

NESNIP PRIVACY WORKGROUP
MINIMUM NECESSARY SUBCOMMITTEE
The “Minimum Necessary” Standard

1. General Rule [§164.502(b) and §164.514(d)]
 - a. A covered entity must implement reasonable procedures to ensure that only the minimum necessary of protected health information (PHI) is used, disclosed or requested when conducting payment activities and health care operations.
 - 1) Requires an assessment as to whether the purpose could be accomplished reasonably with information that is not identifiable.
 - b. The “minimum necessary” standard applies to:
 - 1) Covered entities only
 - 2) Internal and external uses and disclosures
 - a) Worker's Compensation disclosures (§164.12(a)(1))
 - 3) Payment activities
 - a) Collection
 - b) Billing
 - 4) Health care operations, and
 - a) Compliance audits
 - b) Financial information
 - 5) Activities where an authorization is required.
 - d. **Use, Disclosure or Request of Entire Medical Record** - May not use, disclose or request an entire medical record, except when it is specifically justified as the amount that is reasonably necessary to accomplish the purpose of the use, disclosure or request. (164.514(d)(5)) Presumption – The entire medical record is not considered reasonable in the absence of justification.
2. **Exceptions** to the General Rule [§164.502(b)(2) – The “minimum necessary” standard does not apply when it is:
 - a. Disclosures or requests by a health care provider for treatment of the individual; [§164.502(b)(2)(i)]. Examples include:
 - 1) Disclosures to a consulting physician
 - 2) Access by floor nurses treating patients on the floor
 - b. Permitted or required disclosures to the individuals themselves [§164.502(b)(2)(ii)]. Examples include:
 - 1) Individual's right to access to his/her PHI in a designated record set [§164.524]
 - 2) Individual's right to an accounting of disclosures of PHI [§164.528]

- c. Pursuant to an authorization requested by the individual [§164.508(a)-(c) only]. Examples include disclosures to:
 - 1) The individual's attorney
 - 2) An insurer rating the individual for coverage purposes
 - 3) A health care provider not currently treating the individual.
 - 4) An employer.
- d. Disclosures made to the Secretary of HHS for compliance and enforcement purposes [§164.508(b)(2)(iii)]
- e. Disclosures that are required by law, as described in §164.512(a) [§164.508(2)(iv)]. Such disclosure is limited to that required by the law and complies with and limited to the relevant requirements of such law. Examples include:
 - 1) Public Health Activities
 - a) Public Health Authority (Prevention/Disease Control, Vital Statistics reporting)
 - b) Child Abuse or Neglect Reporting
 - c) FDA (adverse event reporting, tracking products, product recalls, repairs or replacement, post marketing surveillance)
 - d) A person who may have been exposed to a communicable disease if authorized by law to notify such person for public health intervention/investigation (i.e. AIDS)
 - e) An employer **if the covered entity is a member of the employer's workforce who provides health care to the individual at the employer's request to:** [§164.512(b)(1)(v)]
 - (i) Conduct an evaluation relating to medical surveillance of the workplace
 - (ii) To evaluate whether the individual has a work-related illness or injury (Worker's Compensation issue)

If required to do so under 29 CFR parts 1904-1928 or under a similar state law. Notice to the individual is required.
 - 2) Victims of Abuse, Neglect or Domestic Violence if the individual does not agree, then to the extent authorized by statute or regulation) [§164.512(c)]
 - 3) Health Oversight Activities authorized by law
 - a) Excludes
 - (i) Private accreditation organizations (JCAHO)
 - b) Includes
 - (i) Audits
 - (ii) Civil, administrative or criminal investigations or proceedings
 - (iii) Inspections (i.e. health inspections)
 - (iv) Licensure or disciplinary actions

- 4) Judicial and Administrative Proceedings
 - a) Response to an order (disclosures expressly authorized by the order, no more)
 - b) Response to a subpoena, discovery request, or other lawful process, not accompanied by an order provided receipt of satisfactory assurance that reasonable efforts were made:
 - (i) to give the individual notice, or
 - (ii) to secure a protective order.
 - §164.512(e)
 - 5) For Law Enforcement Purposes - Disclosure to a law enforcement official pursuant to process and as otherwise required by law, subject to certain restrictions (§164.512(f)(1)(ii))
3. Minimum Necessary Use Implementation Standards (164.514(d)(2)): - Three steps
- a. Identify those persons or classes of persons, in the workforce who need access to PHI to carry out their duties; and
 - b. For each such person or class of persons, the category/categories of PHI to which access is needed and any conditions appropriate to such access.
 - c. Make reasonable efforts to limit the access of such persons or class of persons to protected health information to which they do not need to carry out their duties.
 - d. No case-by-case review required.

Use Checklist

- Develop policies and procedures:
 - Identify and/or classify all levels of employees/contractors who need access to PHI as part of their job function.

<input type="checkbox"/> Those involved in Treatment	<input type="checkbox"/> Billing/Coding Staff
<input type="checkbox"/> Receptionists	<input type="checkbox"/> Medical Records Personnel
<input type="checkbox"/> Residents and Students	<input type="checkbox"/> Volunteers
<input type="checkbox"/> Internal Auditors	<input type="checkbox"/> Management
<input type="checkbox"/> Legal	<input type="checkbox"/> Risk Management
<input type="checkbox"/> Health care providers not involved in treatment	
<input type="checkbox"/> Clergy (Must inform individual in advance (verbally) and allow an opportunity to object) - §164.510(a)]	
<input type="checkbox"/> Others	

- Define the PHI needed by each class of employee within the organization perform their job function.
 - The policy must explicitly include justification where employees are allowed access to the entire medical record.

