Guidance on Providing Hepatitis B Shots to School Students

Q & A

School health services are provided in various ways in North Carolina; therefore, the following guidance may not be applicable to all local public health departments in the same manner. This guidance primarily applies to those local public health departments that are billing electronically to any payer for the Hep B vaccine administration fee in the Sixth-Grade School-Site Hepatitis B Immunization Initiative in the standard formats and receive the funds; however, there are suggestions and guidance throughout the document that address other school health scenarios for providing Hep B vaccine to students in the schools.

NOTE: Local health departments should not be billing any payer for Hepatitis B vaccine for the 6th grade program because the Hepatitis B vaccine is state-supplied vaccine. They may bill any payer for the administration fee.

NOTE: Under HIPAA, it is a permissible activity to enter immunizations into the immunization registry and health departments are encouraged to continue this activity.

Q. If our health department has provided the first and second Hep B shots to school students prior to April 14, 2003, and the third shot is to be given after April 14, 2003, must we again obtain permission from the parent(s) to give the third Hep B shot?

A. No. If you have already obtained permission from the parent(s) to give the student the Hep B series of shots, no additional permission is required from the parent(s).

Q. If our health department has provided the first and second Hep B shots to school students prior to April 14, 2003, and the third shot is to be given after April 14, 2003, are we required to provide our Notice of Privacy Practices to the parent(s) and obtain acknowledgement?

A. Yes. 45 CFR Part 164.520 (c)(2)(i)(A) states that certain health providers must provide the Notice of Privacy Practices no later than the date of the first service delivery to such individual after the compliance date for the covered health care provider except in emergency treatment situations. In addition, except in an emergency treatment situation, the covered health care provider must make a good faith effort to obtain a written acknowledgment of receipt of the notice, and if not obtained, document its good faith efforts to obtain such acknowledgment and the reason why the acknowledgment was not obtained.

Scenario #1: If the nurses administering the shots are employed by the health department, the vaccine is provided by the health department, the health department is billing for the vaccine administration fee electronically, and is receiving the funds, the HIPAA regulations require that the Notice of Practices be given after April 14, 2003, and that a written acknowledgment of the receipt of the notice be obtained or document your good faith effort to obtain the acknowledgment and the reason why the acknowledgment was not obtained.

Alternative #1: Assuming the county or health department has designated itself as a hybrid entity, health departments could decide to submit the claims for the vaccine administration fee on paper and “carve-out” the Hepatitis B Program and not include it in the covered health care
components of the hybrid entity. In this situation, providing the Notice of Privacy Practices and obtaining acknowledgments would not be required.

**Alternative 2:** Assuming the county or health department has designated itself as a hybrid entity, health department could decide not to bill for the vaccine administration fee at all and “carve-out” the Hepatitis B Program and not include it in the covered health care components of the hybrid entity. In this situation, providing the Notice of Privacy Practices and obtaining acknowledgments would not be required.

**Scenario #2:** If the nurses administering the shots are employed by the schools, the vaccine is provided by the health department, the health department is billing for the vaccine administration fee electronically, and receiving the funds, the HIPAA regulations require that the Notice of Privacy Practices be given after April 14, 2003, and that a written acknowledgment of the receipt of the notice be obtained or document your good faith effort to obtain the acknowledgment and the reason why the acknowledgment was not obtained.

The same alternatives suggested under Scenario #1 would apply to Scenario #2.

**Scenario #3:** If the nurses administering the shots are employed by the schools, the vaccine is provided by the health department, the health department is not billing for the vaccine administrative fee electronically, and is not receiving the funds, the health department would not be required to distribute the Notice of Privacy Practices and obtain the acknowledgments because the Hepatitis B Program would not be a covered component of the hybrid entity.

**Scenario #4:** If the nurses administering the shots are employed by the schools, the vaccine is not provided by the health department (not state-supplied vaccine); the school nurse is billing electronically in a standard HIPAA format for the vaccine and/or administrative fee, and the schools are receiving the funds, it is possible that as a health care provider billing electronically in standard HIPAA format, that the school-employed nurse would be subject to HIPAA requirements. The protected health information in education records, however, is subject to the Family Educational Rights and Privacy Act (FERPA) instead of HIPAA. It would be the responsibility of the schools to assess their entities and determine whether or not any of their services or components were covered under HIPAA.

**Q. If our Hepatitis B Program is a covered component and subject to HIPAA requirements, how do we go about distributing the Notice of Privacy Practices and obtaining the acknowledgments for the students who are receiving the third Hep B shot after April 14, 2003?**

**A.** Listed below are two suggestions for distributing the Notice of Privacy Practices and obtaining the acknowledgments. Local health department may choose one of these options or may develop another means of complying with HIPAA requirements that may serve just as well.

**Suggestion #1:** It is permissible to mail the Notice of Privacy Practices to parent(s) of students who receive the third Hep B shots after April 14, 2003. The Notice of Privacy Practices could be mailed to the parent(s) prior to giving the third shot or on the day the shots are given. (In those situations that the first treatment encounter after 4/14/03 is face-to-face, HIPAA requirements state that the Notice of Privacy Practices should be provided on the date of first service delivery after April 14,
2003. In those situations that the first treatment encounter is not face-to-face, for example, a health care provider whose first treatment encounter with a patient is over the phone, the health care provider satisfies the notice provision requirements of the Rule by mailing the notice to the individual no later than the day of that service delivery.

