



# The HIPAA Final Privacy Regulations: Access and Consent


The Second National HIPAA Summit  
March 1, 2001, 3:30 p.m.

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# HIPAA “Consumer Rights”




- Consent and Authorization
  - Privacy Policy Notice
  - Accounting of Disclosures
  - Amendment
  - Access
  - Complaint Process
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# Access

- Right to Inspect and Copy
- Designated Record Set
- Time Limits to Respond
- Exceptions to the Right of Access
- Grounds to Deny Access
- Appeal of Denials

## Access - The Designated Record Set (DRS)




- DRS broader than customary definition of medical record
  - Logistical nightmare - “centralizing” the DRS information
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# Access - Time Limits to Respond

- **Onsite info:** 30 days to act after request, one 30 day extension
- **Offsite info:** 60 days to act after request, one 30 day extension
- **If granted:** allow inspection and copying of PHI in DRS, wherever it may exist (but duplication of efforts for same info is not necessary)
- **If denied:** provide written denial and follow review procedures
- **Duration:** right of access exists as long as PHI is held in the DRS

# Exceptions to the Right of Access



- Psychotherapy Notes
  - Information Compiled for Trial or Similar Proceedings
  - CLIA Information
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# Access - Grounds for Denial Without Review

- Regulatory exceptions to access (psychotherapy notes, compiled for trial, CLIA)
- Promise of confidentiality to source of information, and access would make identification likely
- Privacy Act prohibits access, 5 U.S.C. Section 552a
- Inmates
- Clinical trial information and the individual agreed to “no access” prior to completion of the research

# Access - Reviewable Grounds for Denial

- Information references another person and access is reasonably likely to cause “substantial” harm to that person
- Access reasonably likely to endanger the life or physical safety of the individual or another person
- Access by individual’s personal representative likely to cause “substantial” harm to the individual or another person
- Determinations to deny access must be made by a licensed health care provider (LHCP)



# Due Process Review for Denial of Access

- Independent LHCP review
- Covered Entity must provide written notice of determination to individual
- “Editing Duty” - to the extent possible, access must be given to remaining PHI after excluding denied PHI

# Access and Consent Implementation Challenges

- Obtaining and Tracking Patient Consent
- Obtaining Authorizations
- Multiple Consent Issues
- “Minimum Necessary” Standards
- Change in Medical Records Maintenance
- Responding to Individual Rights
- Integration of All HIPAA Privacy Requirements