



HIPAA 2024

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Agenda



Review

New Prohibition

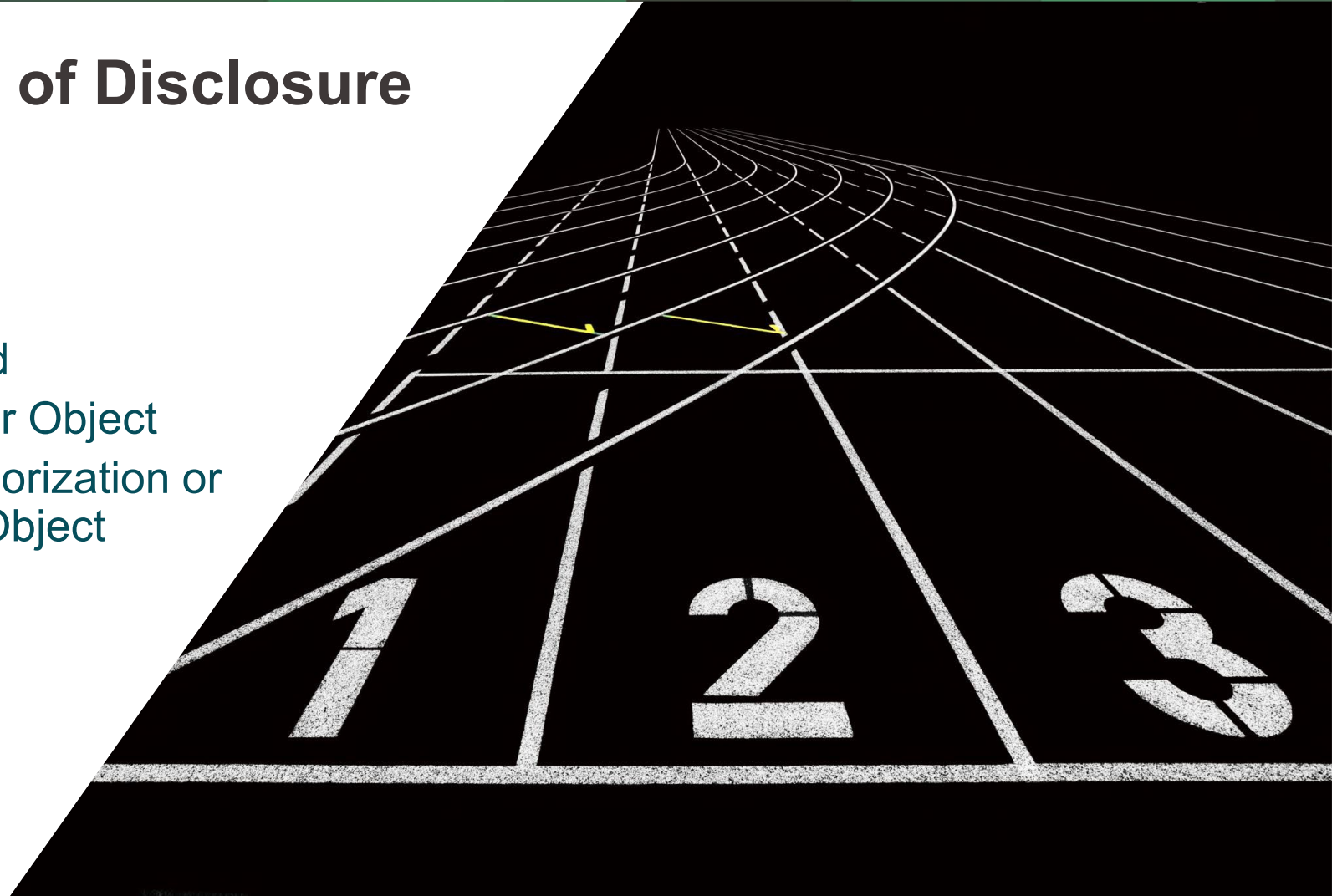
Attestation

NPP Changes

Review

- **Three (3) Categories of Disclosure**

- Required
- Prohibited
- Permitted
 - Authorization Required
 - Opportunity to Agree or Object
 - Permitted without Authorization or Opportunity to Agree/Object



Required Disclosures



- **ONLY 2**
 - To the individual when request
 - Investigation by DHHS (federal)

Prohibited

- Genetic information for underwriting purposes
- PHI for sale
- *****NEW*** -- Reproductive Health Care**



Permitted



- To carry out Treatment, Payment or other Health Care Operations (TPO)
- ***With Valid Authorization***
 - Marketing
 - Sale of PHI
- ***With Valid Attestation ***NEW******

Permitted *continued...*

- **With Opportunity for individual to Agree or Object**
 - Facility Directory
 - Individual present
 - Disaster Relief
 - Deceased



Permitted continued...



