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Community HealthCare Association of the Dakotas

Patient Services Part IV: Navigating Patient Confidentiality Requirements – June 27, 2019

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The National Association of Community Health Centers (NACHC) was founded in 1971 to promote efficient, high quality, comprehensive health care that is accessible, culturally and linguistically competent, community directed, and patient centered for all.

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- Partner and Compliance Counsel at Feldesman Tucker Leifer Fidell, Dianne specializes in assisting health centers with developing and implementing Compliance Programs, assessing compliance risks, HIPAA Privacy and 42 CFR Part 2, and emergency preparedness.
- Manages the array of compliance resources offered through www.HealthCenterCompliance.com.
- Well-versed in the compliance issues facing health centers because of her experience as Chief Compliance Officer and Manager of Government Grants for Boston Health Care for the Homeless Program, one of the largest health center programs in the country.

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- Associate in the firm's Health Law and Federal Grants practice groups
- Assists in matters pertaining to litigation and compliance by conducting legal research and drafting documents
- Works on a wide verity of issues affecting health centers and other federal grantees focusing primary on health care litigation and privacy with specific emphasis on matters relating to the False Claims Act, the Federal Tort Claims Act, Medicare and Medicaid overpayments, HIPAA, and 42 CFR Part 2

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Agenda

- HIPAA Compliance
  - HIPAA Basics
  - Handling Subpoenas and Other Requests for Patient Information
- 42 CFR Part 2 Compliance

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HIPAA Compliance: HIPAA Basics

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HIPAA Privacy Basics

- HIPAA Privacy Rule (2000)
  - Establishes federal protections for certain health information
  - Focus is on uses/disclosures of protected health information (PHI) and individual rights with respect to understanding/controlling how their PHI is used
- HIPAA Security Rule (2003)
  - Establishes federal protections for electronic PHI that is created, received, or maintained by a covered entity
- HIPAA Enforcement Rule (2003)
  - Establishes framework for HIPAA-related investigations and civil monetary penalties
- HIPAA Final Omnibus Rule (2013)
  - Made changes to HIPAA as required under the HITECH Act, including breach notification updates and liability of business associates
- HIPAA Changes in 2019???

HIPAA Privacy Basics

Protected Health Information (PHI)

- "Individually identifiable health information" is information, including demographic data, that relates to:
  - An individual's past, present or future physical or mental health or condition,
  - The provision of health care to the individual, or
  - The past, present, or future payment for the provision of health care to the individual,

  and that identifies the individual or for which there is a reasonable basis to believe it can be used to identify the individual
- Transmitted or maintained in any form or medium (paper, electronic, oral)
- Created or received by a covered entity or business associate
- Relating to health care or payment

HIPAA Privacy Basics

Only two instances in which covered entities *must* disclose:

(1) To patients when requested and required as part of their right to access PHI or an accounting of disclosures; and

(2) To HHS when it is undertaking a HIPAA compliance investigation, review, or enforcement action

See 45 CFR §164.502(a)(2)

HIPAA Privacy Basics

Covered entities *are permitted* to use and/or disclose PHI without the individual's consent:

1. To the individual
2. Treatment, payment, and health care operations
3. Incidental use and disclosure
4. With authorization of individual
5. Use or disclosure with opportunity to agree or object
6. Public interest and benefit activities
7. Limited data set

See 45 CFR §§164.502(a)(1), 164.512

HIPAA Privacy Basics

Minimum Necessary Standard:

- When using, disclosing, or requesting PHI, a covered entity and its employees must make reasonable efforts to limit PHI to the minimum amount necessary to accomplish the intended purposes of the use, disclosure, or request
- Does not apply to:
  - Disclosures to or requests by a health care provider for treatment
  - Uses or disclosures made to the individual
  - Uses or disclosures made pursuant to an authorization
  - Disclosures to HHS, use and disclosures required by law or required for compliance with applicable requirements

See 45 CFR §164.502(b)(2)

HIPAA Privacy Basics

Individual Rights:

