

## Q&A Consents & Authorizations

### **#1 Q. What is the difference between the state supplied Form 3096, "Permission to Use & Disclose Patient Health Information," and Form 4056, "Patient Authorization to Permit Use & Disclosure of Health Information?"**

A. Form 3096-Permission to Use & Disclose Patient Health Information is a form that combines the required "acknowledgment" and the recommended "consent."

HIPAA requires health care providers who are subject to HIPAA to provide a Notice of Privacy Practices (NOPP) to individuals who receive service from the covered health care provider on the first service delivery date after 4/14/03. HIPAA also requires that the covered health care provider must make a good faith effort to obtain a written acknowledgment of receipt of the NOPP. § 164.520(c)(2)(ii).

"Consent" as defined by HIPAA means that the individual (client) is giving the covered health care provider permission to use and disclose their protected health information (PHI) for treatment, payment, and other health care operations (TPO). Although the Privacy Rule does not require covered entities to obtain this permission (consent), the Institute of Government (IOG) recommends that "consent" be obtained for all NC health department clients to allow the covered entity to use and disclose the client's 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 NC law. Please refer to the 1/21/03 email "Consent Guidance and Template" for detailed guidance.

Form 4056-Patient Authorization to Permit Use & Disclosure of Health Information is a form that the client signs giving permission for the covered entity to use and disclose their PHI for purposes outside the realm of TPO unless the uses and disclosures are "otherwise permitted" by the Rule and, therefore, not requiring an authorization.

Uses and disclosures "otherwise permitted" by the rule not requiring an authorization are:

- a. uses and disclosures for treatment, payment, and health care operations made pursuant to § 164.506,
- b. uses and disclosures pursuant to § 164.512 (national priority uses and disclosures, such as uses and disclosures required by state law, for public health activities, for health care oversight activities, for law enforcement purposes, and to avert a serious threat to health or safety). When no provision of the Privacy Rule applies to require or permit a use or disclosure, then the individual's written authorization is required to make the use or disclosure.

### **#2 Q. Are local health departments required to use the state supplied forms?**

A. No. These state forms are being supplied to local health departments as a convenience. If your agency has developed your own "acknowledgment," "consent," and "authorization" forms and they have all the required HIPAA components, then you may use your own forms. If your covered entity does not wish to use the state-supplied forms, please return them and do not order any more in the future.

### **#3 Q. Is it permissible to use the state-supplied forms or must we develop our own forms?**

A. Yes, it is permissible to use the state-supplied forms. Please remember that although the state is providing the forms, it is the responsibility of the covered entity to review the forms to ensure that the forms are HIPAA compliant - no matter where the form comes from. If your covered entity chooses to use the state-supplied forms, you may want to document in your policies and procedures that the DHHS Forms 3096 & 4056 are the forms your covered entity adopts to use for obtaining "acknowledgments," "consents," and "authorizations."

**#4 Q. Are we required to provide the client with a copy of the "consent" and the "authorization?"**

A. § 164.508(c) requires that the covered entity must provide the individual with a copy of the signed "authorization." There is no requirement to provide the individual with a copy of the signed "consent;" however, you may provide a copy to the individual if you wish.

**#5 Q. The cover memo that announced that the state supplied forms were forthcoming indicated that an "authorization" should be used in cases where the client is requesting release of his/her own medical record to himself/herself. Is this a HIPAA requirement?**

A. No it is not required; however, it is permissible. According to HIPAA, the covered entity is not required to obtain an "authorization" form signed by the client to release information to the client themselves.

§ 164.502(a)(1) *Permitted Uses and Disclosures*. A covered entity is permitted to use and disclose protected health information as follows: (i) to the individual." Obtaining an authorization from the client when giving PHI to the client is left to the discretion of the covered entity and providers must use their professional judgment to determine whether or not to request an authorization when releasing PHI to the client. If it is determined that an authorization should be obtained, the same authorization form developed by your agency or adopted by your agency would be used for this purpose. In the August 14, 2002, modifications, the "Comments" section (page 53221, bottom of middle column) states, "To further protect the privacy interests of individuals, when individuals initiate an authorization for their own purposes, the purpose may be stated as "at the request of the individual."