- **Authorization or Opportunity to Agree or Object Not Required**
 - Required by law
 - Public Health Activities
 - Victims of abuse, neglect, or domestic violence* (specific requirements)
 - Health oversight activities *
 - Disclosures for judicial and administrative proceedings *
 - Law Enforcement purposes *
 - Identification and Location Purposes
 - Victims of Crime
 - Decedents *
 - Crime on Premises
 - Reporting Crime in Emergencies
 - Research Purposes
 - Avert a Serious Threat to Health or Safety
 - Specialized Government Functions
 - Workers' Compensation

NEW PROHIBITION

Reproductive Health Care



- **45 CFR 164.502(a)(5)(iii)**
- **REPRODUCTIVE HEALTH CARE**
 - [Subject to the requirements] a covered entity or business associate may not use or disclose protected health information for any of the following activities:
 - (1) to conduct a criminal, civil, or administrative investigation into any person for the mere act of seeking, obtaining, providing or facilitating reproductive health care
 - (2) to impose criminal, civil, or administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care
 - (3) to identify any person for any purposes described in (1) and (2) above.

What is Reproductive Health Care?



- **Non-exclusive list of examples that fit within the definition:**

- contraception, including emergency contraception;
- preconception screening and counseling;
- management of pregnancy and pregnancy-related conditions, including pregnancy screening, prenatal care, miscarriage, management, treatment for preeclampsia, hypertension during pregnancy, gestational diabetes, molar or ectopic pregnancy, and pregnancy termination;
- fertility and infertility diagnosis and treatment, including assisted reproductive technology and its components (e.g., in vitro fertilization (IVF));
- diagnosis and treatment of conditions that affect the reproductive system (e.g., perimenopause, menopause, endometriosis, adenomyosis);
- and other types of care , services, and supplies used for the diagnosis and treatment of conditions related to the reproductive system (e.g., mammography, pregnancy-related nutrition services, postpartum care products).

What is Seeking, Obtaining, Providing or Facilitating?



“seeking, obtaining, providing, or facilitating reproductive health care includes, but is not limited to, any of the following: expressing interest in, using, performing, furnishing, paying for, disseminating information about, arranging, insuring, administering, authorizing, providing coverage for, approving, counseling about, assisting, or otherwise taking action to engage in reproductive health care; or attempting any of the same”

When will this apply?

- **Rule of Applicability**

- Facility receives a request for PHI that related to “seeking, obtaining, providing, or facilitating reproductive health care” and
 - (1) The reproductive health care was lawful under the law of the state it was provided and under the circumstances in which it was provided;

OR

- (2) the reproductive health care is protected, required, or authorized by Federal law...under the circumstances in which such health care is provided, regardless of the state in which it is provided (ex: birth control)

OR

- (3) The Presumption Applies

(1) Lawful in the state and under the circumstances



- **General Preemption Provision**
- **Does not protect ILLEGAL provision of care**

(2) Protected by Federal law

- **Ex: contraception**

(3) Presumption Applies



- If you did not provide the reproductive health care, and you are receiving the request, you **PRESUME** that it was lawful
- How is the Presumption overcome?
 - Actual Knowledge
 - Substantial Factual Basis

ACTUAL KNOWLEDGE

- **You must KNOW it was unlawful**
 - Done outside scope
 - Done by unlicensed individual
 - Done within an unlicensed facility



Substantial Factual Basis



- **You must obtain from the person making the request – factual evidence that demonstrates the reproductive health care was unlawful.**
 - Affidavits from complainants that detail the circumstances under which the reproductive healthcare was provided
 - Anonymous reports would not be sufficient

Recap on Prohibition



- **If Patient or Provider sought, obtained, provided or facilitated reproductive health care**
 - **And the requester is:**
 - Conducting a criminal, civil, or administrative investigation because of that reproductive health care
 - Trying to impose criminal, civil, or administrative liability for that reproductive health care
 - Trying to identify the patient or provider of that reproductive health care
- **YOU ARE PROHIBITED FROM DISCLOSING!!**

**What if the request is not for
one of the prohibited reasons?**

Must meet Requirements for Permitted Purpose



- **Authorized**
 - General valid authorization by the patient is still allowed – even if could be used for a prohibited purpose – allowed and encouraged to educate the patient
- **TPO**
 - Still allowed – get in your Notice of Privacy Practices
- **Any of the others provided meet ALL requirements of the permitted purpose**
 - PLUS the new requirement – ATTESTATION where required

Permitted Purposes that require ATTESTATION

When the PHI to be disclosed is
“potentially related to reproductive health care”

Four (4) Situations that require ATTTESTATION



- **DHHS believes that four (4) situations ripe for criminal, civil, or administrative investigation or imposition of liability**
- **(1) Health Oversight Activities**
- **(2) Judicial and Administrative Proceedings**
- **(3) Law Enforcement Purposes**
- **(4) Disclosures to Coroners and Medical Examiners**

What is an Attestation?