To satisfy the requirement that the provider also make a good faith effort to obtain the acknowledgment of the notice, you may include a tear-off sheet or other document with the notice that requests that the acknowledgment be mailed back to you. You may wish to include a self-addressed stamped envelope for the parents’ convenience. Your covered entity would not be in violation of the Privacy Rule if the parent(s) choose not to mail back the acknowledgment; however, your covered entity is required to document your good faith effort to obtain the acknowledgment and the reason you did not receive it. The documented reason would simply be that the parent(s) did not return the acknowledgment.

**Suggestion #2:** It is permissible to give the Notice of Privacy Practices, the acknowledgment form, and the self-addressed stamped envelope to the student to take home to the parent(s). If the acknowledgment form is not returned, your covered entity would need to document your good faith effort to obtain the acknowledgment, and the reason you did not receive it.

**Q. Should local health departments in North Carolina also obtain a patient’s written permission before disclosing information for the purposes that HIPAA describes as treatment, payment, or health care operations (TPO)?**

**A.** Yes. This is a practice that has been recommended by the Institute of Government (IOG).

The August 2002 HIPAA Privacy Rule modifications made the obtaining of permission (consent) optional for the use and disclosure of protected health information (PHI) for treatment, payment, or health care operations (TPO) for all covered entities, including providers with direct treatment relationships. This Final Rule allows covered entities to have a consent process if they wish to do so and also allows the covered entity complete discretion in designing that process. However, the removal of the consent requirement applies only to consent for TPO; it does not alter the requirement to obtain an authorization under Part 164.508 for uses and disclosures of PHI not otherwise permitted by the Privacy Rule or any other requirements for the use and disclosure of PHI.

Faculty and staff at IOG have reviewed NC law to determine if NC requirements are more stringent than HIPAA relative to obtaining consent for TPO. Although there has been discussion about not needing a consent form under HIPAA, the IOG recommends that consent be obtained for all health department clients to allow the covered entity to use and disclose their PHI for TPO. Although there is no single NC law that specifically states a health department must obtain the client’s permission for these disclosures, the recommendation is based on considerations arising from several sources of law.

A six-page guidance document entitled, “#11-#11B HIPA--Consent Guidance and Template,” was distributed to local health directors and local HIPAA coordinators on January 21, 2003, that discusses the recommended requirement to obtain consent for using and disclosing PHI for TPO and references the applicable NC General Statute and common law standard of care. Please refer to that document for obtaining guidance on obtaining consent. A sample template is also included.
Q. If a health department obtains a parent’s or individual’s consent to use and disclose protected health information about the child or them, does the health department also have to make a good faith effort to obtain the parent’s or individual’s acknowledgment of the notice?

A. Yes. The HIPAA Privacy Rule requires that a covered health care provider with a direct treatment relationship with individuals make a good faith effort to obtain written acknowledgments from those individuals that they have received the provider’s notice, regardless of whether the provider also chooses to obtain the individuals’ consent. However, those providers that choose to obtain consent from individuals have discretion to design one form that includes both a consent and the acknowledgment of receipt of the notice.

Q. For future vaccines given to students in the schools, how should covered entities address the HIPAA requirement for providing the Notice of Privacy Practices, obtaining the acknowledgment, and obtaining the consent for TPO?

A. Suggestion #1: When the initial packet of information about vaccines being given to students goes home to the parent(s), a copy of the Notice of Privacy Practices could be included in the initial packet. (This is a little expensive because some parents will not choose to have their child receive the vaccine; however, this is part of the cost of doing business as a HIPAA covered entity.)

On the form that the parent(s) sign to give permission for their child to receive the vaccine, there could be three places for the parent to sign.

1. One signature line would be for the parent(s) to sign to give permission for their child to receive the vaccine.
2. The second signature line would be for the parent(s) to sign and acknowledge that they have received the Notice of Privacy Practices. This would satisfy the HIPAA requirement that the Notice of Privacy Practices was provided and that the acknowledgment was obtained. If a form comes back to the nurse and the parent(s) only signed the first signature line for permission to give the vaccine and the second signature line indicating their acknowledgment that they had received the Notice of Privacy Practices was left blank, this could be the place the that the nurse documents that a good faith effort was made to obtain the acknowledgment and why the acknowledgment was not received. This also satisfies another HIPAA requirement that the good faith effort be documented.
3. The third signature line would be for the parents(s) to sign giving their permission (consent) to use and disclosure their child’s protected health information (PHI) for treatment, payment, and other health care operations (TPO).

Suggestion #2: The Notice of Privacy Practices could be left out of the initial packet of information that goes home to the parent (in order to save a few dollars on the cost of providing the Notice of Privacy Practices). When the nurse receives the signed forms back from the parent(s) indicating that their child may receive the vaccine, the nurse could then send the Notice of Privacy Practices home to those particular parents along with another form for the parent to sign the acknowledgment and consent to use PHI for TPO and return to the nurse.
Although this particular scenario may save a few dollars on the Notice of Privacy Practices, the rate of return of acknowledgements and consents may not be as great because of so many forms going back and forth. In addition, it will most likely require more time of nursing, school, and support staff – that may wind up being more time-consuming and costly in the long run. It will also most likely require more time of the nursing staff to document the good faith effort to obtain the acknowledgment and why the acknowledgment was not obtained because of many acknowledgments not be returned.

In the first suggestion, everything is done at once and all the required documentation for the permission to give the vaccine, the acknowledgment, and the good faith effort to provide the Notice of Privacy Practices, and obtaining consent is on one form.