§ 164.502(a)(2) *Required Disclosures*. "A covered entity is required to disclose protected health information: (i) to an individual, when requested under, and required by § 164.524 or § 164.528. . . ." (Section 164.524 addresses the access rights of individuals to protected health information and includes several exceptions such as psychotherapy notes; information compiled in reasonable anticipation of, or for use, in a civil, criminal, or administrative action or proceeding; and PHI maintained by a covered entity that is subject to and exempt from CLIA. This section also includes unreviewable grounds for denial. Section 164.528 addresses the accounting of disclosures and Section 164.528 (a)(1) states that "an individual has a right to receive an accounting of disclosures of protected health information made by a covered entity in the six years prior to the date on which the accounting is requested, except for disclosures (ii) to individuals of protected health information about them as provided in § 164.502."

**#6 Q. Why can't we use a "consent" form that also allows us to release information for specific reasons and include exactly what type PHI is to be released?**

A. According to the HIPAA regulations, an "authorization" form cannot be combined with any other form. You may combine the "acknowledgment" and the "consent" but not the "authorization." HIPAA also requires that specific components be included on the "authorization" form to ensure that clients give their permission on an informed basis. The required components of an "authorization" can be found in the regulations in § 164.508(b)(1). Additional guidance on the required components can be found in the IOG Privacy Manual, Section 8, "Using And Disclosing Information with Individual Permission."

**#7 Q. Although HIPAA does not require an "authorization" for use and disclosure of PHI for TPO, my agency is still requiring that we do this. Is this permissible?**

A. Yes. HIPAA defines the minimum standards for the use and disclosure of protected health information to ensure the privacy protections of the individual; however, if your agency wishes to make its policies and procedures more stringent than HIPAA, it is permissible, unless otherwise restricted by law.

If your agency chooses to adopt a policy to require "authorizations" for all uses and disclosures, it is important to follow the policy consistently. It is also noteworthy to point out that this practice will involve

additional agency time and costs due to the specificity of the HIPAA requirements for authorizations used by covered entities. HIPAA regulations do not require a patient authorization to release information within the realm of TPO. Patient "authorization" to permit use and disclosure of PHI is the client giving permission for the covered entity to use and disclose their PHI for purposes outside the realm of TPO unless the uses and disclosures are "otherwise permitted" by the Rule and, therefore, not requiring an authorization. (See further explanation in question #1 above.)

**#8 Q. Some local private physician offices and local hospitals are not willing to release any patient information without a signed authorization from the patient even though the disclosure of the PHI is for TPO which is allowed by the HIPAA regulations. Although we explain that it is allowed, they are continuing to require a signed authorization by the patient. What can we do?**

A. HIPAA defines the minimum standards for the use and disclosure of protected health information to ensure the privacy protections of the individual; however, if an agency wishes to make its policies and procedures more stringent than HIPAA, it is permissible, unless otherwise restricted by law. If an agency has adopted the policy to require a signed authorization from the patient before releasing any patient information, your agency will have to honor their policy in order to obtain the desired information. (See question #9 below for exception for release of immunization records that is required by NC Law.)

**#9 Q. Some local private physician offices are not willing to release immunization records to the health department without a signed authorization from the patient/parent. Is the patient/parent required to sign an authorization for the release of the immunization record to the health department?**

A. No. Listed below is the General statute and the rule from the NC Administrative Code that requires the release of immunization records, upon request, without permission from physicians and local health departments to certain places. The rule from the NC Administrative Code also defines who may receive the immunization records and the information to be released. You may wish to share this information as appropriate.

N.C.G.S.A. § 130A-153

WEST'S NORTH CAROLINA GENERAL STATUTES ANNOTATED  
CHAPTER 130A. PUBLIC HEALTH  
ARTICLE 6. COMMUNICABLE DISEASES  
PART 2. IMMUNIZATION

Current through S.L. 2001-450 of the 2001 Regular Session

§ 130A-153. Obtaining immunization; reporting by local health departments; access to immunization information in patient records; immunization of minors

(a) The required immunization may be obtained from a physician licensed to practice medicine or from a local health department. Local health departments shall administer required and State-supplied immunizations at no cost to the patient. The Department shall provide the vaccines for use by the local health departments. A local health department may redistribute these vaccines only in accordance with the rules of the Commission.

(b) Local health departments shall file monthly immunization reports with the Department. The report shall be filed on forms prepared by the Department and shall state, at a minimum, each patient's age and the number of doses of each type of vaccine administered.

(c) Immunization certificates and information concerning immunizations contained in medical or other records shall, upon request, be shared with the Department, local health departments, and the patient's attending physician. In addition, an insurance institution, agent, or insurance support organization, as those terms are defined in G.S. 58-39-15,

may share immunization information with the Department. The Commission may, for the purpose of assisting the Department in enforcing this Part, provide by rule that other persons may have access to immunization information, in whole or in part.

