

Notice of Privacy Practices checklist

INSTRUCTIONS: The following is the text of 164.520 (containing the requirements for the notice of privacy practices) and Notice of Privacy Practices for Protected Health Information (containing changes effective as of October 15, 2002).

Check off each element if composing your privacy notice or making changes to it, to make sure it contains the required elements.

164.520 Notice of privacy practices for protected health information.

(a) Standard: notice of privacy practices.

1. Right to notice. Except as provided by paragraph (a)(2) or (3) of this section, an individual has a right to adequate notice of the uses and disclosures of protected health information that may be made by the covered entity, and of the individual's rights and the covered entity's legal duties with respect to protected health information.
2. Exception for group health plans.
 - i. An individual enrolled in a group health plan has a right to notice:
 - A. From the group health plan, if, and to the extent that, such an individual does not receive health benefits under the group health plan through an insurance contract with a health insurance issuer or HMO;
 - or
 - B. From the health insurance issuer or HMO with respect to the group health plan through which such individuals receive their health benefits under the group health plan.
 - ii. A group health plan that provides health benefits solely through an insurance contract with a health insurance issuer or HMO, and that creates or receives protected health information in addition to summary health information as defined in § 164.504(a) or information on whether the individual is participating in the group health plan, or is enrolled in or has disenrolled from a health insurance issuer or HMO offered by the plan, must:
 - A. Maintain a notice under this section; and
 - B. Provide such notice upon request to any person. The provisions of paragraph (c)(1) of this section do not apply to such group health plan.
 - iii. A group health plan that provides health benefits solely through an insurance contract with a health insurance issuer or HMO, and does not create or receive protected health information other than summary health information as defined in § 164.504(a) or information on whether an individual is participating in the group health plan, or is enrolled in or has disenrolled from a health insurance issuer or HMO offered by the plan, is not required to maintain or provide a notice under this section.
3. Exception for inmates. An inmate does not have a right to notice under this section, and the requirements of this section do not apply to a correctional institution that is a covered entity.

(b) Implementation specifications: content of notice.

1. Required elements. The covered entity must provide a notice that is written in plain language and that contains the elements required by this paragraph.

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- i. Header. The notice must contain the following statement as a header or otherwise prominently displayed: "THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY."
- ii. Uses and disclosures. The notice must contain:
 - A. A description, including at least one example, of the types of uses and disclosures that the covered entity is permitted by this subpart to make for each of the following purposes: treatment, payment, and health care operations.
 - B. A description of each of the other purposes for which the covered entity is permitted or required by this subpart to use or disclose protected health information without the individual's written consent or authorization.
 - C. If a use or disclosure for any purpose described in paragraphs (b)(1)(ii)(A) or (B) of this section is prohibited or materially limited by other applicable law, the description of such use or disclosure must reflect the more stringent law as defined in § [160.202](#).
 - D. For each purpose described in paragraph (b)(1)(ii)(A) or (B) of this section, the description must include sufficient detail to place the individual on notice of the uses and disclosures that are permitted or required by this subpart and other applicable law.
 - E. A statement that other uses and disclosures will be made only with the individual's written authorization and that the individual may revoke such authorization as provided by § [164.508](#)(b)(5).
- iii. Separate statements for certain uses or disclosures. If the covered entity intends to engage in any of the following activities, the description required by paragraph (b)(1)(ii)(A) of this section must include a separate statement, as applicable, that:
 - A. The covered entity may contact the individual to provide appointment reminders or information about treatment alternatives or other health-related benefits and services that may be of interest to the individual;
 - B. The covered entity may contact the individual to raise funds for the covered entity; or
 - C. A group health plan, or a health insurance issuer or HMO with respect to a group health plan, may disclose protected health information to the sponsor of the plan.
- iv. Individual rights. The notice must contain a statement of the individual's rights with respect to protected health information and a brief description of how the individual may exercise these rights, as follows:
 - A. The right to request restrictions on certain uses and disclosures of protected health information as provided by § [164.522](#)(a), including a statement that the covered entity is not required to agree to a requested restriction;
 - B. The right to receive confidential communications of protected health information as provided by § [164.522](#)(b), as applicable;
 - C. The right to inspect and copy protected health information as provided by § [164.524](#);
 - D. The right to amend protected health information as provided by § [164.526](#);
 - E. The right to receive an accounting of disclosures of protected health information as provided by § [164.528](#); and
 - F. The right of an individual, including an individual who has agreed to receive the notice electronically in accordance with paragraph (c)(3) of

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this section, to obtain a paper copy of the notice from the covered entity upon request.