1. **Notice:** Right to receive a Notice of Privacy Practices from the covered entity
2. **Restriction:** Right to request a restriction on uses and disclosures of PHI
3. **Confidential Communication:** Right to request confidential communications of PHI
4. **Access:** Right to access and copy PHI
5. **Amendment:** Right to amend PHI
6. **Accounting:** Right to receive an accounting of disclosures of PHI

HIPAA Security Basics

Covered entities must maintain reasonable and appropriate administrative, technical and physical safeguards for protecting e-PHI:

- Ensure the confidentiality, integrity, and availability of all e-PHI they create, receive, maintain or transmit;
- Identify and protect against reasonably anticipated threats to the security or integrity of the information;
- Protect against reasonably anticipated, impermissible uses or disclosures; and
- Ensure compliance by their workforce

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HIPAA Security Basics

Security Rule requires covered entity to have:

- **Administrative Safeguards:** Including workforce security, information access management, and security awareness and training
- **Physical Safeguards:** Including workstation use, device and media controls
- **Technical Safeguards:** Including access controls, audit controls, authentication

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HIPAA Breach Basics

Breach means the acquisition, access, use, or disclosure of PHI in a manner not permitted by the HIPAA Privacy Rule which compromises the security or privacy of the PHI.

Risk Assessment

1. Nature and extent of PHI involved
2. Unauthorized person who used the PHI or to whom the disclosure was made
3. Whether the PHI was actually acquired or viewed
4. Extent to which the risk to the PHI has been mitigated

See 45 CFR §164.402

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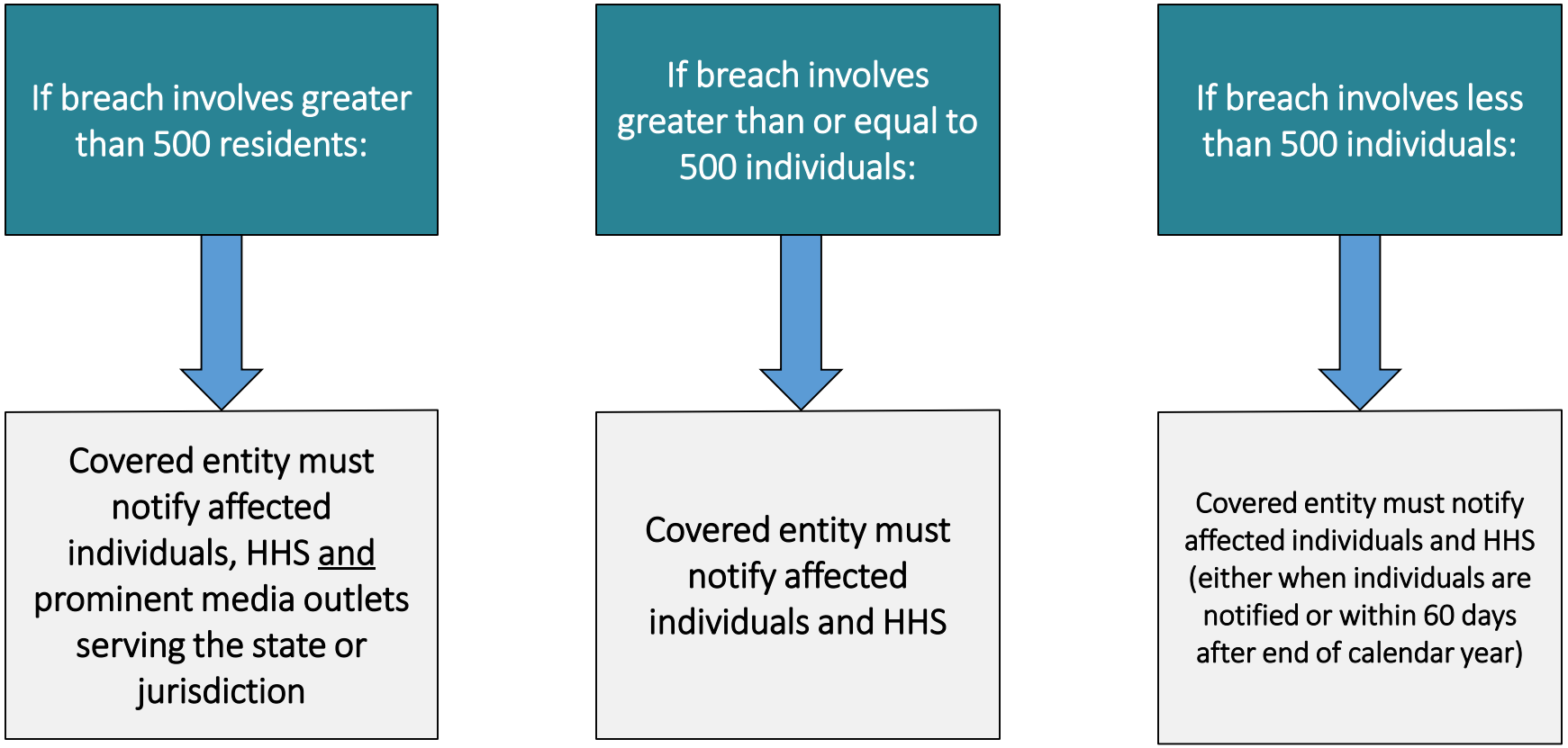
HIPAA Breach Basics



