

**Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under the Health Information Technology for Economic and Clinical Health Act and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules**

**DATES:**

*Effective date:* This final rule is effective on March 26, 2013.

*Compliance date:* Covered entities and business associates must comply with the applicable requirements of this final rule by September 23, 2013.

6. Section 164.512(b)—Disclosure of Student Immunizations to Schools

The Privacy Rule, at § 164.512(b), recognizes that covered entities must balance protecting the privacy of health information with sharing health information with those responsible for ensuring public health and safety, and permits covered entities to disclose the minimum necessary protected health information to public health authorities or other designated persons or entities without an authorization for public health purposes specified by the Rule. We believe that the option to provide oral agreement for the disclosure of student immunization records will relieve burden on parents, schools, and covered entities, and greatly facilitate the role that schools play in public health, while still giving parents the opportunity to consider whether to agree to the disclosure of this information.

Schools play an important role in preventing the spread of communicable diseases among students by ensuring that students entering classes have been immunized. Most States have “school entry laws” which prohibit a child from attending school unless the school has proof that the child has been appropriately immunized. Some States allow a child to enter school provisionally for a certain period of time while the school waits for the necessary immunization information. Typically, schools ensure compliance with those requirements by requesting the immunization records from parents (rather than directly from a health care provider). However, where a covered health care provider is requested to send the immunization records directly to a school, the Privacy Rule generally requires written authorization by the child's parent before a covered health care provider may do so.

Since the Privacy Rule went into effect, we had heard concerns that the requirement for covered entities to obtain authorization before disclosing student immunization information may make it more difficult for parents to provide, and for schools to obtain, the necessary immunization documentation for students, which may prevent students' admittance to school. The National Committee on Vital and Health Statistics submitted these concerns to the HHS Secretary and recommended that HHS regard disclosure of immunization records to schools to be a public health disclosure, thus eliminating the requirement for authorization. See

<http://www.ncvhs.hhs.gov/04061712.html>.

As such, we proposed to amend § 164.512(b)(1) by adding a new paragraph that permits covered entities to disclose proof of immunization to schools in States that have school entry or similar laws.<sup>1101</sup> While written authorization that complies with § 164.508 would no longer have been required for disclosure of such information under the proposal, the covered entity would still have been required to obtain agreement, which may have been oral, from a parent, guardian or other person acting *in loco parentis* for the individual, or from the individual him- or herself, if the individual is an adult or emancipated minor. Because the proposed provision would have permitted a provider to accept a parent's oral agreement to disclose immunization results to a school—as opposed to a written agreement—the NPRM acknowledged a potential for a miscommunication and later objection by the parent. We, therefore, requested comment on whether the Privacy Rule should require that a provider document any oral agreement under this provision to help avoid such problems, or whether a requirement for written documentation would be overly cumbersome, on balance. We also requested comment on whether the rule should mandate that the disclosures go to a particular school official and if so, who that should be.

In addition, the Privacy Rule does not define the term “school” and the types of schools subject to the school entry laws may vary by State. For example, depending on the State, such laws may apply to public and private elementary or primary schools and secondary schools (kindergarten through 12th grade), as well as daycare and preschool facilities, and post-secondary institutions. Thus, we requested comment on the scope of the term “school” for the purposes of this section and whether we should include a specific definition of “school” within the regulation itself. In addition, we requested comment on the extent to which schools that may not be subject to these school entry laws but that may also require proof of immunization have experienced problems that would warrant their being included in this category of public health disclosures.

### Overview of Public Comments

Most commenters were generally in favor of permitting covered entities to disclose student immunization records based on obtaining agreement, which may be oral, from a parent, guardian or other person acting *in loco parentis* for the individual, or from the individual himself or herself, if the individual is an adult or emancipated minor, rather than written authorization. Commenters supported the intent to facilitate the transmission of immunization records to ease the burden on parents, schools and covered entities, and to minimize the amount of school missed by students.

Some commenters opposed the proposal to require oral or written agreement, claiming that a new form of “agreement” would introduce unnecessary complexity and confusion, and would not help to reduce burden. These commenters asserted that covered entities would document the verbal agreements for their own liability purposes, even if not required by the Privacy Rule. In this manner, the documentation burden would still be present. Some commenters recommended

that instead of an oral agreement or authorization requirement, disclosure of immunization records to schools should be considered an exempt public health disclosure. A small minority of commenters felt that the current authorization system should be maintained as it is the best way to ensure patient safety and privacy while avoiding miscommunications and misunderstandings.