(d) A physician or local health department may immunize a minor with the consent of a parent, guardian, or person standing in loco parentis to the minor. A physician or local health department may also immunize a minor who is presented for immunization by an adult who signs a statement that he or she is authorized by a parent, guardian, or person standing in loco parentis to the minor to obtain the immunization for the minor.

15A NCAC 19A.0406

NORTH CAROLINA ADMINISTRATIVE CODE  
TITLE 15A. DEPARTMENT OF ENVIRONMENT AND NATURAL RESOURCES  
CHAPTER 19. HEALTH: EPIDEMIOLOGY  
SUBCHAPTER 19A. COMMUNICABLE DISEASE CONTROL  
SECTION .0400. IMMUNIZATION

Current through October 12, 2001

.0406 ACCESS TO IMMUNIZATION INFORMATION

(a) Physicians, local health departments and the Department shall, upon request and without consent release the immunization information specified in Paragraph (b) of this Rule to the following organizations:

- (1) schools K-12, whether public, private or religious;
- (2) licensed and registered childcare facilities as defined in G.S. 110-86(3) and G.S. 110-101;
- (3) Head Start;
- (4) colleges and universities, whether public, private or religious;
- (5) Health Maintenance Organizations; and
- (6) Other state and local health departments outside of North Carolina.

(b) The following is the immunization information to be released to the organizations specified in Paragraph (a) of this Rule:

- (1) name and address;
- (2) name of the parent, guardian, or person standing in loco parentis;
- (3) date of birth;
- (4) gender;
- (5) race and ethnicity;
- (6) vaccine type, date and dose number administered;
- (7) the name and address of the physician or local health department that administered each dose; and
- (8) the existence of a medical or religious exemption determined by the Immunization Section to meet the requirements of G.S. 130A-156 and 15A NCAC 19A .0404 or G.S. 130A-157. If such a determination has not been made by the Immunization Section, the person shall have access to the certification of medical and religious exemptions required by G.S. 130A-156 or G.S. 130A-157 and 15A NCAC 19A .0404.

**#10 Q. Are we required to include in the accounting of disclosures the disclosures that have been authorized by the patient?**

A. No, you do not have to include in the accounting of disclosures the disclosures that have been authorized by the patient. Section 164.528 addresses the accounting of disclosures. § 164,528(a)(1) states that "an individual has a right to receive an accounting of disclosures of protected health information made by a covered entity in the six years prior to the date on which the accounting is requested, except for disclosures: (ii) to individuals of protected health information about them as provided in § 164.502."

**#11 Q. What is the difference between a "consent for treatment" and a "consent" that is required by HIPAA?**

A. A "consent for treatment" means that the client is giving permission to the health care provider to provide medical care and treatment to the client. "Consent" as defined by HIPAA means that the client is giving the covered health care provider permission to use and disclose protected health information for treatment, payment, and other health care operations.

**#12 Q. Are local public health departments required to obtain "consent for treatment" as well as "consent" to use and disclose PHI for TPO?**

A. Yes. Under North Carolina law, in most circumstances a health care provider must obtain a patient's informed consent before proceeding to treat the patient. However, this consent does not always have to be in writing. It may be required or advisable for consent for certain specific treatments to be in writing, but it is not necessary for local health department to obtain a written "blanket" consent for treatment from all patients. Jill Moore of the Institute of Government provided the following summary of North Carolina's informed consent law and specific concerns under that law for local health departments.

In general, North Carolina's informed consent statute (GS 90-21.13) requires health care providers to explain treatments to their patients and obtain the patient's permission before proceeding with the treatment. The statute specifies that a valid consent for treatment must:

- (1) Be obtained in accordance with the standards of practice among members of the same health care and profession with similar training and experience situated in the same or similar communities, AND
- (2) Provide information such that a reasonable person would have a general understanding of the procedures or treatments and the usual and most frequent risks and hazards inherent in the proposed procedures or treatments, which are recognized and followed by other health care providers engaged in the same field of practice in the same or similar communities.

The statute does not REQUIRE that informed consent for treatment be given in writing. It MAY be in writing, and if it is in writing and meets the standards described above, it will be presumed to be valid. Health departments may want to consider getting informed consent in writing in some circumstances so that they can benefit from this presumption of validity. In addition, there may be other laws or policies that require or recommend obtaining written consent for specific treatments. (For example, both IOG and DPH have consistently advised health departments to obtain written consent for HIV testing.)