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HIPAA Compliance: Handling Subpoenas and Other Requests for Patient Information

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Disclosures to Law Enforcement and for Judicial Proceedings

The following sections discuss relevant rules under HIPAA for disclosures to law enforcement and for judicial proceedings.

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HIPAA: Disclosures to Law Enforcement and for Judicial Proceedings

HIPAA: 45 CFR § 164.512 (Uses and disclosures for which an authorization or opportunity to agree or object is not required)

Two key subsections:

- 45 CFR § 164.512(e)
  - Disclosures for judicial and administrative proceedings
- 45 CFR § 164.512(f)
  - Disclosures for law enforcement purposes

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HIPAA: Disclosures for Judicial and Administrative Proceedings

45 CFR § 164.512(e) (Disclosures for judicial and administrative proceedings)

- Many steps to check! But here it goes…

HIPAA: Disclosures for Judicial and Administrative Proceedings

45 CFR § 164.512(e)(1) (Disclosures for judicial and administrative proceedings)

- **Covered entity may disclose PHI in the course of any judicial or administrative proceeding:**
  - (i) In response to an order of a court or administrative tribunal, provided the covered entity discloses only the PHI expressly authorized by the order; or
  - (ii) In response to a subpoena, discovery request, or other lawful process, that if *not* accompanied by an order of a court or administrative tribunal, if: . . .

HIPAA: Disclosures for Judicial and Administrative Proceedings

45 CFR § 164.512(e)(1)(ii)

(A) The covered entity receives *satisfactory assurance* (as described in (e)(1)(iii)), from the party seeking the information that reasonable efforts have been made by such party to ensure that the individual who is the subject of the PHI has been given notice; or

(B) The covered entity receives *satisfactory assurance* (as described in (e)(1)(iv)), from the party seeking the information that reasonable efforts have been made by such party to secure a qualified protective order that meets certain requirements

HIPAA: Disclosures for Judicial and Administrative Proceedings

What constitutes "satisfactory assurance" (as referenced in (e)(1)(ii)(A)) that the individual has been given notice of the request?

- The covered entity must receive from the requesting party a written statement and accompanying documentation that:
  - (A) The requesting party made a good faith attempt to provide written notice to the individual;
  - (B) The notice included sufficient information about the litigation/proceeding to permit the individual to raise an objection to the court/administrative tribunal; and
  - (C) The time for the individual to raise objections has elapsed and: (1) none were filed; or (2) all objections have been resolved and the disclosures being sought are consistent with the resolution

HIPAA: Disclosures for Judicial and Administrative Proceedings

What constitutes "satisfactory assurance" (as referenced in (e)(1)(ii)(B)) that reasonable efforts have been made to secure a qualified protective order?