Commenters were divided on the issue of requiring written documentation of the agreement. Some commenters were in favor of documenting oral agreements, citing that the documentation would be less cumbersome than obtaining written authorizations while also helping to avoid miscommunications. On the other hand, some commenters felt that requiring written documentation would be burdensome and would eliminate the benefits introduced by permitting oral agreements. Some commenters also requested flexibility for covered entities to determine whether or not written documentation is appropriate and necessary for their purposes.

The majority of commenters requested that a designated recipient of the student immunization records not be defined, and that schools be allowed flexibility to identify the appropriate individual(s) that can act as the school official permitted to receive the records. Commenters indicated that while the disclosures would ideally be made to a nurse or licensed health professional at the school, such a health professional may not always be present. In such instances, it should be permissible that the immunization records be disclosed to another official designated by the school as a suitable representative. One commenter recommended that the school nurse be designated as the recipient and custodian of the records.

Most commenters recommended that the definition of “school” be interpreted broadly in order to best support public health efforts. Commenters provided suggestions on the types of schools that should be included, for example, K-12 schools, public and private schools, and post-secondary schools. Many commenters also suggested that daycare, preschool and nursery school facilities be encompassed in the definition of school. One commenter expressly recommended that child care facilities or day care programs not be included in the definition of school, despite acknowledging the need to protect the health of these children, due to the fact that many States have different laws for these settings and are separate from school systems. Two commenters suggested defining schools as being open to children up to age 18, since students become adults at age 18 and can authorize the disclosure of their own information. A few commenters suggested that the definition include all schools that require immunization documentation as a prerequisite to enrollment, not just those that are subject to State entry laws, in order to protect public health in all school settings, since the threat of un-immunized children exists regardless of State school entry laws. Additionally, some commenters recommended that the term “school” not be defined in the Privacy Rule due to the variation across States in the types of schools that are subject to the entry laws.

## Final Rule

The final rule adopts the proposal to amend § 164.512(b)(1) by adding a new paragraph that permits a covered entity to disclose proof of immunization to a school where State or other law requires the school to have such information prior to admitting the student. While written authorization will no longer be required to permit this disclosure, covered entities will still be required to obtain agreement, which may be oral, from a parent, guardian or other person acting *in loco parentis* for the individual, or from the individual himself or herself, if the individual is an adult or emancipated minor. We believe that the option to provide oral agreement for the disclosure of student immunization records will relieve burden on parents, schools, and covered entities, and greatly facilitate the role that schools play in public health, while still giving parents the opportunity to consider whether to agree to the disclosure of this information.

The final rule additionally requires that covered entities document the agreement obtained under this provision. The final rule does not prescribe the nature of the documentation and does not require signature by the parent, allowing covered entities the flexibility to determine what is appropriate for their purposes. The documentation must only make clear that agreement was obtained as permitted under this provision. For example, if a parent or guardian submits a written or email request to a covered entity to disclose his or her child's immunization records to the child's school, a copy of the request would suffice as documentation of the agreement. Likewise, if a parent or guardian calls the covered entity and requests over the phone that his or her child's immunization records be disclosed to the child's school, a notation in the child's medical record or elsewhere of the phone call would suffice as documentation of the agreement. We emphasize that the agreement is not equivalent to a HIPAA-compliant authorization, and covered entities are not required to document a signature as part of this requirement. We disagree with comments that documentation would be as burdensome on covered entities as written authorization, since an authorization form contains many required statements and elements, including a signature by the appropriate individual, which are not required for the agreement and documentation contemplated here. Furthermore, we believe that documentation of oral agreements will help to prevent miscommunications and potential future objections by parents or individuals, and the concerns that covered entities may have regarding liability, penalty or other enforcement. Several commenters recommended that in lieu of an oral agreement, disclosure of immunization records to schools are presumed to be permitted, while giving individuals the option to opt out of this presumption or request a restriction to the disclosure. One commenter advocated for this public health exemption for disclosure of immunization records as being particularly critical for children who may be, for example, homeless, living with someone other than a parent or legal guardian, or living with a parent that does not speak English. We remove the written authorization requirement to help facilitate these disclosures with as much flexibility as possible. However, we do not intend this provision to change the current practice of parents, guardians, or other persons acting *in loco parentis* contacting a child's health care provider to request proof of immunization be sent to the child's school. Therefore, we still require active agreement from the appropriate individual, and a health care provider may not disclose immunization records to a

school under this provision without such agreement. The agreement must be an affirmative assent or request by a parent, guardian, or other person acting *in loco parentis* (or by an adult individual or emancipated minor, if applicable) to the covered entity, which may be oral and over the phone, to allow the disclosure of the immunization records. A mere request by a school to a health care provider for the immunization records of a student would not be sufficient to permit disclosure under this provision (and such a request by a school might also raise implications under other laws, such as FERPA).actions for disclosures made pursuant to an oral agreement.

