INSTRUCTIONS: The following is the text of 164.508 (containing the requirements for a valid authorization), excerpts from Restructuring Authorizations (containing changes effective as of October 15, 2002), and excerpts from Research Authorizations (containing changes effective as of October 15, 2002).

Check off each element if reviewing an Authorization, to make sure it contains the required elements.

§164.508 Uses and disclosures for which an authorization is required.

(a) Standard: authorizations for uses and disclosures.

1. Authorization required: general rule. Except as otherwise permitted or required by this subchapter, a covered entity may not use or disclose protected health information without an authorization that is valid under this section. When a covered entity obtains or receives a valid authorization for its use or disclosure of protected health information, such use or disclosure must be consistent with such authorization.
2. Authorization required: psychotherapy notes. Notwithstanding any other provision of this subpart, other than transition provisions provided for in § 164.532, a covered entity must obtain an authorization for any use or disclosure of psychotherapy notes, except:
    i. To carry out the following treatment, payment, or health care operations, consistent with consent requirements in § 164.506:
        A. Use by originator of the psychotherapy notes for treatment;
        B. Use or disclosure by the covered entity in training programs in which students, trainees, or practitioners in mental health learn under supervision to practice or improve their skills in group, joint, family, or individual counseling; or
        C. Use or disclosure by the covered entity to defend a legal action or other proceeding brought by the individual; and
    ii. A use or disclosure that is required by § 164.502(a)(2)(ii) or permitted by § 164.512(a); § 164.512(d) with respect to the oversight of the originator of the psychotherapy notes; § 164.512(g)(1); or § 164.512(j)(1)(i).

(b) Implementation specifications: general requirements.

1. Valid authorizations.
    i. A valid authorization is a document that contains the elements listed in paragraph (c) and, as applicable, paragraph (d), (e), or (f) of this section.
    ii. A valid authorization may contain elements or information in addition to the elements required by this section, provided that such additional elements or information are not be inconsistent with the elements required by this section.
2. Defective authorizations. An authorization is not valid, if the document submitted has any of the following defects:
    i. ☐ The expiration date has passed or the expiration event is known by the covered entity to have occurred;
    ii. ☐ The authorization has not been filled out completely, with respect to an element described by paragraph (c), (d), (e), or (f) of this section, if applicable;
    iii. ☐ The authorization is known by the covered entity to have been revoked;
    iv. ☐ The authorization lacks an element required by paragraph (c), (d), (e), or (f) of this section, if applicable;
    v. ☐ The authorization violates paragraph (b)(3) of this section, if applicable;

vi. ☐ Any material information in the authorization is known by the covered entity to be false.

3. Compound authorizations. An authorization for use or disclosure of protected health information may not be combined with any other document to create a compound authorization, except as follows:
   i. ☐ An authorization for the use or disclosure of protected health information created for research that includes treatment of the individual may be combined as permitted by § 164.506(b)(4)(ii) or paragraph (f) of this section;
   ii. ☐ An authorization for a use or disclosure of psychotherapy notes may only be combined with another authorization for a use or disclosure of psychotherapy notes;
   iii. ☐ An authorization under this section, other than an authorization for a use or disclosure of psychotherapy notes may be combined with any other such authorization under this section, except when a covered entity has conditioned the provision of treatment, payment, enrollment in the health plan, or eligibility for benefits under paragraph (b)(4) of this section on the provision of one of the authorizations.
4. Prohibition on conditioning of authorizations. A covered entity may not condition the provision to an individual of treatment, payment, enrollment in the health plan, or eligibility for benefits on the provision of an authorization, except:
   i. ☐ A covered health care provider may condition the provision of research-related treatment on provision of an authorization under paragraph (f) of this section;
   ii. ☐ A health plan may condition enrollment in the health plan or eligibility for benefits on provision of an authorization requested by the health plan prior to an individual's enrollment in the health plan, if:
      A. ☐ The authorization sought is for the health plan's eligibility or enrollment determinations relating to the individual or for its underwriting or risk rating determinations; and
      B. ☐ The authorization is not for a use or disclosure of psychotherapy notes under paragraph (a)(2) of this section;
   iii. ☐ A health plan may condition payment of a claim for specified benefits on provision of an authorization under paragraph (e) of this section, if:
      A. ☐ The disclosure is necessary to determine payment of such claim; and
      B. ☐ The authorization is not for a use or disclosure of psychotherapy notes under paragraph (a)(2) of this section; and
   iv. A covered entity may condition the provision of health care that is solely for the purpose of creating protected health information for disclosure to a third party on provision of an authorization for the disclosure of the protected health information to such third party.
5. ☐ Revocation of authorizations. An individual may revoke an authorization provided under this section at any time, provided that the revocation is in writing, except to the extent that:
   i. ☐ The covered entity has taken action in reliance thereon; or
   ii. ☐ If the authorization was obtained as a condition of obtaining insurance coverage, other law provides the insurer with the right to contest a claim under the policy.
6. Documentation. A covered entity must document and retain any signed authorization under this section as required by § 164.530(j).