However, the law does not require health departments to get a general or "blanket" consent for treatment in writing from all patient upon intake. Some private health care providers obtain blanket consents, and IOG has sometimes advised health departments to adopt practices that are common among private providers. In this case, however, it is questionable as to whether there is any value to the health department in adopting this practice. A consent that covered any and all treatments would have to be written in very general terms—so general that it would be questionable as to whether it is really an "informed" consent at all. Furthermore, when it comes to this issue, health departments differ from private providers in a very important respect: they provide some treatments that individuals are legally obligated to accept. Treatments that individuals are legally obligated to accept are somewhat out of the usual realm of informed consent. Although health departments should still go through the steps of explaining the legally required treatment and attempting to obtain the person's agreement, they can require the treatment if the person refuses. (Important note: When a person refuses a legally required treatment, health department staff should explain the legal consequences of the refusal. If the person continues to physically or verbally resist the treatment, the health department should not attempt to restrain the person or otherwise force the treatment, but should seek legal assistance in

obtaining a court order or pursuing prosecution.) A health department that obtains (or is considering obtaining) blanket consents may want to think about the practical and public relations dilemmas it could face if it is perceived as saying one thing (we won't treat you without your written consent) and doing another (but we'll get a court to order you to accept our treatment in some circumstances).

Health departments that have further questions about this issue may contact Jill Moore at the Institute of Government at 919-966-4442, or [moore@iogmail.iog.unc.edu](mailto:moore@iogmail.iog.unc.edu).

Portions of the General Statute § 90-21.13 are below for your information:

Informed consent to health care treatment or procedure.

(a) No recovery shall be allowed against any health care provider upon the grounds that the health care treatment was rendered without the informed consent of the patient or the patient's spouse, parent, guardian, nearest relative or other person authorized to give consent for the patient where:

(1) The action of the health care provider in obtaining the consent of the patient or other person authorized to give consent for the patient was in accordance with the standards of practice among members of the same health care profession with similar training and experience situated in the same or similar communities; and

(2) A reasonable person, from the information provided by the health care provider under the circumstances, would have a general understanding of the procedures or treatments and of the usual and most frequent risks and hazards inherent in the proposed procedures or treatments which are recognized and followed by other health care providers engaged in the same field of practice in the same or similar communities; or

(3) A reasonable person, under all the surrounding circumstances, would have undergone such treatment or procedure had he been advised by the health care provider in accordance with the provisions of subdivisions (1) and (2) of this subsection.

(b) A consent which is evidenced in writing and which meets the foregoing standards, and which is signed by the patient or other authorized person, shall be presumed to be a valid consent. This presumption, however, may be subject to rebuttal only upon proof that such consent was obtained by fraud, deception or misrepresentation of a material fact.

(c) A valid consent is one which is given by a person who under all the surrounding circumstances is mentally and physically competent to give consent.

(d) No action may be maintained against any health care provider upon any guarantee, warranty or assurance as to the result of any medical, surgical or diagnostic procedure or treatment unless the guarantee, warranty or assurance, or some note or memorandum thereof, shall be in writing and signed by the provider or by some other person authorized to act for or on behalf of such provider.

(e) In the event of any conflict between the provisions of this section and those of Article 7 of Chapter 35 and Articles 1A and 19 of Chapter 90, the provisions of those Articles shall control and continue in full force and effect. (1975, 2nd Sess., c. 977, s. 4.)

**#13 Q. There are many "consent" forms that are provided by various Division of Public Health (DPH) programs/sections. Does the HIPAA "consent" to use and disclose PHI for TPO eliminate the necessity for these program consent forms? If not, are they going to be revised to be HIPAA compliant? If so, when?**

A. Many of the state forms are program-specific and are used to provide or collect information from the client regarding the program's financial requirements and client's participation in the program. These forms are not intended to replace the general consent for treatment or the consent to use and disclose information for TPO. Presently, you should continue using the DPH program level forms in addition to the recommended "consent" to use and disclose PHI for TPO (see further explanation in question #1 above) and obtain the required "consent" for treatment (see further explanation in question #12 above).

There are many forms at the DPH program level that are going to require review and evaluation. Some may be revised and some may be eliminated; however, the inventory and evaluation process is on-going. As new forms or program requirements are determined, you will be given guidance from program level staff on how to proceed with that particular program form.