The HIPAA Privacy Rule

45 CFR Sections 160 & 164

I. Regulations Apply to Covered Entities (CEs) (§ 160.102(a))

- Health Plans
- Health Care Clearinghouses
- Health Care Providers who transmit one or more covered transactions electronically (including processing claims, payment/remittance, coordination of benefits, claim status, referral certification/authorization, etc.)

II. Different Organizational Structures (including, but not limited to)

- Hybrid Entity (§ 164.103 & 164.105(a))
- Affiliated CE (§ 164.105(b))
- Organized Health Care Arrangement (§ 160.103)

III. Minimal Protections for all types of health care individuals (§ 164.502)

- General Rule PROHIBITS the use or disclosure of Protected Health Information (PHI) (§ 164.502(a))
- Required Exceptions
  - ➢ When an Individual requests access regarding PHI about themselves (§ 164.502(a)(2)(i))
  - ➢ When compelled by the Secretary for compliance/enforcement purposes (§ 164.502(a)(2)(ii) & 160.310)
- Permitted Exceptions
  - ~ With Written Authorization** (§ 164.502(a)(1)(iv))
    - ➢ Certain Psychotherapy Notes (§ 164.501 & 164.508(a)(2))
    - ➢ Marketing (§ 164.501 & 164.508(a)(3))
    - ➢ Uses/Disclosures Not Otherwise Required or Permitted (§ 164.508(a)(1))

** Required Elements in a Valid Written Authorization (§ 164.508(c))♦

- ✓ Who can use/disclose PHI
- ✓ To whom the PHI can be used/disclosed
- ✓ Purpose of the use/disclosure
- ✓ Specific description of PHI to be used/disclosed
- ✓ Expiration date or event
- ✓ Signature of patient and date
- ✓ Right to revoke *in writing*, exceptions, *and instructions regarding procedure*
- ✓ *A statement about the CE's ability/inability to condition the authorization on treatment, payment, eligibility, or enrollment*
- ✓ *A statement that the PHI may no longer be protected by Federal HIPAA privacy law*
- ✓ *For marketing, a statement when CE gets direct or indirect remuneration* (§ 164.508(a)(3)(ii))

***NOTE:** A CE must provide the individual with a copy of any signed authorization that it seeks from the individual! (§ 164.508(c)(4))*

♦*The italicized items represent necessary elements for a HIPAA-compliant authorization in addition to standard elements otherwise required of a written consent by the Alcohol and Other Drug (AOD) Confidentiality Rule within 42 CFR Part 2.*

  - ~ Without Written Authorization (generally, limited by the minimum necessary standard)
    - ➢ To the Individual (§ 164.502(a)(1)(i))
    - ➢ For Treatment, Payment, and Health Care Operations (TPO) within a CE, Treatment (T) by a Health Care Provider, Payment (P) of another CE or a health care provider, and Operations (O) of another the CE as set forth within the regulations (§ 164.502(a)(1)(ii) & 164.506)
    - ➢ Incidental Uses/Disclosures, provided that the minimum necessary standard, where applicable, and reasonable safeguards were applied (§ 164.502(a)(1)(iii))

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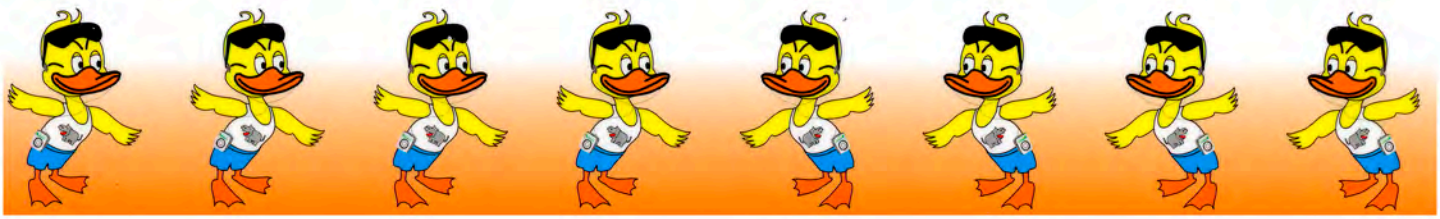

- Facility Directory (§ 164.502(a)(1)(v) & 164.510(a))
- Next of Kin/Caregiver (§ 164.502(a)(1)(v) & 164.510(b))
- Business Associate—requires a written agreement (§ 164.502(e), 164.504(e) & 164.532(d) and (e))
- Averting a Serious Threat to Health or Safety (§ 164.502(a)(1)(vi) & 164.512(j))
- Health Oversight Activities (§ 164.502(a)(1)(vi) & 164.512(d))
- Judicial & Administrative Proceedings (§ 164.502(a)(1)(vi) & 164.512(e))
- For Law Enforcement Purposes (§ 164.502(a)(1)(vi) & 164.512(f))
- For Public Health Activities (§ 164.502(a)(1)(vi) & 164.512(b))
- As Required by Law (§ 164.502(a)(1)(vi) & 164.512(a))
- For Research (§ 164.502(a)(1)(vi) & 164.512(i))
- Concerning Victims of Abuse, Neglect, or Domestic Violence (§ 164.502(a)(1)(vi) & 164.512(c))
- About Decedents (§ 164.502(a)(1)(vi) & 164.512(g))
- For Workers Compensation (§ 164.502(a)(1)(vi) & 164.512(l))
- For Cadaveric Donation (§ 164.502(a)(1)(vi) & 164.512(h))
- For Specialized Government Functions (§ 164.502(a)(1)(vi) & 164.512(k))

IV. Minimal Rights (within specified limits)

- Right to Inspect and Copy (§ 164.524)
- Right to an Accounting of Disclosures (§ 164.528)
- Right to Request Amendment (§ 164.526)
- Right to Request Restrictions (§ 164.522(a))
- Right to Request Confidential Communications (§ 164.522(b))
- Right to File a Complaint (§ 160.306 & 164.520(b)(1)(vi))

V. Administrative Requirements

- Written Notice of Privacy Practices (§ 164.520)
  - Required header and content, in plain language
  - Reservation of right to change terms of the privacy notice
  - Distribution & Acknowledgement Requirements
  - Posting Requirement
- Customized Privacy Policy and Procedures (§ 164.530(i), 164.514(d) & 164.530(j))
  - Setting minimum necessary standards and review criteria
  - Establishing methods of implementing required protections and adhering to individual rights
  - Revisions required to comply with the law
  - Retention period—retain written or electronic copy for 6 years from the date of its creation or the date when it last was in effect, whichever is later
- Designated Privacy Officer (§ 164.530(a))
- Training, and related documentation (§ 164.530(b))
- Administrative, Technical, and Physical Safeguards (§ 164.530(c))
- Established Grievance Process (including a designated person/office to receive privacy-related questions and complaints) (§ 164.530(d))
- Personnel Sanctions for Breaches, and related documentation (§ 164.530(e))
- Mitigate results of violations (§ 164.530(f))
- Prohibition against intimidating or retaliatory acts (§ 164.530(g))
- Prohibition against forcing individuals to waive their HIPAA rights as a condition of treatment, payment, eligibility, or enrollment (§ 164.530(h))

VI. Preemption of State Law—State laws that are less protective and contrary to HIPAA are preempted. State privacy laws that are more stringent (i.e., which provide the individual with greater privacy protection and/or greater control of or access to PHI) remain in effect (§ 160.202 & 160.203)

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CSAT Confidentiality & Ethics TRAINING