We decline to include definitions of “school official” and “school” in the final rule. The motivation for this new permissive disclosure is to promote public health by reducing the burden associated with providing schools with student immunization records and we do not wish to create additional difficulties or confusion in doing so. We therefore agree with commenters that schools are best equipped to determine the appropriate individual to receive student immunization records at their location and will benefit from having this flexibility. We also agree with commenters that “school” should remain undefined in the Privacy Rule due to the variation across States in the types of schools that are subject to the entry laws. We believe that this will best align with State law and cause the least amount of confusion. We did not receive sufficient comment regarding the breadth of schools that are not subject to school entry laws or the burden that these institutions face to justify expanding this provision to allow disclosure of proof of immunization to such schools without an authorization.

### **Response to Other Public Comments**

*Comment:* Several commenters raised concerns about the dynamic between the Privacy Rule requirements and State law requirements regarding immunization disclosures. Commenters indicated that some State laws require providers to directly share immunization records with schools and provide parents with the opportunity to opt out of this direct sharing. Commenters also indicated the use of State immunization registries in many States, to which schools are permitted direct access. One commenter suggested that the Privacy Rule permit State law to determine what is the minimum necessary for proof of immunization.

*Response:* We take this opportunity to clarify that the Privacy Rule at § 164.512(a) permits a covered entity to use or disclose protected health information to the extent that such use or disclosure is required by law and the use or disclosure complies with and is limited to the relevant requirements of such law. As such, the Privacy Rule does not prohibit immunization disclosures that are mandated by State law, nor does it require authorization for such disclosures. With regard to State laws that require covered entities to disclose immunization records to schools and allow parents to opt out, this is not in any way prohibited by the Privacy Rule. However, with regard to State laws that permit but do not require covered entities to disclose immunization records to schools, this does not meet the requirements of the provisions at § 164.512(a), and disclosures of immunization records are subject to the Privacy Rule agreement

and documentation requirements described in this part. We also note that the Privacy Rule at § 164.512(b) permits a covered entity to disclose protected health information for public health activities. Disclosures of protected health information to State immunization registries are therefore permitted by the Privacy Rule and also do not require authorization. The Privacy Rule at § 164.514(d)(3)(iii)(A) provides that a covered entity, when making a permitted disclosure pursuant to § 164.512 to a public official, may determine, if such a determination is reasonable under the circumstances, that information requested by a public official is the minimum necessary information for the stated purpose, if the public official represents that the information requested is the minimum necessary for the stated purpose(s). Under this provision, a covered entity may rely on State law or a State official's determination of the minimum necessary information required for proof of immunization, unless such determination is unreasonable.

*Comment:* Commenters requested guidance on when and how often to obtain agreement for immunization disclosures.

*Response:* We anticipate that covered entities will obtain agreement for the disclosure of immunization records on a case-by-case basis as needed. For example, a parent may call and request that a covered entity provide his or her child's immunization records before the child begins elementary school, if required by State school entry laws. If that child moves to a different school and is unable to transfer their immunization records to the new school, the parent may need to request that the covered entity provide his or her child's immunization records to the new school, if required by State school entry laws. A parent might also generally indicate to a covered entity that he or she affirmatively agrees to the immediate or future disclosure of his or her child's immunization records to the child's school as necessary, or the continued disclosure of such information if, for example, updates are required by the school when a series of vaccinations have been completed.

*Comment:* Commenters requested clarification on the length of time an agreement may be relied upon.

*Response:* An agreement to permit the disclosure of immunization records is considered effective until revoked by the parent, guardian or other person acting *in loco parentis* for the individual, or by the individual himself or herself, if the individual is an adult or emancipated minor.

*Comment:* Commenters requested clarification regarding any requirement for schools to maintain the immunization records.

*Response:* The Privacy Rule does not require schools to keep student immunization records; however individual State or other laws may require this.