- **Written representation from the person requesting the PHI that their request is NOT for a prohibited purpose**
- **Must be Valid & NOT Defective**
 - **Valid =**
 - on its face is has all required elements;
 - do not know it is false;
 - reasonable to believe its true
 - **Defective = BREACH**
 - Lacks a required element
 - Includes an element not required
 - Is combined with another document
 - You know its false
 - Its not reasonable for you to believe it is true
- **CANNOT be combined any other documents**

Attestation: Required Elements



1. Name of any Individual/Description of the Class of Individuals
2. Name or Specific Identification of who the information is being requested by
3. Name or Specific Identification of who the information is being used by/disclosed to
4. Clear statement that the use or disclosure is not for a purposes prohibited by 164.502(a)(5)(iii) (i.e., the reproductive health care prohibition)
5. Statement that the requester may be subject to criminal penalties pursuant to 42 USC 1320d-6 if that person knowingly and in violation of HIPAA obtains individually identifiable health information (“IIHI”) or discloses IIHI to another person
6. Signature of the person requesting the PHI, if on behalf of an organization description of person’s authority
7. Date

***Plain Language**

***Model Attestation Available**

Model Attestation

- HHS OCR Model Attestation Form re Reproductive Health Care Use of Attestation Required
 - NOT required to use the Model
 - NOT required to use your form
 - Make sure there are NO additional elements!
 - Not combined with other forms, but may be “accompanied by” other forms

Model Attestation Regarding a Requested Use or Disclosure of Protected Health Information Potentially Related to Reproductive Health Care

The entire form must be completed for the attestation to be valid.

Name of person(s) or specific identification of the class of persons to receive the requested PHI. <i>e.g., name of investigator and/or agency making the request</i>
Name or other specific identification of the person or class of persons from whom you are requesting the use or disclosure. <i>e.g., name of covered entity or business associate that maintains the PHI and/or name of their workforce member who handles requests for PHI</i>
Description of specific PHI requested, including name(s) of individual(s), if practicable, or a description of the class of individuals, whose protected health information you are requesting. <i>e.g., visit summary for [name of individual] on [date]; list of individuals who obtained [name of prescription medication] between [date range]</i>

I attest that the use or disclosure of PHI that I am requesting is not for a purpose prohibited by the HIPAA Privacy Rule at 45 CFR 164.502(a)(5)(iii) because of one of the following (check one box):

- ☐ The purpose of the use or disclosure of protected health information is **not** to investigate or impose liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care or to identify any person for such purposes.
- ☐ The purpose of the use or disclosure of protected health information **is** to investigate or impose liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care, or to identify any person for such purposes, but the reproductive health care at issue was **not lawful** under the circumstances in which it was provided.

I understand that I may be subject to criminal penalties pursuant to 42 U.S.C. 1320d-6 if I knowingly and in violation of HIPAA obtain individually identifiable health information relating to an individual or disclose individually identifiable health information to another person.

Signature of the person requesting the PHI

Date _____

If you have signed as a representative of the person requesting PHI, provide a description of your authority to act for that person.

This attestation document may be provided in electronic format, and electronically signed by the person requesting protected health information when the electronic signature is valid under applicable Federal and state law.

The Attestation has all the Elements...Now What?



- **Is it reasonable to rely on the attestation that the PHI will not be used for a prohibited purpose?**
 - *“the attestation requirement is intended to reduce the burden of determining whether the PHI request is for a purpose prohibited...but it does not absolve regulated entities of the responsibility of making this determination, nor does it absolve regulated entities of the responsibility for ensure such requests meet the other condition of the relevant permission.”*

What if the request for PHI is based on allegedly *unlawful* reproductive health care?



- Did regulated entity (you) provide the reproductive health care?
- NO, then
 - Presumption applies – (1) actual knowledge, or (2) substantial factual basis
 - Statement that the reproductive health care is not “substantial factual basis” and therefore would NOT be reasonable to rely on the Attestation

What if the request for PHI is based on allegedly *unlawful* reproductive health care?

- Did regulated entity (you) provide the reproductive health care?
- Yes, then
 - You must conduct your own thorough review



What to consider?



- License of the facility
- License of the provider
- Who is requesting the information?
- What permitted purpose are they relying on?
- Does the information provided satisfy the condition for that permission?
- Does the PHI requested relate to the purpose of the request?
- Where was the reproductive health care provided?
- Do you have actual knowledge that the reproductive health care was unlawful?
- Is there a substantial factual basis to determine that the reproductive health care was unlawful?