(c) Implementation specifications: core elements and requirements.

1. Core elements. A valid authorization under this section must contain at least the following elements:

i. ☐ A description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion;
ii. ☐ The name or other specific identification of the person(s), or class of persons, authorized to make the requested use or disclosure;
iii. ☐ The name or other specific identification of the person(s), or class of persons, to whom the covered entity may make the requested use or disclosure;
iv. ☐ An expiration date or an expiration event that relates to the individual or the purpose of the use or disclosure;
v. ☐ A statement of the individual's right to revoke the authorization in writing and the exceptions to the right to revoke, together with a description of how the individual may revoke the authorization;
vi. ☐ A statement that information used or disclosed pursuant to the authorization may be subject to redisclosure by the recipient and no longer be protected by this rule;
vii. ☐ Signature of the individual and date; and
viii. ☐ If the authorization is signed by a personal representative of the individual, a description of such representative's authority to act for the individual.

2. ☐ Plain language requirement. The authorization must be written in plain language.

☐ **(d) Implementation specifications: authorizations requested by a covered entity for its own uses and disclosures.** If an authorization is requested by a covered entity for its own use or disclosure of protected health information that it maintains, the covered entity must comply with the following requirements.

1. ☐ Required elements. The authorization for the uses or disclosures described in this paragraph must, in addition to meeting the requirements of paragraph (c) of this section, contain the following elements:
   i. ☐ For any authorization to which the prohibition on conditioning in paragraph (b)(4) of this section applies, a statement that the covered entity will not condition treatment, payment, enrollment in the health plan, or eligibility for benefits on the individual's providing authorization for the requested use or disclosure;
   ii. ☐ A description of each purpose of the requested use or disclosure;
   iii. ☐ A statement that the individual may:
      A. ☐ Inspect or copy the protected health information to be used or disclosed as provided in § 164.524; and
      B. ☐ Refuse to sign the authorization; and
   iv. ☐ If use or disclosure of the requested information will result in direct or indirect remuneration to the covered entity from a third party, a statement that such remuneration will result.
2. ☐ Copy to the individual. A covered entity must provide the individual with a copy of the signed authorization.

☐ **(e) Implementation specifications: authorizations requested by a covered entity for disclosures by others.** If an authorization is requested by a covered entity for another covered entity to disclose protected health information to the covered entity requesting the authorization to carry out treatment, payment, or health care operations, the covered entity requesting the authorization must comply with the following requirements.

1. ☐ Required elements. The authorization for the disclosures described in this paragraph must, in addition to meeting the requirements of paragraph (c) of this section, contain the following elements:

i. ☐ A description of each purpose of the requested disclosure;
ii. ☐ Except for an authorization on which payment may be conditioned under paragraph (b)(4)(iii) of this section, a statement that the covered entity will not condition treatment, payment, enrollment in the health plan, or eligibility for benefits on the individual's providing authorization for the requested use or disclosure; and
iii. ☐ A statement that the individual may refuse to sign the authorization.