Use Checklist, cont'd

- Identify the conditions and type of PHI accessible by each category of employee.
- Make sure that each job description identifies level of access.
- Develop appropriate policies and procedures limiting access to PHI to the identified persons(s) and identified PHI.

4. Two Types of **Disclosures and Requests**

- a. Routine
 - 1) Establish policies and procedures, which may be standardized protocols.
- b. Non-Routine
 - 1) Establish criteria to limit disclosed PHI to that reasonably necessary to accomplish the purpose.
 - 2) Review requests on individual basis based on the established criteria.

5. Minimum Necessary **Disclosure** Implementation Standards (164.514(d)(3)):

- a. Routine and recurring basis: implement policies and procedures (which may be standard protocols) that limit the PHI to the amount reasonably necessary to achieve the purpose of the disclosure.
 - 1) Workers Compensation disclosure
 - 2) Oversight agencies (i.e. JCAHO, etc.)
- b. Non-routine disclosures
 - 1. Develop criteria designed to limit the PHI disclosed to the information reasonably necessary to accomplish the purpose for which disclosure is sought
 - a) According to the OIG's recent Guidance (7/01) this should not apply to patient authorizations.
 - 2. Review requests for disclosure on an individual basis in accordance with such criteria.
- c. Reasonable Reliance. No need to rely on policies (protocols) or criteria 164.514(d)(3)(iii) for requests made by:
 - 1. Public officials as permitted under 164.512, if the public official represents that the information requested is the minimum necessary for the stated purpose(s).
 - 2. Another covered entity.
 - 3. A professional who is a member of the workforce or business associate of the covered entity for the purpose of providing professional services if he/she represents that the information requested is the minimum necessary for the stated purpose(s).
 - 4. Researcher who has documentation from an IRB or privacy board that complies with the applicable requirements of 164.512(i), allowing waiver of authorization for use or disclosure.

Disclosure Checklist

- Identify types of routine disclosures and non-routine disclosures that are not otherwise subject to an exception or the reasonable reliance rule.
 - Permissive Disclosures allowed under §164.512(b)
 - Reporting criminal conduct
 - To avert threat of serious harm
 - Organ donations
 - Disclosures to Business Associates
 - Other types of disclosure
- Determine the need for written policies/procedures v. standard protocols for routine disclosures not subject to an exception or reasonable reliance.
 - Identify the types of PHI
 - Identify the individuals who would receive the PHI
 - Accrediting Organizations (i.e. JCAHO)
 - Identify the conditions that would apply for access/disclosure
- Provide justification in the policy for routine disclosures of the entire medical record.
- Develop written criteria to limit non-routine disclosure of PHI to that reasonably needed to accomplish the purpose.
- Identify those individuals within the organization who will review non-routine requests and who will have final authority if there is any question.
- Develop a written tracking process for each non-routine disclosure reviewed on an individual basis.
- Does reasonable reliance apply? (Optional) If utilized, develop process and written tracking system.
 - Has a public official represented that the information requested is the minimum amount necessary? (Written v. Oral)
[Would recommend receipt of a written representation]
 - Is the request from another covered entity?
 - Is the request from a professional within the workforce or business associate who has represented that the information requested is the minimum amount necessary? (Written v. Oral)
[Written preferred from a professional of a business associate.]
 - Attorneys
 - Accountants
 - Consultants
 - Outside Auditors
 - Others:

Disclosure Checklist, cont'd

- Request by a researcher with IRB or Privacy Board written determination of minimum necessary.
 - The documentation must describe the PHI for which use or disclosure has been determined to be necessary for the research.
 - Documentation must state that voting procedures were followed in approving the waiver of approval for either full Board review or expedited review.
- Researcher represents that requested use or disclosure is for reviews preparatory to research (§164.512(I)(1)(iii)) or for research solely on the PHI of decedents (§164.512(1)(iii)). (See 65 FR 82537)
 - For decedents, obtain a copy of the death certificate, if not already in the covered entity's medical records.
 - Documentation from researcher that PHI is necessary for research.
 - Documentation from researcher that request meets the minimum necessary requirement

6. Minimum Necessary **Request** Implementation Specifications: (164.514(d)(4))
- a. Limited to that which is reasonably necessary to accomplish the purpose for which the request is made, when requesting such information from other covered entities.
 - b. Key Items
 - 1) The burden is on the requesting party, not the recipient.
 - 2) This appears only to apply requests made by covered entities to covered entities.
 - 3) The recipient can use the reasonable reliance standard when responding to a request from another entity.
 - c. Routine - Develop policies and procedures (which may be standard protocols).
 - d. Non-routine - Individual review required.

Checklist for Requests

- Develop policies/procedures or standard protocols for routine and recurring PHI requests
 - Identify individual(s) responsible for making such requests.
 - Identify requests that are "routine and recurring".
 - Require documented justification for requests requiring the entire medical record.
- Designate individual(s) responsible for making individual determinations of minimal necessary for non-routine requests.