Code be treated as state law, for preemption purposes.

*Response:* We agree that, to the extent a state treats local law as substituting for state law it could be considered to be “state law” for purposes of this definition. If, however, a local law is local in scope and effect, and a tier of state law exists over the same subject matter, we do not think that the local law could or should be treated as “state law” for preemption purposes. We do not have sufficient information to assess the situation raised by this comment with respect to this principle, and so express no opinion thereon.