2. Copy to the individual. A covered entity must provide the individual with a copy of the signed authorization.

☐ **(f) Implementation specifications: authorizations for uses and disclosures of protected health information created for research that includes treatment of the individual.**

1. ☐ Required elements. Except as otherwise permitted by § 164.512(i), a covered entity that creates protected health information for the purpose, in whole or in part, of research that includes treatment of individuals must obtain an authorization for the use or disclosure of such information. Such authorization must:
   i. ☐ For uses and disclosures not otherwise permitted or required under this subpart, meet the requirements of paragraphs (c) and (d) of this section; and
   ii. Contain:
      A. ☐ A description of the extent to which such protected health information will be used or disclosed to carry out treatment, payment, or health care operations;
      B. ☐ A description of any protected health information that will not be used or disclosed for purposes permitted in accordance with §§ 164.510 and 164.512, provided that the covered entity may not include a limitation affecting its right to make a use or disclosure that is required by law or permitted by § 164.512(j)(1)(i); and
      C. ☐ If the covered entity has obtained or intends to obtain the individual's consent under § 164.506, or has provided or intends to provide the individual with a notice under § 164.520, the authorization must refer to that consent or notice, as applicable, and state that the statements made pursuant to this section are binding.
2. ☐ Optional procedure. An authorization under this paragraph may be in the same document as:
   i. ☐ A consent to participate in the research;
   ii. ☐ A consent to use or disclose protected health information to carry out treatment, payment, or health care operations under § 164.506; or
   iii. ☐ A notice of privacy practices under § 164.520.

E. Uses and Disclosures for Which Authorization Is Required

1. Restructuring Authorization

Final Modifications

Although the requirements regarding uses and disclosures of psychotherapy notes are not changed substantively, the Department made minor changes to the language in paragraph (a)(2) to clarify that a covered entity may not use or disclose psychotherapy notes for purposes of another covered entity's treatment, payment, or health care operations without obtaining the individual's authorization. ☐ However, covered entities may use and disclose psychotherapy notes, without obtaining individual authorization, to carry out its own limited

treatment, payment, or health care operations as follows: ☐ (1) Use by the originator of the notes for treatment, ☐ (2) use or disclosure for the covered entity's own training programs for its mental health professionals, students, and trainees, and ☐ (3) use or disclosure by the covered entity to defend itself in a legal action or other proceeding brought by the individual.

Section 164.508(a)(3) requires covered entities to obtain an authorization to use or disclose protected health information for marketing purposes, with two exceptions. The authorization requirements for marketing and the comments received on these provisions are discussed in detail in section III.A.1. of the preamble.

☐ If the marketing involves any direct or indirect remuneration to the covered entity from a third party, the authorization must state that fact. The comments on this requirement also are discussed in section III.A.1. of the preamble. ☐ However, a statement concerning remuneration is not a required notification for other authorizations.

Pursuant to Sec. 164.508(b)(1), an authorization is not valid under the Rule unless it contains all of the required core elements and notification statements, which are discussed below. ☐ Covered entities may include additional, non-required elements so long as they are not inconsistent with the required elements and statements. The language regarding defective authorizations in Sec. 164.508(b)(2) is not changed substantively. However, some changes are made to conform this paragraph to modifications to other parts of the authorization provision, as well as other sections of the Rule. An authorization is not valid if it contains any of the following defects: ☐ (1) The expiration date has passed or the expiration event has occurred, and the covered entity is aware of the fact, ☐ (2) any of the required core elements or notification statements are omitted or incomplete, ☐ (3) the authorization violates the specifications regarding compounding or conditioning authorizations, or ☐ (4) the covered entity knows that material information in the authorization is false.

Section 164.508(b)(4) prohibits the conditioning of treatment, payment, enrollment in a health plan, or eligibility for benefits on obtaining an authorization, with a few exceptions. The exceptions to this requirement for research-related treatment, eligibility for benefits and enrollment in a health plan, and health care solely for creating protected health information for disclosure to a third party are not changed. ☐ Moreover, the Department eliminates the exception to the prohibition on conditioning payment of a claim on obtaining an authorization. Although some insurers urged that this conditioning authority be retained to provide them with more collection options, the Department believes this authorization is no longer necessary because we are adding a new provision in Sec. 164.506 that permits covered entities to disclose protected health information for the payment purposes of another covered entity or health care provider. Therefore, that exception has been eliminated.