Example 1

Federal Officer provides you with a warrant; signed attestation that the reproductive health care was not lawful, however, will NOT give you any evidence or further information about why it was unlawful.

What if you provided the health care?

What if someone else provided the health care?



Example #2

- **Federal officer provides you a warrant; attestation; and an affidavit that says the Office of Inspector General is investigating Provider A for billing fraud and he is not seeking the PHI for a prohibited purpose.**
- **Do NOT forget the attestation does not REPLACE requirements of other permissible disclosures**
- **Work in conjunction with other permissible disclosures**
 - Subpoena
 - Discovery requests
 - Lawful process
 - Administrative requests – **ONLY WHEN A RESPONSE IS REQUIRED BY LAW**

Other Considerations



- **What if the requester (public official) has made public statements that he/she is seeking to prosecute providers who are providing reproductive health care?**
- **What if you later learn that the PHI is going to be used for a prohibited purpose?**
- **What if a requester makes additional requests?**
 - **Need a new Attestation each time!!**

You have decided you can disclose:



- **Minimum necessary still applies**
- **When using or disclosing protected health information or when requesting protected health information from another covered entity or business associate, a covered entity or business associate must make reasonable efforts to limit protected health information to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request.**



BUT WHAT ABOUT...

Business Associates



- **These requirements do apply to them just as they do to you**
- **May want to consider setting out clearly that requests should be handled by you as the covered entity and business associate is not allowed to release PHI or at least limit the types of requests Business Associates are allowed to respond to**

Mandatory Reporting



- **45 CFR 164.512(a) permits certain uses and disclosures of PHI that are required by law**
- **45 CFR 164.512(a)(2) has always been subject to the additional requirements of 45 CFR 164.512(c), (e), or (f)**

(c) Disclosures about victims of abuse, neglect, or domestic violence

- ***Rule of construction.*** Nothing in this section shall be construed to permit disclosures prohibited by § 164.502(a)(5)(iii) when the sole basis of the report of abuse, neglect, or domestic violence is the provision or facilitation of reproductive health care



Public Health Reporting



- **Public health, as used in the terms “public health surveillance,” “public health investigation,” and “public health intervention,” means population-level activities to prevent disease in and promote the health of populations.**
- **Such activities include identifying, monitoring, preventing, or mitigating ongoing or prospective threats to the health or safety of a population, which may involve the collection of protected health information. But such activities do not include those with any of the following purposes:**
 - (1) To conduct a criminal, civil, or administrative investigation into any person for the mere act of seeking, obtaining, providing, or facilitating health care.
 - (2) To impose criminal, civil, or administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating health care.
 - (3) To identify any person for any of the activities described at paragraphs (1) or (2) of this definition.

Public Health Reporting continued

- Any disclosures made pursuant to 45 CFR 164.512(b), which includes disclosures for public health surveillance, investigations, or interventions, do not require an attestation.
- However, we note that requests made pursuant to other permissions of the rule remain subject to and must be evaluated for compliance with the prohibition at 45 CFR 164.502(a)(5)(iii)



Personal Representatives



Covered entity may elect not to treat a person as the personal representative, provided that the conditions at paragraphs (g)(5)(i) and (ii) of this section are met:

(i) Paragraphs (g)(5)(i)(A) and (B) of this section both apply.

(A) The covered entity has a reasonable belief that any of the following is true:

- (1) The individual has been or may be subjected to domestic violence, abuse, or neglect by such person.**
- (2) Treating such person as the personal representative could endanger the individual.**

(B) The covered entity, in the exercise of professional judgment, decides that it is not in the best interest of the individual to treat the person as the individual's personal representative.

(ii) The covered entity does not have a reasonable belief under paragraph (g)(5)(i)(A) of this section if the basis for their belief is the provision or facilitation of reproductive health care by such person for and at the request of the individual.

COMPLIANCE DATES

COMPLIANCE DATES

- **June 25, 2024 – Rule Effective**
- **December 24, 2024 – Compliance Date for Covered**
 - Reproductive Health
- **Notice of Privacy Practices**
 - February 2026



CONCLUSION

New Prohibition



- **Prohibition – disclosure of reproductive health care for the purpose of:**
 1. Criminal, civil, or administrative investigation
 2. Criminal, civil, or administrative liability
 3. To identify an individual for (1) or (2)
- **Presumption – presumed reproductive health care was lawful if you did not provide**

New Requirement for Permissible



- **Four (4) Permissible that now require ATTESTATION**
 - (1) Health Oversight Activities**
 - (2) Judicial and Administrative Proceedings**
 - (3) Law Enforcement Purposes**
 - (4) Disclosures to Coroners and Medical Examiners**

Attestation

**Specific
Elements**



**Must be
Reasonable**



QUESTIONS??