- The covered entity receives from such party a written statement and accompanying documentation that:

  (A) The parties to the dispute giving rise to the request for information have agreed to a qualified protective order and have presented it to the court or administrative tribunal with jurisdiction over the dispute; or

  (B) The party seeking the PHI has requested a qualified protective order from such court or administrative tribunal

HIPAA: Disclosures for Judicial and Administrative Proceedings

What is meant by a "qualified protective order"?

- An order of a court or of an administrative tribunal or a stipulation by the parties to the litigation or administrative proceeding that:

  (A) Prohibits the parties from using or disclosing the PHI for any purpose other than the litigation or proceeding for which such information was requested; and

  (B) Requires the return to the covered entity or destruction of the PHI (including all copies made) at the end of the litigation or proceeding

HIPAA: Disclosures for Judicial and Administrative Proceedings

One final note on disclosures for judicial and administrative proceedings…

- Notwithstanding the previous slides, a covered entity may disclose PHI in response to lawful process *without receiving satisfactory assurances* (as described in previous slides) if the covered entity makes reasonable efforts to provide notice to the individual (sufficient to meet the notice requirement described previously) or to seek a qualified protective order (sufficient to meet the qualified protective order requirement described previously)

HIPAA: Disclosures for Law Enforcement Purposes

45 CFR § 164.512(f) (Disclosures for law enforcement purposes)

- Covered entity may disclose PHI for a law enforcement purpose to a law enforcement official (if certain conditions are met) in the following circumstances:
  - (1) Pursuant to process and as otherwise required by law
  - (2) Limited information for identification and location purposes
  - (3) Victims of a crime
  - (4) Decedents
  - (5) Crime on premises
  - (6) Reporting crime in emergencies
- We will address each in turn. . .

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HIPAA: Disclosures for Law Enforcement Purposes

45 CFR § 164.512(f) (Disclosures for law enforcement purposes)

(1) Pursuant to process and as otherwise required by law

- Covered entity may disclose PHI:
  - (i) As required by law including laws that require the reporting of certain types of wounds or other physical injuries (with certain exceptions at 45 CFR §§ 164.512(b)(1)(ii) or (c)(1)(i); or
  - (ii) In compliance with and as limited by the relevant requirements of:
    - (A) A court order or court-ordered warrant, or a subpoena or summons issued by a judicial officer;
    - (B) A grand jury subpoena; or
    - (C) An administrative request, a civil or an authorized investigative demand, or similar process authorized by law, provided that:
      - (1) The information sought is relevant and material to a legitimate law enforcement inquiry;
      - (2) The request is specific and limited in scope to the extent reasonably practicable in light of the purpose for which it is sought; and
      - (3) De-identified information could not reasonably be used

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HIPAA: Disclosures for Law Enforcement Purposes

45 CFR § 164.512(f) (Disclosures for law enforcement purposes)

(2) Limited information for identification and location purposes

- Except for disclosures discussed on the previous slide, a covered entity may disclose PHI in response to a law enforcement official's request for information for the purpose of identifying or locating a suspect, fugitive, material witness, or missing person, provided that:

  (i) The covered entity may disclose only the following:

  (A) Name and address;

  (B) Date and place of birth;

  (C) SSN;

  (D) ABO blood type and rh factor;

  (E) Type of injury;

  (F) Date and time of treatment;

  (G) Date and time of death, if applicable; and

  (H) A description of distinguishing characteristics, including height, weight, gender, race, hair and eye color, presence or absence of facial hair, scars, and tattoos

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HIPAA: Disclosures for Law Enforcement Purposes

45 CFR § 164.512(f) (Disclosures for law enforcement purposes)

(3) Victims of a crime

- Except for disclosures required by law, a covered entity may disclose PHI in response to a law enforcement official's request for such information about an individual who is or is suspected to be a victim of a crime, other than disclosures that are subject to 45 CFR §§ 164.512(b) or (c), if:
  - (i) The individual agrees to the disclosure; or
  - (ii) The covered entity is unable to obtain the individual's agreement because of incapacity or other emergency circumstance, provided that:
    - (A) The law enforcement official represents that such information is needed to determine whether a violation of law by a person other than the victim has occurred, and such information is not intended to be used against the victim;
    - (B) The law enforcement official represents that immediate law enforcement activity that depends upon the disclosure would be materially and adversely affected by waiting until the individual is able to agree to the disclosure; and
    - (C) The disclosure is in the best interests of the individual as determined by the covered entity, in the exercise of professional judgment.