- v. Covered entity's duties. The notice must contain:
 - A. A statement that the covered entity is required by law to maintain the privacy of protected health information and to provide individuals with notice of its legal duties and privacy practices with respect to protected health information;
 - B. A statement that the covered entity is required to abide by the terms of the notice currently in effect; and
 - C. For the covered entity to apply a change in a privacy practice that is described in the notice to protected health information that the covered entity created or received prior to issuing a revised notice, in accordance with § 164.530(i)(2)(ii), a statement that it reserves the right to change the terms of its notice and to make the new notice provisions effective for all protected health information that it maintains. The statement must also describe how it will provide individuals with a revised notice.
 - vi. Complaints. The notice must contain a statement that individuals may complain to the covered entity and to the Secretary if they believe their privacy rights have been violated, a brief description of how the individual may file a complaint with the covered entity, and a statement that the individual will not be retaliated against for filing a complaint.
 - vii. Contact. The notice must contain the name, or title, and telephone number of a person or office to contact for further information as required by § 164.530(a)(1)(ii).
 - viii. Effective date. The notice must contain the date on which the notice is first in effect, which may not be earlier than the date on which the notice is printed or otherwise published.
2. Optional elements.
- i. In addition to the information required by paragraph (b)(1) of this section, if a covered entity elects to limit the uses or disclosures that it is permitted to make under this subpart, the covered entity may describe its more limited uses or disclosures in its notice, provided that the covered entity may not include in its notice a limitation affecting its right to make a use or disclosure that is required by law or permitted by § 164.512(j)(1)(i).
 - ii. For the covered entity to apply a change in its more limited uses and disclosures to protected health information created or received prior to issuing a revised notice, in accordance with § 164.530(i)(2)(ii), the notice must include the statements required by paragraph (b)(1)(v)(C) of this section.
3. Revisions to the notice. The covered entity must promptly revise and distribute its notice whenever there is a material change to the uses or disclosures, the individual's rights, the covered entity's legal duties, or other privacy practices stated in the notice. Except when required by law, a material change to any term of the notice may not be implemented prior to the effective date of the notice in which such material change is reflected.

(c) Implementation specifications: provision of notice. A covered entity must make the notice required by this section available on request to any person and to individuals as specified in paragraphs (c)(1) through (c)(4) of this section, as applicable.

- 1. Specific requirements for health plans.
 - i. A health plan must provide notice:
 - A. No later than the compliance date for the health plan, to individuals then covered by the plan;

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2. The joint notice meets the implementation specifications in paragraph (b) of this section, except that the statements required by this section may be altered to reflect the fact that the notice covers more than one covered entity; and
 - i. Describes with reasonable specificity the covered entities, or class of entities, to which the joint notice applies;
 - ii. Describes with reasonable specificity the service delivery sites, or classes of service delivery sites, to which the joint notice applies; and
 - iii. If applicable, states that the covered entities participating in the organized health care arrangement will share protected health information with each other, as necessary to carry out treatment, payment, or health care operations relating to the organized health care arrangement.
3. The covered entities included in the joint notice must provide the notice to individuals in accordance with the applicable implementation specifications of paragraph (c) of this section. Provision of the joint notice to an individual by any one of the covered entities included in the joint notice will satisfy the provision requirement of paragraph (c) of this section with respect to all others covered by the joint notice.

(e) Implementation specifications: documentation. A covered entity must document compliance with the notice requirements by retaining copies of the notices issued by the covered entity as required by § [164.530\(j\)](#).

H. Section 164.520--Notice of Privacy Practices for Protected Health Information

Final Modifications

After consideration of the public comment, the Department adopts in this final Rule at Sec. 164.520(c)(2)(ii), the proposed requirement that a covered health care provider with a direct treatment relationship with an individual make a good faith effort to obtain the individual's written acknowledgment of receipt of the notice. Other covered entities, such as health plans, are not required to obtain this acknowledgment from individuals, but may do so if they choose. The Department agrees with those commenters who stated that the notice acknowledgment process is a workable alternative to the prior consent process, retaining the beneficial aspects of the consent without impeding timely access to quality health care. The Department continues to believe strongly that promoting individuals' understanding of privacy practices is an essential component of providing notice to individuals. Through this requirement, the Department facilitates achieving this goal by retaining the opportunity for individuals to discuss privacy practices and concerns with their health care providers. Additionally, the requirement provides individuals with an opportunity to request any additional restrictions on uses and disclosures of their health information or confidential communications, as permitted by Sec. 164.522.

As proposed in the NPRM, the final Rule requires, with one exception, that a covered direct treatment provider make a good faith effort to obtain the written acknowledgment no later than the date of first service delivery, including service delivered electronically, that is, at the time the notice is required to be provided. During emergency treatment situations, the final Rule at Sec. 164.520(c)(2)(i)(B) delays the requirement for provision of the notice until reasonably practicable after the emergency situation, and at Sec. 164.520(c)(2)(ii) exempts health care providers from having to make a good faith effort to obtain an individual's acknowledgment in such emergency situations. The Department agrees with commenters that such exceptions are practical and necessary to ensure that the notice and acknowledgment requirements do not impede an individual's timely access to quality health care.

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The Department also agrees with commenters that the notice acknowledgment process must be flexible and provide covered entities with discretion in order to be workable. Therefore, the final modification adopts the flexibility proposed in the NPRM for the acknowledgment requirement. The Rule requires only that the acknowledgment be in writing, and does not prescribe other details such as the form that the acknowledgment must take or the process for obtaining the acknowledgment. For example, the final Rule does not require an individual's signature to be on the notice. Instead, a covered health provider is permitted, for example, to have the individual sign a separate sheet or list, or to simply initial a cover sheet of the notice to be retained by the provider. Alternatively, a pharmacist is permitted to have the individual sign or initial an acknowledgment within the log book that patients already sign when they pick up prescriptions, so long as the individual is clearly informed on the log book of what they are acknowledging and the acknowledgment is not also used as a waiver or permission for something else (such as a waiver to consult with the pharmacist). For notice that is delivered electronically as part of first service delivery, the Department believes the provider's system should be capable of capturing the individual's acknowledgment of receipt electronically. In addition, those covered health care providers that choose to obtain consent from an individual may design one form that includes both a consent and the acknowledgment of receipt of the notice. Covered health care providers are provided discretion to design the acknowledgment process best suited to their practices.