Section 164.508(b)(5) provides individuals the right to revoke an authorization at any time in writing. The two exceptions to this right are retained, but with some modification. ☐ An individual may not revoke an authorization if the covered entity has acted in reliance on the authorization, or ☐ if the authorization was obtained as a condition of obtaining insurance coverage and other law gives the insurer the right to contest the claim or the policy itself. The Department adopts the proposed modification to the latter exception so that insurers can exercise the right to contest an insurance policy under other law. Public comment was generally supportive of this proposed modification.

The different sets of implementation criteria are consolidated into one set of criteria under Sec. 164.508(c), thus eliminating the confusion and uncertainty associated with different requirements for specific circumstances. Covered entities may use one authorization form for all purposes. The Department adopts in paragraph (c)(1), the following core elements for a valid authorization: ☐ (1) A description of the information to be used or disclosed, ☐ (2) the

identification of the persons or class of persons authorized to make the use or disclosure of the protected health information, (3) the identification of the persons or class of persons to whom the covered entity is authorized to make the use or disclosure, (4) a description of each purpose of the use or disclosure, (5) an expiration date or event, (6) the individual's signature and date, and (7) if signed by a personal representative, a description of his or her authority to act for the individual. An authorization that does not contain all of the core elements does not meet the requirements for a valid authorization. The Department intends for the authorization process to provide individuals with the opportunity to know and understand the circumstances surrounding a requested authorization.

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." Other changes to the core elements pertain to authorizations for research, and are discussed in section III.E.2. of the preamble.

Also, under Sec. 164.508(c)(2), an authorization is not valid unless it contains all of the following: (1) A statement that the individual may revoke the authorization in writing, and either a statement regarding the right to revoke, and instructions on how to exercise such right or, to the extent this information is included in the covered entity's notice, a reference to the notice, (2) a statement that treatment, payment, enrollment, or eligibility for benefits may not be conditioned on obtaining the authorization if such conditioning is prohibited by the Privacy Rule or, if conditioning is permitted, a statement about the consequences of refusing to sign the authorization, and (3) a statement about the potential for the protected health information to be redisclosed by the recipient. Although the notification statements are not included in the paragraph on core elements an authorization is not valid unless it contains both the required core elements, and all of the required statements. This is the minimum information the Department believes is needed to ensure individuals are fully informed of their rights with respect to an authorization and to understand the consequences of authorizing the use or disclosure. The required statements must be written in a manner that is adequate to place the individual on notice of the substance of the statements.

In response to comments, the Department clarifies that the statement regarding the potential for redisclosure does not require an analysis of the risk for redisclosure, but may be a general statement that the health information may no longer be protected by the Privacy Rule once it is disclosed by the covered entity. Others objected to this statement because individuals might be hesitant to sign an authorization if they knew their protected health information could be redisclosed and no longer protected by the Rule. In response, the Department believes that individuals need to know about the consequences of authorizing the disclosure of their protected health information. As the commenter recognized, the potential for redisclosure may, indeed, be an important factor in an individual's decision to give or deny a requested authorization.

E. Uses and Disclosures for Which Authorization Is Required

2. Research Authorizations

Final Modifications

The Department agrees with the commenters that supported the NPRM's proposed simplification of authorizations for research uses and disclosures of protected health information and, therefore, adopts the modifications to these provisions as proposed in the NPRM. The final Rule requires a single set of authorization requirements for all uses and disclosures, including those for research purposes, and permits an authorization for the use or disclosure of protected health information to be combined with any other legal permission

related to the research study, including another authorization or consent to participate in the research.

In addition, in response to commenters' concerns that the Rule would prohibit important uses and disclosures of protected health information after the termination of a research project, the final Rule eliminates the requirement for an expiration date for all uses and disclosures of protected health information for research purposes, not only for the creation and maintenance of a research database or repository. The Department agrees that the line between research repositories and databases in particular, and research data collection in general, is sometimes arbitrary and unclear. If the authorization for research uses and disclosures of protected health information does not have an expiration date, the final Rule at Sec. 164.508(c)(1)(v), requires that this fact be stated on the authorization form. Patients continue to control whether protected health information about them may be used or disclosed for research, since the authorization must include an expiration date or event, or a statement that the authorization will have no expiration date. In addition, patients will be permitted to revoke their authorization at any time during the research project, except as specified under Sec. 164.508(b)(5). However, the Department notes that researchers may choose to include, and covered entities may choose to require, an expiration date when appropriate.