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HIPAA: Disclosures for Law Enforcement Purposes

45 CFR § 164.512(f) (Disclosures for law enforcement purposes)

(4) Decedents

- Covered entity may disclose PHI about an individual who has died to a law enforcement official for the purpose of alerting law enforcement of the death of the individual if the covered entity has a suspicion that such death may have resulted from criminal conduct

(5) Crime on premises

- Covered entity may disclose to a law enforcement official PHI that the covered entity believes in good faith constitutes evidence of criminal conduct that occurred on the premises of the CE

HIPAA: Disclosures for Law Enforcement Purposes

45 CFR § 164.512(f) (Disclosures for law enforcement purposes)

(6) Reporting crime in emergencies

- A covered health care provider providing emergency health care in response to a medical emergency, other than such emergency on the premises of the covered health care provider, may disclose PHI to a law enforcement official if such disclosure appears necessary to alert law enforcement to:
  - (A) The commission and nature of a crime;
  - (B) The location of such crime or of the victim(s) of such crime; and
  - (C) The identity, description, and location of the perpetrator of such crime.

- Note: If the covered entity believes the emergency is the result of abuse, neglect, or domestic violence, then the provisions of 45 CFR § 164.512(c) apply

42 CFR Part 2 ("PART 2") Compliance

Part 2: Basics

- Statute: 42 U.S.C. § 290dd-2
- Regulations: 42 CFR Part 2 ("Confidentiality of Substance Use Disorder Patient Records"): Current text:
  - https://www.ecfr.gov/cgi-bin/text-idx?rgn=div5&node=42:1.0.1.1.2
- Federal Agency: Substance Abuse and Mental Health Services Administration ("SAMHSA")
- Purpose: Enacted to encourage people to seek and receive substance use disorder treatment when needed and without stigma

Part 2: Basics

Part 2 applies to:

1. Federally assisted Part 2 programs
2. Lawful holders of Part 2 protected information

Part 2: Basics

Program:

1. An individual or entity (*other than a general medical care facility*) who holds itself out as providing, and provides, substance use disorder diagnosis, treatment, or referral for treatment

2. *An identified unit within a general medical facility* which *holds itself out* as providing, and provides, substance use disorder diagnosis, treatment, or referral for treatment

3. *Medical personnel or other staff in a general medical facility* whose *primary function* is the provision of substance use disorder diagnosis, treatment or referral for treatment and *who are identified as such* providers

See 42 CFR § 2.11

Part 2: Basics

- Restrictions on disclosure apply to:
  - Individuals or entities who receive patient records directly from a Part 2 program or other lawful holder of patient identifying information and who are notified of the prohibition on re-disclosure in accordance with § 2.32.

See 42 CFR § 2.12 (d)(2)(i)(C)

Part 2: Basics

- **General Rule on Disclosure of Patient Information Protected by Part 2:** Information that identifies an individual as a patient of a Part 2 program is confidential and may not be disclosed without patient consent, unless an exception applies
  - Unlike HIPAA, *patient consent is required* even for disclosures for the purposes of treatment, payment or health care operations

Part 2: Basics

Required Elements of Patient Consent

1. Name of patient
2. Amount and kind of information to be disclosed
3. "From Whom"
4. "To Whom"
5. Purpose of disclosure
6. Statement that the consent is subject to revocation at any time
7. The date, event, or condition of expiration
8. Signature of patient
9. Date of signature

See 42 CFR § 2.31

Part 2: Basics

Compliance Requirements Include:

- Security for Records
- Disposition of records by discontinued program
- Minor patients
- Notice to patients of federal confidentiality requirements
- Patient access and restrictions on use
- Limited disclosures for medical emergencies, research, audit and evaluation
- Court orders authorizing disclosure and use

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